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Canada's National Advisory Committee on Immunization (NACI): Evidence-based decision-making on vaccines and immunization

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ABSTRACT

The National Advisory Committee on Immunization (NACI) provides medical, scientific, and public health advice on the use of vaccines in Canada. This article describes the structure and processes of NACI, as well as its approach to evidence-based decision-making. In a rapidly evolving and complex immunization environment, NACI has faced challenges in its endeavour to make thorough and timely evidence-based recommendations. Making population-level recommendations without formally considering the full spectrum of public health science (e.g. cost-effectiveness) presents difficulties in the implementation of NACI's recommendations. Although an improved and more transparent evidence-based NACI decision-making process is now in place, this is continuing to evolve with a current review of structures and processes underway to further improve effectiveness and efficiencies.

1. Introduction

The scientific body in Canada that addresses one of the World Health Organization's (WHO's) priorities for "national immunization technical advisory committees. . .as part of the process of ensuring evidence-based decision-making at the country level" is the National Advisory Committee on Immunization (NACI) [1].

As a federal state, responsibility for health in Canada is shared by the national and provincial-territorial governments. Numerous federal–provincial–territorial consultative processes enable coordination and collaboration among different levels of government while preserving local independence. The Public Health Agency of Canada (PHAC), created in 2004 and led by Canada's Chief Public Health Officer, is the main federal agency responsible for public health. PHAC reports to Parliament through the Minister of Health, and collaborates closely with all levels of government (provincial, territorial, municipal), as well as non-governmental organizations, other countries, and international organizations like the WHO. NACI is an expert advisory committee of the PHAC and was established and mandated by the agency itself through its legislative ability to seek views about public health issues [2].

NACI is charged with providing medical and scientific advice on immunization for Canadians, focusing on scientific evidence to evaluate vaccine safety and efficacy. The planning and delivery of immunization programs in Canada falls under the jurisdiction of each province/territory. A federal/provincial/territorial committee, the Canadian Immunization Committee, considers these programmatic issues, including economic considerations, in light of NACI statements, and produces recommendations to the Pan-Canadian Public Health Network. The overarching framework for the administration of these committees is the National Immunization Strategy (available at: http://www.phac-aspc.gc.ca/publicat/nis-sni-03/index-eng.php). Recommendations for the prevention of vaccine-preventable infections and other health hazards for Canadians who travel outside Canada's borders are made by a separate scientific committee, the Committee to Advise on Tropical Medicine and Travel.

A broad range of stakeholders depend on NACI's recommendations, including decision-makers in provinces and territories, public health practitioners, health care providers, individuals; as well as vaccine manufacturers, non-governmental organizations

Abbreviations: ACIP, United States Advisory Committee on Immunization Practices; CDC, United States Centers for Disease Control and Prevention; NACI, National Advisory Committee on Immunization; PHAC, Public Health Agency of Canada; WHO, World Health Organization.

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(e.g. professional societies and immunization advocacy groups), and federal departments (e.g. First Nations Inuit Health Branch, Citizenship & Immigration Canada, Department of National Defence). In fact, in a recent report from the national Advisor on Healthy Children and Youth, it was recommended that "the federal government continue to support the work of the National Advisory (Committee) on Immunization in getting valuable information to health care providers and parents" [3].

2. Description and background

In 1964, a committee called "The National Advisory Committee on Immunizing Agents" was established in Canada to facilitate coordination with the provinces, and served as the principal advisory agency to the Minister of National Health and Welfare. The Committee's name was formally changed to the National Advisory Committee on Immunization (NACI) in June 1978. Since October 2004, NACI has reported to the Chief Public Health Officer of Canada who heads the Public Health Agency of Canada. The current mandate of NACI is "to provide the Public Health Agency of Canada with ongoing and timely medical, scientific, and public health advice relating to vaccines and certain prophylaxis agents (e.g., immunoglobulins)".

