This article was extracted from the bilingual publication "Canada Communicable Disease Report". For reference purposes, citing should refer to the printed copy as indicated at the bottom of this page.

An Advisory Committee Statement (ACS)

*National Advisory Committee on Immunization (NACI)**

GUIDELINES FOR CHILDHOOD IMMUNIZATION PRACTICES

PREAMBLE

The National Guidelines for Childhood Immunization Practices have been developed by the National Advisory Committee on Immunization (NACI) through an extensive consultation process. They are an integral part of achieving our national goals and targets for vaccine-preventable diseases of infants and children. The purpose of these guidelines is to achieve a standard of practice that will ensure vaccines are handled properly and delivered to all children as recommended by provincial and territorial programs.

Immunization is a major cornerstone in our efforts to improve the health of people all over the world. It was responsible for the global eradication of smallpox in 1977 and the elimination of paralytic poliomyelitis in the western hemisphere as certified by the Pan American Health Organization in 1994. Vaccine-preventable diseases have experienced a tremendous decrease in Canada, demonstrating the effectiveness of existing provincial and territorial programs, and the successful role played by private and public providers. Compared to the pre-vaccine era, the Canadian achievements have been remarkable: over a 95% decrease in the incidence of many diseases – measles, invasive infections due to ***Haemophilus influenzae*** *type b – and the complete elimination of polio.*

Outbreaks of vaccine-preventable diseases occur, however, as highlighted by recent epidemics of measles and pertussis. In addition, cases of congenital rubella syndrome continue to occur. These have been attributed largely to inadequate immunization in certain populations. The increase in pertussis cases in Canada over recent years, the importation of wild polio virus in 1993 and 1996 into Canada and the diphtheria epidemic in Eastern European countries remind us that the risk for these diseases still exists despite current programs, and that the level of protection of the population must be kept as high as possible.

The value of immunization has been definitely established. One tends to take its benefits for granted and its very success leads to complacency. We no longer see the devastating effects of vaccine-preventable diseases. Moreover, because of the low frequency of occurrences, the apparent balance of risks and benefits begins to shift towards a greater perception of the risks. The unfortunate implication is that more people may abandon or even oppose immunization. A recent national survey revealed that the public was well informed by health-care providers about the risks of side effects but less informed about the benefits of receiving vaccines.

Some of the established national goals and targets have been achieved and good progress is being made towards the others, but much effort is still needed to reach them all.

Several factors point to the need for National Guidelines for Childhood Immunization Practices.

- *Population-based estimates of vaccination coverage for 2-year-olds in Canada show areas for concern. Coverage with four doses of pertussis, tetanus and diphtheria vaccine was 87% versus a target of 95%. In addition, there is low to no coverage for groups that oppose vaccination on religious grounds, and coverage is unknown for the annual influx to Canada of about 60,000 newcomers < 18 years of age.*
- *There are missed opportunities for vaccination in Canada, resulting in preventable morbidity and mortality. In 1993 and 1994, respectively, 17.5% and 25.0% of cases with* ***Haemophilus influenzae*** *type b infection occurred in children who were eligible to receive vaccine but did not – some as a result of parental decisions not to immunize but others as a*

* **Members:** Dr. D. Scheifele (Chairperson); Dr. J. Spika (Executive Secretary); N. Armstrong (Advisory Committee Secretariat Officer); Dr. G. DeSerres; Dr. P. DeWals; Dr. I. Gemmill; Dr. S. Halperin; Dr. B. Law; Dr. M. Naus; Dr. P. Orr; Dr. W. Schlech III; Dr. B. Ward.

Liaison Members: Dr. J. Carsley (CPHA); Dr. T. Freeman (CFPC); Dr. J. Levingood (CDC); Dr. V. Marchessault (CPS); Dr. A. McCarthy (ND); Dr. J. Salzman (CATMAT); Dr. J. Waters (ACE).

Ex-Officio Members: Dr. P. Duclos (LCDC); Dr. L. Palkonyay (BB); Dr. H. Robinson (MSB).

Members of the Working Group for the National Guidelines for Childhood Immunization Practices: N. Armstrong, Dr. A. Carter (CMA); Dr. P. Duclos; Dr. B. Law (Chairperson); Dr. V. Marchessault; Dr. M. Naus; Dr. P. Varughese (LCDC); Dr. J. Waters.

result of inappropriate deferral of immunization or failure to give the vaccine as recommended.

- *Some provincial studies indicate that up to 13% of vaccines were exposed to freezing during distribution and storage.*
- *The reporting of vaccine-associated adverse events varies widely across jurisdictions in Canada.*

The continued success of routine childhood immunization requires that all those involved, including policy makers, program administrators, and providers take a pro-active approach to childhood immunization, and work together to achieve and maintain a high standard of excellence in planning, conducting, and reviewing childhood immunization programs.

