

National Advisory Committee on Immunization (NACI)

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1.0 BACKGROUND

The National Advisory Committee on Immunizing Agents was initially established in 1964 to report to the Dominion Council of Health. Its purpose was “to advise and make recommendations on immunizing agents” and “...to propose to the Council aspects of immunizing agents that appear to warrant special consideration”. The first meeting of the Committee was held in November 1964.

From 1975 to 2000, the Committee reported to the Assistant Deputy Minister, Health Protection Branch, Health Canada. The Committee's name was formally changed to the NACI in June 1978. From 2000-2004 the Committee reported to the Assistant Deputy Minister, Population and Public Health Branch (PPHB), following a restructuring within Health Canada. Since October 2004, the NACI reports to the Chief Public Health Officer of Canada, Public Health Agency of Canada (PHAC).

In June 2003, The Conference of F/P/T Deputy Ministers of Health (CDMH) accepted the final report on the National Immunization Strategy as advice in moving forward with immunization issues in Canada. (<http://www.phac-aspc.gc.ca/publicat/nis-sni-03/index-eng.php>)

An advisory committee to the Public Health Network, the Canadian Immunization Committee (CIC) was established as the mechanism for making continued, collaborative progress to address immunization issues in Canada. The CIC is the means to effect F/P/T collaboration for the purpose of providing leadership in immunization through the analysis, development and recommendation of national goals, effective and efficient immunization programs, policies, practices, guidelines and standards.

NACI works collaboratively with the CIC and is part of an overall national structure addressing Immunization issues in Canada.

2.0 MANDATE

To provide the Public Health Agency of Canada (PHAC) with ongoing and timely medical, scientific, and public health advice relating to vaccines and certain prophylaxis agents. More specifically, advice may relate to the use of vaccines in humans, vaccine evaluation, and the monitoring of vaccine-associated adverse events.

3.0 ROLES AND RESPONSIBILITIES

Without limiting the foregoing, the Committee will carry out its mandate in the following manner:

3.1 Advising the PHAC on vaccine use by:

- a. recommending practices relating to the use of currently or newly authorized for sale vaccines in Canada.
- b. reviewing proposed product monographs, with the consent of the manufacturers, for consistency with NACI statements, and recommending updates to existing product

monographs for consistency with current NACI recommendations (based on available science);

- c. identifying merits of specific product(s) authorized for sale;

3.2 Advising the PHAC on vaccine research and surveillance by:

- a. recommending phase IV post marketing assessment and surveillance activities for specific authorized vaccines (including surveillance of vaccine failures and adverse-events and immunization coverage);
- b. identifying research questions of interest to provincial, territorial and national immunization programs;
- c. recommending criteria for assessment of vaccines not authorized for sale upon request of the Biologics and Genetic Therapies Directorate, Health Canada.
- d. recommending vaccine preventable disease surveillance prior to recommendation of vaccine use when available data is insufficient to make a recommendation for its use in Canada

3.3 Advising the PHAC and the CIC on vaccine programs by:

- a. advising on vaccine(s) authorized for sale for consideration for inclusion in provincial/territorial immunization programs;
- b. advising on the development of national goals and objectives for immunization coverage and disease incidence and encouraging uniformity of programs between provinces/territories;
- c. Advising on best practices in immunization (e.g. record keeping, immunization technique, vaccine cold chain).

4.0 GOVERNANCE

4.1 Reporting Relationship:

To: Chief Public Health Officer (CPHO)
Public Health Agency of Canada (PHAC)

Via: Director General, Centre for Immunization and Respiratory Infections Diseases (CIRID),
(IRID)

4.2 Membership

4.2.1 Chair

The Chair will be appointed by the CPHO (upon recommendation by the Director General of IRID). Selection will be based on expertise and knowledge in the fields of immunization practices, public health, and use of vaccines and prophylaxis agents for the prevention of vaccine preventable diseases. The Chair will be the NACI representative on CIC. The Chair is a non-voting member, except when there is a tie vote.

4.2.2 Vice-Chair

A Vice-Chair will be appointed by the CPHO (upon recommendation by the Director General of the CIDPC, the Director of CIRID). The Vice-Chair will be selected from existing membership. The Vice-Chair will act only when the Chair is unavailable as an alternate acting Chair.

4.2.3 Executive Secretary

The Director of CIRID will assign an Executive Secretary who will provide leadership and strategic advice in the management of the Committee and will work closely with the Chair and the Secretariat.