NACI publishes its recommendations in an open-access electronic periodical called the *Canada Communicable Disease Report (CCDR)* (http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/index-eng.php), which is indexed in the MEDLINE of the National Library of Medicine, and Advisory Committee Statements also appear on the public website of NACI. With the support of the Centre for Immunization and Respiratory Infectious Diseases at PHAC, NACI publishes a handbook on vaccine and immunization information called the *Canadian Immunization Guide* every four years in hardcopy and pdf format. In the future, the Guide will be published in an evergreen, evolving electronic format. The guide is seen as a useful and reliable resource by immunization providers across the country and is available at: http://www.phac-aspc.gc.ca/naci-ccni/index-eng.php.

Membership on NACI consists of twelve voting members from across Canada who are recognized experts in the fields of pediatrics, infectious diseases, immunology, medical microbiology, internal medicine, nursing, pharmacy and public health. There are eleven liaison members from various organizations with interests in immunization, as well as six ex officio members from relevant areas within the federal government who contribute to working groups and full committee discussions (Table 1). While liaison and ex officio members do not vote on NACI recommendations, they are integral to NACI's work, and bring essential knowledge and perspectives to the recommendation process.

Selection of *NACI members* is based on expertise in relevant fields. Members are expected to express their personal opinions as informed by their professional expertise, rather than, for example, the province or region they live in. Appointments are by the Chief Public Health Officer, and 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 appointed for a term of four years and may be requested to renew their membership for a second term of four years. Membership is reviewed on a regular basis by the Chair and Executive Secretary. When vacancies occur, calls for members are made public through the NACI website and to professional groups (e.g. liaison groups). Interested individuals are encouraged to submit their curriculum vitae through the website.

The *Chair* of NACI is also appointed by the Chief Public Health Officer for a four-year term and is a non-voting member of the Committee (unless there is a tie vote). Selection of the Chair is based on expertise and knowledge in the field of immunization practices, public health, and use of vaccines and prophylaxis agents for the prevention of vaccine-preventable diseases. A Vice-Chair selected from existing membership is also appointed for a four-year term. The Vice-Chair becomes the NACI Chair when the Chair's term is complete. The Director of the Immunization and Respiratory Infectious Disease Division designates an Executive Secretary who provides leadership and strategic advice for the Committee and works closely with the Chair and the NACI Secretariat (currently comprised of two project managers/assistants and one nurse epidemiologist). Secretariat functions to NACI are provided for or funded by the federal public health agency.

Table 1
List of Liaison Groups and ex officio representation on National Advisory Committee on Immunization (NACI).

Liaison Groups	Ex officio representation
Association of Medical Microbiology and Infectious Disease Canada	Biologic & Genetic Therapies Directorate, Health Canada
Canadian Nursing Coalition for Immunization	Canadian Forces Health Services Group, Department of National Defence
Canadian Pediatric Society	Canadian Immunization Committee, Immunization Programs Division, Public Health Agency of Canada
Canadian Public Health Association	First Nations & Inuit Health Branch, Health Canada
Centres for Disease Control	Surveillance and Outbreak Response, Public Health Agency of Canada
College of Family Physicians of Canada	Vaccine Safety, Public Health Agency of Canada
Community Hospital Infection Control Association	
Committee to Advise on Tropical Medicine and Travel	
Council of Chief Medical Officers of Health	
Society of Obstetricians and Gynaecologists of Canada	

Liaison members of NACI are representatives from groups identified by the Chief Public Health Officer to provide expertise on vaccine safety and effectiveness, and/or provide input to ensure appropriate interpretation of NACI's advice, and/or have access to relevant research on specific issues. Liaison members are selected by their organizations, and are 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.

Ex officio representatives on NACI are assigned by the Director General of the Centre for Immunization & Respiratory Infectious Diseases of the Public Health Agency of Canada. The role of the ex officio members is to support the work of NACI and the agency by providing additional knowledge and expertise, communicating the views of the Department/Agency/Division they represent (e.g. First Nations and Inuit Health Branch), and communicating NACI's advice as permitted by the PHAC.

Vaccine industry representatives cannot be members of NACI, and do not participate in group discussions. Industry experts do provide information about vaccines to the Committee, and may be invited to make presentations to the full committee or its working groups. NACI is not funded in any way by the vaccine industry.

