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**Canadian Immunization Conference
Conférence canadienne sur l'immunisation**

Making Recommendations on Vaccines: Marrying Science and Best Judgment, a provincial perspective

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Disclosure Statement



- I received research grant from GSK
- I was reimbursed expenses to travel to ad hoc advisory board meeting by GSK but received no honorarium

Formulation of a recommendation



- Objective component
 - The scientific evidence
- Subjective component
 - Interpretation and judgement of the evidence
 - Making a decision

The scientific evidence (objective part)

- What is the frequency of the disease?
- What is its severity (disease, hospitalization, death, etc....)
- Who are the people at greatest risk?
- Is the vaccine efficacious and safe?
- How many cases, hospitalizations, deaths, sequelae attributable to a disease will be prevented by different vaccination strategies?
- What is the cost per outcome averted by various strategies?

Interpreting the science (subjective part)

- To interpret and judge the quality and significance of scientific evidence
 - Is a study methodologically « good »?
 - Is the disease frequent « enough », severe « enough »?
 - Is the vaccine efficacious « enough »?
 - Is it safe « enough »?
- To decide which strategy is best to reach our health objectives at a « reasonable » cost

Making a recommendation (subjective part)

- A recommendation is not a scientific « action ».
- A recommendation is making a decision based on values (subjective).
- A recommendation is meant to determine resource allocation
 - It is an economico-political action which will determine resource allocation necessary to implement strategies to reach the health objectives (values).

Values



- Professional values
- Social values
- Individual (personal) values
- Are not « scientific »

Members of committees



- Clinicians
- Public health experts
- Scientists
- Liaison members
- Men-women
- Young-old
- People with different personal or professional values

Who is right?

- Judgment call will vary largely between these different types of individuals



Analytic framework for immunization programs in Canada

- Burden of disease
- Vaccine characteristics (safety, efficacy)
- Immunization strategy and program
- Cost-effectiveness of program
- Acceptability of program
- Feasibility of program
- Ability to evaluate programs
- Equity of the program
- Ethical considerations
- Legal considerations
- Conformity of program
- Political considerations

NACI

**Provinces
& territories**

NACI: a hybrid mandate



- To formulate recommendations for clinicians (individual perspective)
- To formulate recommendations for public health (population perspective)
- No distinction between recommendations for clinicians and for public health

Individual vs population perspective

Individual	Population
Efficacy of the vaccine	Efficacy of the vaccine
Safety of the vaccine	Safety of the vaccine
Patient is in front of us	Population has to be reached
Patient's level of risk can be low	Hierarchy in the levels of risk
Maximal protection of the patient	Protection of the population (direct and indirect)
	Cost-effectiveness
The patient bears the cost	Political authorities decide
Decision depends upon the other needs of the patient and his/her capacity to pay	Decision depends of the other needs of the society and its capacity to pay

V.2.1 People at High Risk of Influenza-Related Complications or Hospitalization

- **Adults (including pregnant women) and children with the following chronic health conditions**

A number of chronic health conditions are associated with increased risk of influenza-related complications and influenza can lead to exacerbation of the chronic disease. These conditions especially include cardiac or pulmonary disorders (including bronchopulmonary dysplasia, cystic fibrosis and asthma), but also diabetes mellitus and other metabolic diseases; cancer; immune compromising conditions (due to underlying disease and/or therapy); renal disease; anemia or hemoglobinopathy; and conditions that

- **All children 6 to 59 months of age**

On the basis of existing data, NACI now recommends the inclusion of all children 6 to 59 months of age among high-priority recipients of influenza vaccine.


This is a revised recommendation from the 2011-2012 statement, which only included children 6 to 23 months of age. NACI has reviewed the burden of illness, and influenza vaccine effectiveness, efficacy, immunogenicity and safety for children 24 to 59 months of age, and now includes this age group among recommended recipients of seasonal influenza vaccine. Please note, NACI's detailed review of the literature is published as a separate appendix to this statement.