4.2.4 Members

Membership will consist of twelve voting members from authorities who are knowledgeable in the field of immunization practices, have multidisciplinary expertise in public health, and have expertise in the use of vaccines and prophylaxis agents for the prevention of vaccine preventable disease. Selection will be based on expertise. Membership may also include one or more members with expertise in pharmacy medicine. Members are expected to express their personal opinions as informed by their professional expertise. Appointments should reflect the PHAC's policy that committee membership be fairly balanced in terms of points of view represented, diverse geographic areas and the committee's function. Members are to be appointed by the CPHO for a term of four years (upon recommendation by the Director General of the CIDPC and the Director of CIRID, in consultation with the Chair).

The membership will be reviewed on a regular basis by the Chair and Executive Secretary. Suggestions will be sought from current and former NACI members. A list of potential nominees will be maintained by the Secretariat. The candidate remains on the list until withdrawn or nominated to the committee. In appropriate circumstances, the CPHO may extend an individual's term of office for up to another four years. When a member is unable to complete his or her term, a letter of resignation should be submitted to the Chair of the committee and the CPHO via the Secretariat. A new member will be appointed for the full four-year term.

4.2.5 Liaison Groups

The CPHO will identify liaison groups to NACI that can provide expertise on Vaccines safety and effectiveness, and/or can provide input to ensure proper interpretation of NACI's advice, and/or have access to relevant research on specific issues (upon recommendation by the Director General of the CRID in consultation with the Chair). Each liaison group identified will be invited to assign a non-voting representative that will be expected to: bring knowledge and input into the NACI discussions; express the views of the organization; and communicate NACI's advice to the organization as permitted by the PHAC. The Executive Secretary will review the liaison groups on a regular basis and make recommendation to the Director of CIRID, in consultation with the Chair. The ongoing review will consider the CIC structure, communication and linkages. Suggestions will be sought from NACI members. Liaison representatives can serve on working groups and subcommittees.

4.2.6 Ex-officio Members

The Director of CIRID can assign ex-officio non-voting members. The role of the Ex-officio members is to support the work of NACI and the PHAC by: providing additional knowledge and expertise, by communicating the views of the Department/Agency/Division they represent, and by communicating NACI's advice as permitted by the PHAC.



5.0 VOTING AND QUORUM

Voting will be restricted to the twelve members only. A quorum of at least 2/3 of members is required to authenticate a vote. Members who have been absent for all discussions and not able to review all background documentation will not be permitted to vote in advance of meetings or calls. An abstention will count as a neutral vote. Where there is a tie, the Chair can cast the deciding vote.

6.0 RESOURCES AND SUPPORT

Secretariat functions to the committee (or working group) will be provided by the PHAC. Scientific, research, policy, monitoring, and other technical support will be provided and/or funded by the PHAC, CIRID, CIDPC. The members' travel expenses to participate at regular and ad hoc NACI meetings will be paid by the PHAC in accordance with Treasury Board Policies. Liaison representatives and Ex-officio members will be expected to pay for their travel expenses.

7.0 MEETINGS

NACI meets three times a year (face-to-face) and by teleconference as needed.

7.1 Attendance

Members of NACI assume the responsibility for attending all meetings. If a meeting is missed, background material will be provided on issues discussed and the member will be expected to be prepared for the next meeting. Members will not be expected to identify an alternate should they be unable to attend meetings.

Liaison representatives will be encouraged to attend all meetings. Should they be unable to attend a meeting, they can assign an alternate.

7.2 Record of Decisions

For each meeting, a Summary of Discussions will be prepared by the Secretariat. Once reviewed by the Chair/Executive Secretary it will be distributed to members/liaison representatives and Ex-officio members for comments within one month following the meeting. Once approved by all NACI members, the Summary can be used for information sharing.

For each meeting, Record of Decisions will also be prepared by the Secretariat. Once reviewed by the Chair/Executive Secretary it will be distributed to the members/liaison representatives/Ex-officio members. Upon approval by all NACI members a final version of the Record of Decisions will be sent to the committee as a Confidential document. (Not to be distributed Further)

7.3 Invitees

Experts, including representatives from manufacturers, may be invited to make presentation on a need basis and should not participate in group discussions.

7.4 Selection of topics (on a needs basis)

At each meeting a list of future topics will be listed;

Suggestions can be submitted between meetings to the Secretariat;

Six weeks before each meeting, agenda items will be requested and a list of current agenda items will be distributed. Those suggesting new agenda items are asked to

specify the topic, issues of concern, and specific questions to be addressed by NACI;

Agenda items are accepted for presentation by the Executive Secretary, in consultation

with the Chair;
NACI will review every major vaccine preventable disease at least once every 4 years, to consider whether a revised recommendation is needed.