NACI *Working Groups* are established to address specific vaccine and immunization issues. These groups review evidence and draft Advisory Committee Statements on specific vaccines, including options for vaccine recommendations for the full committee to consider. Working groups may prepare guidance in response to

specific inquiries or other issues as they arise, and are also asked to contribute to and revise relevant chapters of the *Canadian Immunization Guide*. Working Groups are comprised of voting and liaison members, PHAC staff and external experts as necessary.

Working group chairs are members of NACI or others who are appointed as deemed appropriate by the Committee Chair. Members (including voting members, liaison members, and ex officio members) are asked to volunteer to participate in working groups based on their expertise and interest. Working groups must include one or more regular voting members as well as one medical specialist from the PHAC (as Medical Lead). There are currently two Medical Leads (including the Executive Secretary) distributed among eighteen working groups. A PHAC Medical Lead is a physician who works closely with the Working Group chair and NACI Secretariat to assist with the technical analysis, literature review, and drafting of Advisory Committee Statements in addition to other roles and responsibilities, such as responding to medical inquiries to NACI. External content experts or other consultants may be invited to serve on a Working Group (e.g. representatives from the Canadian Immunization Committee or the Committee to Advise on Tropical Medicine and Travel) as necessary to provide broad input.

3. Terms of reference, meeting processes, and declaration of conflicts of interest

3.1. Terms of reference

Information on NACI's structure and processes is contained within its Terms of Reference, available publicly on the PHAC website (http://www.phac-aspc.gc.ca/naci-ccni/tor-eng.php#12). These Terms of Reference may be amended at any meeting by consensus or by vote.

3.2. Meeting processes

The National Advisory Committee on Immunization has three face-to-face meetings a year which occur over 2 days. Ad hoc teleconferences of the full committee are held as needed, and email correspondence occurs regularly. Meetings are not open to the public. Additional observers (e.g. health care students/post-graduate physician trainees or PHAC staff) may attend upon request and approval of the NACI Executive Committee, and after agreeing to confidentiality requirements. Experts, including representatives from vaccine manufacturers, may be invited to make presentations as needed.

For each meeting, detailed *Minutes* and a succinct *Summary of Discussions* are prepared by the Secretariat, reviewed by the Executive Secretary and Chair of NACI, and approved by the NACI. The *Summary of Discussions* is used for information sharing beyond NACI however the detailed *Minutes* is a confidential document that is not distributed beyond the Committee.

The agenda for NACI meetings is created based on changes in the epidemiology of vaccine-preventable diseases, new products, or new evidence about existing products. Potential topics may be submitted by committee members and other stakeholders, and are accepted for addition to the agenda by the Executive Secretary, in consultation with the Chair. An executive committee (consisting of the Chair, Vice-Chair, Executive Secretary, PHAC Medical Leads and NACI Secretariat) meets regularly by teleconference between meetings to oversee the progress of the Working Groups, plan full NACI meetings and deal with inter-current issues that arise.

3.3. Declaration of conflicts of interest

Members, liaison representatives and consultants are required to submit annual conflict of interest declarations to the Executive Secretary, based on *Conflict of Interest Guidelines*. Any circumstances that may place, or be seen to place the member in a real, apparent or potential conflict of interest should be disclosed on a written form. It is incumbent upon the member to update this disclosure should his/her personal situation change. Members, representatives and consultants are expected to conduct themselves in an appropriate manner and in accordance with the NACI guidelines.

In situations where a conflict of interests or the appearance thereof arises in the course of the work of the committee, the individual involved must declare its existence and either work with the Executive Secretary to resolve the conflict, or if necessary, disqualify himself/herself from participation in the discussion or from further participation on the committee according to the circumstances of specific situations.

4. Development of recommendations and the basis for decision-making

In January 2009, NACI formally introduced its process to develop and grade evidence-based recommendations through the publication of its Statement: "Evidence-based recommendations for immunization—Methods of the National Advisory Committee on Immunization" (available at: http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/09vol35/acs-1/index-eng.php). Publication of this process is intended to provide a transparent and clear description of the methods used for retrieving, synthesizing and weighing evidence that leads to a NACI recommendation.

