

How are recommendations from the National Advisory Committee on Immunization made?

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Membership

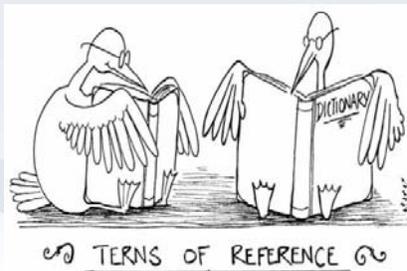
- 12 voting members, with expertise in
 - Public health
 - Clinical infectious diseases: pediatric and adult
 - Medical Microbiology
 - Immunology
 - Nursing science
 - Consumer
 - 4 year term
- Liaison and Ex-officio:
 - professional and other associations
 - federal government



Cette présentation a été effectuée le 26 octobre 2006, au cours du Symposium "Mettre la science au service des programmes d'immunisation, le rôle des comités d'experts" dans le cadre des Journées annuelles de santé publique (JASP) 2006. L'ensemble des présentations est disponible sur le site Web des JASP, à l'adresse <http://www.inspq.qc.ca/jasp>.

Mandate

- Provide PHAC with ongoing, timely, medical, scientific and public health advice relating to vaccines and certain prophylactic agents, related to use of vaccines in humans



Vaccine Recommendations:

Optimal use of the vaccine in Canada

- Recommendations on vaccines which have been newly approved
- Revise existing vaccine recommendations if new information becomes available (changes in: epidemiology, effectiveness/efficacy, safety, product approvals)
- Canadian Immunization Guide



Vaccine Recommendations: Process

- Identify NACI lead for vaccine
- Develop workgroup:
 - NACI members
 - PHAC lead
 - External experts
- Collate/Review Data
- Workgroup review
- NACI review/approval
- PHAC approval and publication in CCDR



Vaccine Recommendations: Data Required

- Disease characteristics
- Burden of Disease: Canadian epidemiology
- Vaccine efficacy, effectiveness, safety
 - Product Monograph
 - Manufacturer presentations
 - Literature review (clinical trials, program effectiveness)
 - Surveillance data

Product Monograph

- Produced by manufacturer and submitted to Biologics and Genetic Therapies Directorate
- Contains detail information about product (trials, safety, use)
- Not peer-reviewed
- Confidential
- Permission to share with NACI
- NACI does not have access to BGTD document

Literature Retrieval / Review

- Systematic review
- Detailed referenced document produced
- Reference database created
- Document used as a basis for statement
- Published on NACI website (www.naci.gc.ca)



Vaccine Statement Developed

- Epidemiology
- Vaccine Characteristics: efficacy and immunogenicity
- Recommended use (general / high risk)
- Dosage and Schedule
- Adverse Reaction
- Contraindications and Precautions
- Other considerations



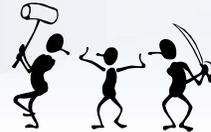
Recommendation Approval Process

- Statement reviewed at NACI meeting and reviewed/approved via email
- Approved by NACI (consensus)
- Approved by CPHO
- Published in CCDR



Contentious issues:

- Methodology of review not explicit
- Evidence versus expert opinion
- Off label recommendations
- Scientific vs programmatic recommendations



Evidence vs Expert Opinion

- Data available varies with vaccine / disease
- Often data not available:
 - High risk groups
 - Long term effectiveness
- Explicit when recommendations are based on “expert opinion”
- Recommendations given a grade, level of evidence and quality of evidence



Evidence-Based Recommendations for Preventive Interventions

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 quantity and/or quality) to make a recommendation, however other factors may influence decision-making

Off Label Recommendations

- Committee can and does make off-label recommendations
- Examples:
 - Age recommendations: hindered by manufacturer's submission
 - Intradermal rabies vaccine use
- Consensus
 - Evidence (Canadian and international)
 - Biologic plausibility

NACI Recommendations

- “Scientific” vs “Programmatic”: Optimal use of vaccine in Canada
- Provider perspective (cost effectiveness not considered)
- PTs determine what is included within publicly funded system
- Implementation issues in domain of Canadian Immunization Committee

NACI Statements published in past year

1. October 2005
 - Interval between administrations of diphtheria, pertussis and tetanus containing vaccines
2. December 2005
 - Update on Thimerosal-Containing vaccines in Canada
3. March 2006
 - Update for Influenza vaccination for 2005-2006 season
4. May 2006
 - Update On the Recommendations For The Routine Use of Pneumococcal Conjugate Vaccine For Infants
5. June 2006
 - Statement On Influenza Vaccination for The 2006-2007 Season
6. October 2006
 - VariZIG™ as the Varicella Zoster immune globulin for the prevention of Varicella In at-risk patients

Upcoming

- 2006 Canadian Immunization Guide:
 - 3 reviews by committee
 - Includes recommendations for all vaccines
- New vaccines
 - HPV, rotavirus, zoster, meningococcal
 - Joint NACI-CIC HPV Working Group



THANK YOU