NACI embarked on a process of developing guidelines for childhood immunization practices which could be applied to current public and private systems for vaccine delivery. The guidelines were first drafted in 1995. They were revised after 2 years of consultation with provincial and territorial health authorities; professional medical, nursing, public-health, and hospital organizations; individual providers; and child advocacy groups; and discussion at the 1996 National Immunization Conference. They have been endorsed by the Canadian Paediatric Society, Health Canada's Advisory Committee on Epidemiology, the College of Family Physicians of Canada, the Canadian Medical Association, the Canadian Nurses Association, the Aboriginal Nurses Association of Canada, and the Society of Obstetricians and Gynaecologists of Canada.

The guidelines are deliberately broad, far-reaching, and rigorous. Defined as directing principles, they represent the most desirable immunization practice. Providers can use them to assess their current practices, and to identify areas of excellence as well as areas requiring improvement. Some of the guidelines require the involvement of the provinces and territories (e.g. the need to track immunizations and audit coverage levels). Furthermore, some providers and programs may not have the necessary funds to implement the guidelines fully at this time. In such cases, the guidelines can act as a tool to better define immunization needs, and to demonstrate the need for additional resources to achieve national goals and targets.

These guidelines are recommended for use by all health professionals in the public and private sectors who administer vaccines or manage immunization services for infants and children. Some of the guidelines will be more applicable to particular settings or situations but all should be considered in reviewing current practices.

Certain terms have been used throughout. "Provider" refers to any individual, nurse, or physician qualified to give a vaccine. The individual usually responsible for a given child's routine immunization is referred to as the "regular immunization provider". Given the variations in practices and populations across Canada, it is understood that there may be no identifiable regular provider in some cases and the term may encompass a collective group in other cases. "Child" or "children" is used to refer to individuals, from infancy through adolescence, being considered for immunization, as prescribed by routine immunization schedules. Terms such as "client" and "patient" have not been used but could be considered inter-changeable with "child" in the text. "Parent" is used throughout to designate the individual(s) legally responsible for the child and includes both parents as well as legal guardians.

Ideally, immunization should be part of comprehensive childhood health-care programs to ensure that children of all ages are up-to-date with recommended schedules. The delivery of primary care to infants, children, and adolescents and routine immunization in Canada is done in a variety of settings – from physicians' offices to public-health clinics. Private providers and local health officials should cooperate in their efforts to assure high coverage rates in the community to achieve and maintain the highest possible degree of community protection against vaccine-preventable diseases.

On behalf of the collaborating groups, we ask for your full cooperation in striving to follow these guidelines for childhood immunization practices.

GUIDELINES FOR CHILDHOOD IMMUNIZATION PRACTICES

GUIDELINE 1

Immunization services should be readily available.

Immunization services should be responsive to the needs of parents and children. When feasible, providers should schedule immunization appointments in conjunction with appointments for other health services for children. Immunization services, whether public-health clinics or physicians' offices, should be available during the week and at hours that are convenient for working parents. Services should be available on working days, as well as during some other hours (e.g. weekends, evenings, early mornings, or lunch hours).

GUIDELINE 2

There should be no barriers or unnecessary prerequisites to the receipt of vaccines.

While appointment systems facilitate clinic planning and avoid unnecessarily long waits for children, appointment only systems may act as barriers to the receipt of vaccines. Children who appear on an unscheduled basis for vaccination should be accommodated when possible. Such children should be rapidly and efficiently screened without requiring other comprehensive health services.

A reliable decision to vaccinate can be based exclusively on the information elicited from a parent, and on the provider's observations and judgment about the child's wellness at the time. At a minimum, this includes

- asking the parent if the child is well
- questioning the parent about potential contraindications (Table 1)
- questioning the parent about reactions to previous vaccinations
- observing the child's general state of health.

Policies and protocols should be developed and implemented so that the administration of vaccine does not depend on individual written orders or on a referral from a primary-care provider.

GUIDELINE 3

Routine childhood immunization services should be publicly funded.

All routine childhood immunizations, as recommended by NACI, should be considered necessary medical services. As such, they should be provided at no charge to patients under provincial and territorial health-service systems.

GUIDELINE 4

Providers should use all clinical encounters to screen for needed vaccines and, when indicated, vaccinate children.