In brief, the stages for the development of NACI recommendations are:

1. Knowledge synthesis (retrieval and summary of individual studies on vaccine safety, efficacy, immunogenicity, effectiveness, ranking of the level and quality of evidence of each study).
2. Synthesis of the body of evidence of benefits and harms, considering the relevance, quality of the evidence and magnitude of effects observed.
3. Translation of summarized evidence into recommendations associated with a qualitative recommendation grade (Table 2).

The relevant NACI Working Group is responsible for establishing the scope of and requirements for the literature review. The literature review may be contracted out to an external group/consultant, or performed within the PHAC. As part of the literature review, evidence tables are assembled in which each study is assigned a level of evidence based on research design (e.g. Level I for evidence from randomized controlled trials) and an assessment of the quality (internal validity) of the study is made (i.e. Good, Fair, Poor-based on design-specific criteria as outlined in Harris et al., 2001 [4]). The full knowledge synthesis includes a review of the product mono-

Table 2
National Advisory Committee on Immunization (NACI) recommendation for immunization—grades.

A	NACI concludes that there is good evidence to recommend immunization.
B	NACI concludes that there is fair evidence to recommend immunization.
C	NACI concludes that the existing evidence is conflicting and does not allow making a recommendation for or against immunization, however other factors may influence decision-making.
D	NACI concludes that there is fair evidence to recommend against immunization.
E	NACI concludes that there is good evidence to recommend against immunization.
I	NACI concludes that there is insufficient evidence (in either quantity and/or quality) to make a recommendation, however other factors may influence decision-making.

graph, scientific literature on the burden of disease (epidemiology, morbidity, mortality) in the population in general and in specific risk groups, vaccine characteristics (e.g. safety, immunogenicity, efficacy, effectiveness), in addition to various scientific factors outlined in "An Analytic Framework for Immunization Programs in Canada" [5]. Recommendations from other groups (e.g. WHO, Advisory Committee on Immunization Practices, Canadian Pediatric Society) are reviewed. The Working Group prepares recommendation options for consideration by the full NACI committee. The Medical Lead and the NACI Working Group Chair review all individual studies, but all the assembled evidence is available to the Working Group and to NACI.

Following full committee review and discussion of the data, draft Advisory Committee Statement, and recommendation options prepared by the Working Group, the NACI votes. Voting is restricted to the twelve members of NACI and occurs through an open process. A quorum of at least two thirds of members is required to authenticate a vote. Members who have been absent for all discussions and not able to review all background documentation are not permitted to vote in advance of meetings or calls.

The final NACI Advisory Committee Statement, incorporating committee discussion and vote, is circulated by email for approval. After this approval and final review by the NACI Chair and Executive Secretary, the document is sent to the Chief Public Health Officer for final approval. Once edited and translated into both official languages in Canada (French and English), approved NACI statements are usually published in the *Canada Communicable Disease Report* (http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/) and occasionally reprinted in other publications. They are also available on the PHAC website (http://www.phac-aspc.gc.ca/naci-ccni/recs-eng.php), along with the separately posted literature review that supported the development of the Advisory Committee Statement and the recommendations.

Recently NACI agreed to use a common template for Advisory Committee Statements. This includes: (1) an introduction (overview of previous NACI recommendations, national goals for the vaccine-preventable disease/immunization coverage, new evidence triggering the need for a new statement, methodology of the evidence-based review); (2) summary of the disease epidemiology; (3) summary of the vaccine characteristics; (4) recommendations and rationale; (5) research priorities; and (6) surveillance gaps.

5. Consideration of various scientific (e.g. vaccine efficacy) and programmatic (e.g. cost) factors for decision-making

As noted, national immunization recommendations are developed using an "Analytic Framework for Immunization Recommendations in Canada" [5]. This framework outlines a number of scientific (e.g. disease burden, vaccine characteristics) and programmatic (e.g. feasibility, acceptability, ethics, cost) factors that should be considered when making decisions regarding immunization programs. NACI considers the scientific factors within this framework, and the Canadian Immunization Committee builds on NACI's work to additionally consider the factors inherent in program planning and delivery that are outlined in the framework.