8.0 PRIVACY OF INFORMATION

Matters discussed at the meeting are confidential and should not be discussed by members in public until they are so permitted by the PHAC. Reports to respective associations by liaison members should be in general terms only and should be maintained in confidence by that member's organization. All members are required to sign confidentiality agreements. The draft NACI statements should not be shared. However, in some cases it may be acceptable to share information on the general directions that NACI is going with a statement. In an event that it would be useful to share a draft statement with specific groups for feedback, the Chair and Executive Secretary should be consulted.

9.0 MEDIA INTERACTION

All media request related to NACI statements or activities should be directed to the PHAC, Media Relations Division. Media response will be coordinated by the PHAC. NACI members, liaison members and ex-officio members may speak to the media as immunization experts on non-confidential issues and express their personal opinions but are not authorized to speak on behalf of the committee. The Chair and Vice-Chair are authorized spokespersons for NACI. When appropriate, the PHAC, in consultation with the Chair, may appoint a member of the committee to act as its spokesperson. The PHAC Media Relations Office will coordinate media interviews and provide support to the spokesperson (i.e. media training, provide media lines and Q's and A's etc. for their reference)

10. CONFLICT OF INTEREST

Members, representatives and consultants are expected to conduct themselves in an appropriate manner and in accordance with the NACI conflict of interest guidelines. They must refrain from any real or perceived conflict of interest. In situations where conflict of interest, or the appearance thereof, arises in the course of the work of a committee, the individual involved must declare its existence and disqualify himself/herself from participation in the discussion or from further participation on the committee according to the circumstances of specific situations. Prior to of each meeting, members will be given an opportunity to advise on any potential conflict of interest. Members, liaison representatives and consultants will be required to submit annual conflict of interest declarations to the Executive Secretary and disclose any circumstances that may place, or be seen to place the member in a real, apparent or potential conflict of interest. It will be incumbent upon the member to update their disclosure in writing, should their his/her personal situation change.

Members, representatives and consultants are expected to protect and maintain as confidential any trade secret or privileged information divulged during the work of the committee. They must not discuss or divulge information obtained from the work of the committee, including its recommendations, until such time as this information has been officially released by the PHAC for public distribution.

11.0 RECOMMENDATIONS

11.1 Development Process

NACI members or CIRID staff from the relevant programs may take the lead for drafting

recommendations on behalf of the working group. The working group is responsible to analyze the research data prior to presentation to the full committee. Documents should be submitted in a timely manner for members to have time to analyze the information prior to discussion and decision making.

Smaller working groups will be established to deal with specific vaccine-related issues. Working group chairs should be members of NACI or as deemed appropriate by the Committee Chair. Members will be asked to volunteer to participate in working groups based on their expertise. A working group membership list will be maintained by the Secretariat and reviewed on a regular basis. Working groups will review technical aspects and prepare recommendations to be discussed by the full committee. These working groups must include one or more regular voting members as well as one staff member of the PHAC. They may also include liaison members or other consultants (e.g. representatives from the Canadian Immunization Committee or the Committee to Advise on Tropical Medicine and Travel).. Experts, including representatives from manufacturers, may be invited to present to the group but may not join the group or participate in group discussions.

The process of developing NACI recommendations includes:

1. review of Product Monograph;
2. thorough review of the scientific literature on the burden of disease (morbidity, mortality) in the population in general and in specific risk groups, vaccine characteristics (e.g. safety, efficacy, effectiveness), in addition to various factors outlined in "An Analytic Framework for Immunization Programs in Canada". Consideration will be given to the relevance, quality and quantity of published and unpublished data.
3. a review of the recommendations of other groups: i.e. Advisory Committee on Immunization Practices (ACIP), American Academy of Pediatrics (AAP), Canadian Pediatrics Society (CPS).
4. the committee will grade and report the level of evidence associated with its recommendations. In the absence of data or when data are inadequate, the expert opinions of members and other experts will be used to make recommendations.

The methods used for developing recommendations will be made explicit in the published recommendations.

11.2 Publication of Recommendations

After approval by the CPHO, NACI recommendations may be published in the Canada Communicable Disease Report and occasionally reprinted in other publications. They may also be made available on the PHAC Website.

12.0 TERMS OF REFERENCE

Minor Amendments to the Terms of Reference can be made by the Executive Secretary, in consultation with the Chair, subject to informing the members at the next meeting.

The Terms of Reference may be amended at any meeting by consensus or by vote.

Source: <http://www.phac-aspc.gc.ca/naci-ccni/tor-eng.php>