Each encounter with a health-care provider, including those that occur during hospitalization, is an opportunity to review the immunization status, and if indicated, administer needed vaccines. Physicians who offer care to infants and children should consider the immunization status at every visit and offer immunization service as a routine part of that care or encourage attendance at the appropriate public health or physician clinic. At each hospital admission the vacci- nation record should be reviewed, and before discharge from the hospital, children should receive the vaccines for which they are eligible by age or health status. The child's current immunization provider should be informed about the vaccines administered in hospital. However, successful implementation requires significant improvements in keeping records of immunization histories (see Guideline 9).

GUIDELINE 5

Providers should educate parents in general terms about immunization.

Providers should educate parents in a culturally sensitive way, preferably in their own language, about the importance of vaccination, the diseases vaccines prevent, the recommended immunization schedules, the need to receive vaccines at recommended ages, and the importance of bringing their child's vaccination record to every health-care visit. Parents should be encouraged to take responsibility for ensuring that their child completes the full series. Providers should answer all questions parents may have and provide appropriate education materials at suitable reading levels, preferably in the parents' preferred language. Providers should familiarize themselves with information on immunization provided by the appropriate health departments as well as other sources.

GUIDELINE 6

Providers should inform parents in specific terms about the risks and benefits of vaccines their child is to receive.

Information pamphlets about routine childhood vaccines are available from ministries of health in many provinces and the territories, and also from the Canadian Paediatric Society. Such pamphlets are helpful in answering many questions that parents may have about immunization. Providers should document in the medical record that they have asked the parents if they have any questions and should ensure that satisfactory answers to any questions were given.

Providers should explain where and how to obtain medical care during daytime and nighttime in case of an adverse event following vaccination.

GUIDELINE 7

Providers should recommend deferral or with-holding of vaccines for true contraindications only.

There are very few true contraindications to vaccination according to current Canadian guidelines and providers must be aware of them. Accepting conditions that are not true contraindications often results in the needless deferral of indicated vaccines.

Minimal acceptable screening procedures for precautions and contraindications include asking questions to elicit a history of possible adverse events following prior vaccinations, and determining any existing precautions or contraindications (Table 1).

GUIDELINE 8

Providers should administer all vaccine doses for which a child is eligible at the time of each visit.

Available evidence indicates that most routine childhood vaccines can be administered at the same visit, safely and effectively. Some vaccines are provided in a combination format whereby more than one is given in a single injection and others require separate injection.

GUIDELINE 9

Providers should ensure that all vaccinations are accurately and completely recorded.

9.1 Data to be recorded in the child's record at the time of vaccination

For each vaccine administered the minimum data to be recorded in the child's record should include the name of the vaccine, the date (day, month, and year) and route of administration, the name of the vaccine manufacturer, the lot number, and the name and title of the person administering the vaccine.

Table 1: Contraindications and precautions for childhood vaccines[†]

Vaccines	True Contraindications	Precautions[††]	Not Contraindications
All vaccines	• Anaphylactic reaction to previous vaccine dose • Anaphylactic reaction to vaccine constituent • Moderate or severe illness with or without fever		• Mild to moderate local reactions following injection of vaccine • Mild acute illness with or without fever • Current antimicrobial therapy • Convalescent phase of illness • Prematurity • Recent exposure to infectious disease • Personal or family history of allergy, except personal history of anaphylaxis to one or more vaccine components
DPT	• Anaphylactic reaction to previous dose of vaccine	• Hypotonic-hyporesponsive state within 48 hours of prior dose of DPT	• History of pertussis • Fever $\geq 40.5^{\circ}$ C after prior dose of DPT • Family history of sudden infant death syndrome • Convulsion within 48 hours of prior dose of DPT • Family history of convulsions • Persistent, inconsolable crying lasting $\geq$ 3 hours, within 48 hours of prior dose of DPT
OPV	• Infection with HIV or household contact with HIV • Immunodeficiency state • Immunodeficient household contact	• Pregnancy	• Breast feeding • Current antimicrobial therapy • Diarrhea
IPV	• Anaphylactic reaction to neomycin		
MMR	• Anaphylactic reaction to neomycin • Pregnancy (Note: The theoretical risk of fetal damage, if any, is very small. Thus rubella immunization in the first trimester should not be a reason to consider termination of pregnancy.) • Immunodeficiency state	• Anaphylactic reaction to egg ingestion • Recent IG administration	• Tuberculosis or positive PPD • Simultaneous TB skin testing • Current antimicrobial therapy • Infection with HIV • Non-specific allergy
Hib			• History of Hib disease
HBV			• Pregnancy
Influenza	• Anaphylactic reaction to eggs		• Pregnancy

† Adapted from the *Canadian Immunization Guide*, 4th edition, 1993. For further information consult appropriate sections of the guide.
†† The events or conditions listed as precautions are not contraindications but should be carefully considered in determining the benefits and risks of administering a specific vaccine. If the benefits are believed to outweigh the risks (e.g. during an outbreak or foreign travel), the vaccine should be given.