One challenge that NACI has faced is that it does not explicitly consider economic aspects of vaccine use since this responsibility has been delegated to the Canadian Immunization Committee. Awareness of the cost of vaccines and vaccine programs may be difficult to partition from discussions of the value of a vaccine to individual Canadians or broader populations. NACI may recommend that such factors be considered by local decision-makers or individual healthcare providers when applying NACI guidance. The following excerpt from the recent "Update on the Invasive Meningococcal Disease (IMD) and Meningococcal Vaccine Conjugate Recommendations" illustrates this [6]:

Choice of products for early adolescent dose:

> "The early adolescent dose could be given using either meningococcal C conjugate vaccine or quadrivalent conjugate meningococcal vaccine. Provinces/territories will need to consider their burden of illness from serogroups A, Y and W135 and the age distribution of cases by serogroup which provide an indication of the number of IMD cases that might be prevented. They will also need to consider the differential in cost between monovalent and quadrivalent products and other local factors."

<http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/09vol35/acs-dcc-3/index-eng.php>

6. Role of the committee in the ultimate decision-making process

NACI recommendations are used by provinces, territories, professional associations, advocacy groups and individual care providers. Since health care delivery in Canada is a provincial/territorial responsibility, variation in application of recommendations does occur. For the most part, jurisdictions adhere to NACI recommendations but the timing and logistics of program implementation may vary due to differences in local existing programs, resources and epidemiology. Jurisdictions also may consider the Canadian Immunization Committee's recommendations regarding program delivery options before planning local programs. Vaccines delivered by individual care providers outside of governmental programs could be paid for by the patient, by their employer or by individual or group health insurance plans.

Variability in the implementation of NACI recommendations, for example, is apparent in provincial schedules for meningococcal vaccine across the country, and the timing of program implementation. Since 2001, NACI has recommended the use of meningococcal C conjugate vaccine for infants, children from 1 to 4 years of age, adolescents and young adults [7]. While some provinces began implementing routine meningococcal C conjugate vaccination programs in 2002, it was not until 2007 that every province had a routine program.

NACI recommendations are seen in many cases as setting a standard of care or "best practice". According to the Canadian Medical Protection Association – the organization through which most physicians hold malpractice insurance – a physician is obliged to inform a patient of new vaccine recommendations made by agencies such as NACI. They note that patients must be made aware of "any official recommendations from authoritative groups, such as governments and medical specialty associations" as well as "any cost of the vaccine if it is not covered by the provincial/territorial health plan. Physician concerns regarding cost issues should not preclude informing the patient/legal guardian about vaccination options" [8].

7. Communication activities and training practices

7.1. Communication activities

NACI disseminates information related to its activities to health professionals and the public via electronic mail distribution alerts that a new Advisory Committee Statement has been posted on the publicly available *CCDR* site, via the *Canadian Immunization Guide* (http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php) and on the main NACI website (http://www.phac-aspc.gc.ca/naci-ccni/). NACI also responds to inquiries submitted by stakeholders (including members of the public and health professionals) about its recommendations and guidance.

Communication between members, liaison and ex officio representatives and the NACI Secretariat occurs via email, telephone conference and face-to-face meetings. NACI also communicates with its counterpart committee in the United States, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC). CDC has a standing liaison member on NACI and a representative of NACI is a liaison member of ACIP.

7.2. Training

The NACI Secretariat provides a new member orientation, including provision of materials addressing administrative matters (e.g. confidentiality guidelines), and key background documents on the process and methodology of Working Groups and the recommendation development process. Documents on the role of liaison and voting member responsibilities are provided.

Learning objectives for each NACI meeting are outlined in the agenda, and continuing professional development credits are assigned for educational components of the meeting. Experts in a particular field may be invited to present to NACI to inform members on a particular topic of interest with relevance to the mandate of the Committee. Additional training topics may be suggested by Committee members and arrangements for information/training sessions are made by the Secretariat.

8. Challenges, limitations and future developments

Like most immunization advisory committees, NACI has faced challenges in a rapidly evolving and complex immunization environment. Expectations of this committee have escalated with an increasing number of vaccines for the same infectious agent (e.g. multivalent pneumococcal conjugate vaccines), increasing complexity of vaccines (e.g. new adjuvants), increasing spectrum of vaccine recipients (e.g. older females for HPV vaccine), increasing spectrum of vaccine-preventable diseases (e.g. cervical cancer as a chronic disease with a long incubation period), increasing surveillance needs to consider the public health impact of vaccines (e.g. diseases that are not reportable), increasing complexity of immunization schedules, and increasing demands from stakeholders for improved information sharing and shorter timelines from vaccine regulatory approval to public statement release. Over the years, a rising number of Advisory Committee Statements have been required (e.g. four published in 2004 compared to nine in 2007). NACI's commitment to a systematic, transparent evidence-based process involves a great deal of effort, especially with the volume of evidence that is rapidly generated and published. This involves a tremendous effort on the part of volunteer members, and new public health human resource capacity from the PHAC. The Advisor on Healthy Children and Youth recognized these challenges and noted in her report that "NACI is a committee resourced by volunteers, and support for these individuals is required" [3].

NACI members have noted the challenge in making population-level recommendations without formally considering the full spectrum of public health science (e.g. cost-effectiveness), especially in an era of increasingly expensive vaccines. While NACI and the Canadian Immunization Committee have successfully collaborated in making immunization recommendations, it has been noted that streamlining the work of the committees to reduce duplication of efforts may lead to improved efficiency and effectiveness of immunization recommendations. As such, a review to ***I**mprove the **N**ational **S**tructures and **P**rocesses for making **I**mmunization **R**ecommendations* (INSPIR) is in progress.

9. Summary and conclusions

While NACI has faced challenges in effectively and efficiently fulfilling its mandate in an increasingly complex immunization environment, it has been successful in providing relatively timely immunization recommendations to Canadians. NACI is a respected, credible, scientific advisory committee of dedicated expert members, as evidenced by comments on the value of NACI by the Advisor on Healthy Children and Youth in her recent report [3], links to NACI statements on various national organizations' websites (e.g. Canadian Pediatric Society), implementation of immunization programs across Canada following the publication of NACI's Advisory Committee Statements, and specific reference to NACI by the Canadian Medical Protective Agency outlining physicians' obligations to inform their patients of vaccine recommendations.

As noted previously, there are several other committees in Canada, not reviewed in detail here, that play roles in an overarching Canadian National Immunization Strategy. Communication, collaboration, and coordination between NACI and other stakeholders is improving. The process and timeliness of release of NACI statements is improving through the formalization of working group review process and support, and the development of project plans. Support for continuing professional development and recruitment of the next generation of vaccine experts has become a priority, with the development of procedures for post-graduate physician trainees and health care students to get exposure to NACI as observers. Furthermore, face-to-face NACI meetings are now accredited for continuing professional development credits.

Support for evidence-based recommendations has improved through formal literature reviews, and a transparent approach of critical appraisal and ranking of evidence in NACI statements. In recognition of rapidly evolving evidence and the need for up-to-date recommendations for immunization providers, the *Canadian Immunization Guide* is being transformed to a web-based evergreen format aligned with the NACI Statement development process (rather than as a hardcopy manual published every four years). Planning is underway to organize alerts to stakeholders as chapters are updated, and to have the chapters of the Guide available to download and print and be PDA-accessible. The evergreen, evolving, electronic *Canadian Immunization Guide* is intended to improve the efficiency, timeliness, and access to up-to-date immunization information that is consistent with the recommendations of new NACI statements as they are published.

Canada's national immunization technical advisory committee has evolved since its establishment in 1964, and continues to evolve with the changing immunization environment. Through ongoing collaboration with partners within and outside Canada, the NACI endeavours to meet the WHO's priority to "strengthen national immunization technical advisory committees (NITAGs), increasingly called for given the complexity of immunization programmes and high cost of new vaccines" [1].

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Conflict of interest statement

The authors state that they have no conflict of interest.

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