9.2 Updating and maintaining the personal vaccination record

All providers should encourage the parents to maintain a copy of their child's personal vaccination record card and present it at each health-care visit so that it can be updated. If a parent fails to bring a child's card, the provider should ensure that adequate information is given so the parent can update the card with the name(s) of the vaccine(s), the date, the provider and the facility.

9.3 Documentation for vaccines given by other providers

Providers should facilitate the transfer of information in the vaccination record to other providers and to appropriate agencies in accordance with legislation.

When a provider who does not routinely vaccinate or care for a child administers a vaccine to that child, the regular provider should be informed.

GUIDELINE 10

Providers should maintain easily retrievable summaries of the vaccination records to facilitate age-appropriate vaccination.

Providers should maintain separate or easily retrievable summaries of vaccination records to facilitate assessment of coverage as well as the identification and recall of children who miss appointments. In addition, immunization files should be

sorted periodically, with inactive records placed into a separate file. Providers should indicate in their records, or in an appropriately identified place, all primary-care services that each child receives in order to facilitate scheduling with other services.

GUIDELINE 11

Providers should report clinically significant adverse events following vaccination – promptly, accurately, and completely.

Prompt reporting of adverse events following vaccination is essential to ensure vaccine safety, allowing for timely corrective action when needed, and to continually update information regarding vaccine risk-benefit and contraindications.

Providers should instruct parents to inform them of adverse events following vaccination. Providers should report all clinically significant events to the local public-health authority, regardless of whether they believe the events are caused by the vaccine or not. Providers should fully document the adverse event in the medical record at the time of the event or as soon as possible thereafter. At each immunization visit, information should be sought regarding serious adverse events that may have occurred following previous vaccinations.

GUIDELINE 12

Providers should report all cases of vaccine-preventable diseases as required under provincial and territorial legislation.

Providers should know the local requirements for disease reporting. Reporting of vaccine-preventable diseases is essential for the ongoing evaluation of the effectiveness of immunization programs, to facilitate public-health investigation of vaccine failure, and to facilitate appropriate medical investigation of a child's failure to respond to a vaccine appropriately given.

GUIDELINE 13

Providers should adhere to appropriate procedures for vaccine management.

Vaccines must be handled and stored as recommended in manufacturers' package inserts. The temperatures at which vaccines are transported and stored should be monitored daily. Vaccines must not be administered after their expiry date.

Providers should report usage, wastage, loss, and inventory as required by provincial, territorial or local public-health authorities.

Providers should be familiar with published national and local guidelines for vaccine storage and handling. Providers must ensure that any office staff designated to handle vaccines are also familiar with the guidelines.

GUIDELINE 14

Providers should maintain up-to-date, easily retrievable protocols at all locations where vaccines are administered.

Providers administering vaccines should maintain a protocol that, at a minimum, discusses the appropriate vaccine dosage, vaccine contraindications, the recommended sites and techniques of vaccine administration, as well as possible adverse events and their emergency management. The Canadian Immunization Guide and updates, along with package inserts, can serve as references for the development of protocols. Such protocols should specify the necessary emergency equipment, drugs (including dosage), and personnel to manage safely and competently any medical emergency arising after administration of a vaccine. All providers should be familiar with the content of these protocols, their location, and how to follow them.

GUIDELINE 15

Providers should be properly trained and maintain ongoing education regarding current immunization recommendations.

Vaccines must be administered only by properly trained persons who are recognized as qualified in their specific jurisdiction. Training and ongoing education should be based on current guidelines and recommendations of NACI and provincial and territorial ministries of health, the Guidelines for Childhood Immunization Practices, and other sources of information on immunization.

GUIDELINE 16

Providers should operate a tracking system.

A tracking system should generate reminders of upcoming vaccinations as well as recalls for children who are overdue for their vaccinations. A system may be manual or automated, and may include mailed or telephone messages. All providers should identify, for additional intensive tracking efforts, children considered at high risk for failing to complete the immunization series on schedule (e.g. children who start their series late or children who fall behind schedule).

As an added measure, providers should encourage the development of, and cooperation with, a comprehensive provincial and territorial immunization tracking system.

GUIDELINE 17

Audits should be conducted in all immunization clinics to assess the quality of immunization records and assess immunization coverage levels.

In both public and private sectors, an audit of immunization services should include assessment of all or a random sample of immunization records to assess the quality of documentation, and to determine the immunization coverage level (e.g. the percentage of 2-year-old children who are up-to-date). The results of the audit should be discussed by providers as part of their ongoing quality assurance reviews, and used to develop solutions to the problems identified.