COMITÉ SUR L'IMMUNISATION DU QUÉBEC

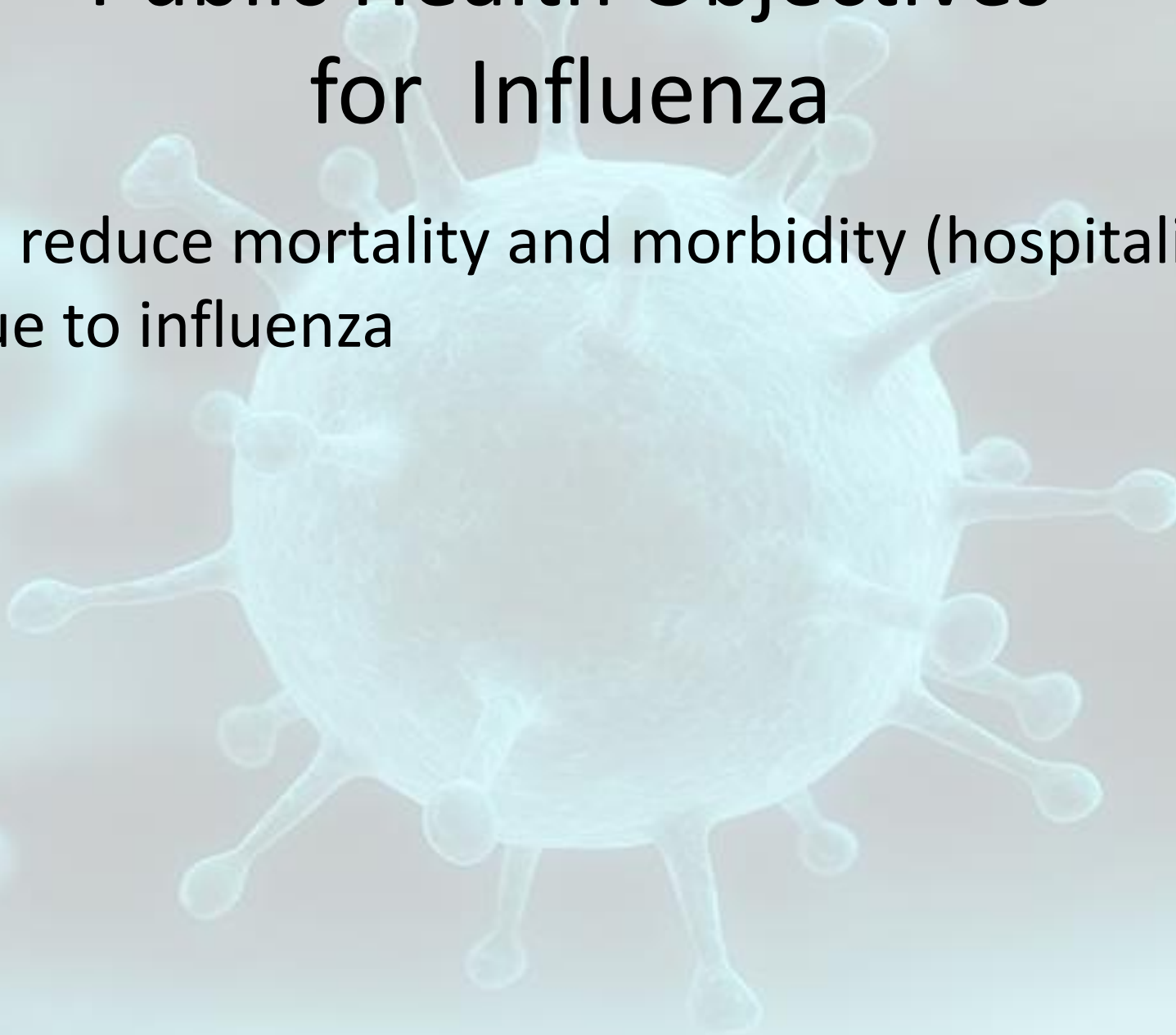
Avis sur la pertinence d'ajouter les enfants âgés de 24 à 59 mois dans le Programme québécois de vaccination contre l'influenza

INSTITUT NATIONAL
DE SANTÉ PUBLIQUE
DU QUÉBEC

Québec 

Public Health Objectives for Influenza

- To reduce mortality and morbidity (hospitalisation) due to influenza



Vaccine coverage targets

Les taux de couverture vaccinale visés

Immunisation de base	95 %
.....
Hépatite B en 4 ^e année du primaire	90 %
.....
Pneumocoque groupes vulnérables	80 %
.....
Influenza groupes vulnérables	80 %
.....
VPH en 4 ^e année du primaire	90 %
.....
VPH en 3 ^e année du secondaire	85 %
.....

Vaccine coverage

Children 6 to 23 months old

Tableau 20 Couverture vaccinale contre l'influenza selon la cohorte et la saison influenza

Saison influenza	Cohorte 1 an (n = 740)				Cohorte 2 ans (n = 710)			
	1 dose influenza		2 doses influenza		1 dose influenza		2 doses influenza ^a	
	n	%	n	%	n	%	n	%
2011-2012	152	20,5	82	11,1	116	16,3	89	12,5
IC-95 %				(8,9-13,6)				(10,2-15,2)
2010-2011	Non éligible				178	25,1	106	14,9
IC-95 %								(12,4-17,8)

^a Un enfant peut avoir reçu sa première dose à l'automne-hiver 2010-2011 et sa seconde dose à l'automne-hiver 2011-2012.

Vaccine coverage

Patients with underlying conditions

Tableau 25 Vaccination contre la grippe par groupe d'âge et par sexe des malades chroniques âgés de 18-59 ans

	Hommes		Femmes		Tous*		En excluant les asthmatiques [†]	
	%	IC à 95 %	%	IC à 95 %	%	IC à 95 %	%	IC à 95 %
18-49 ans	19,3	12,3 ; 26,3	29,2	22,5 ; 35,8	24,6	19,7 ; 29,4	27,9	20,1 ; 35,7
50-59 ans [‡]	42,3	34,2 ; 50,5	38,6	32,3 ; 44,9	40,3	35,3 ; 45,4	42,0	36,1 ; 47,8
Ensemble	27,0	21,4 ; 32,6	32,4	27,5 ; 37,3	29,9	26,2 ; 33,6	34,7	29,7 ; 39,7

* Moins de 1 % des participants ont refusé de répondre à cette question ou ont répondu *Ne sait pas*

† Cette information est présentée à des fins de comparaison avec d'autres enquêtes (comme NICS[60]) qui n'incluent pas cette maladie dans leur définition de « malades chroniques ».

‡ Couvertures vaccinales statistiquement différentes par groupe d'âge ($p < 0,001$).

Vaccine coverage 60 years and older

Tableau 5 Vaccination contre la grippe saisonnière par groupe d'âge et par sexe, population de 50 ans ou plus

	Hommes		Femmes		Sexes réunis*	
	%	IC à 95 %	%	IC à 95 %	%	IC à 95 %
50 à 59 ans [†]	24,9	21,1 ; 28,7	28,1	25,0 ; 31,2	26,5	24,1 ; 29,0
60 à 64 ans [†]	41,8	35,1 ; 48,5	47,9	42,6 ; 53,3	44,9	40,7 ; 49,2
65 ans ou plus*	62,5	58,0 ; 67,1	60,3	56,6 ; 63,9	61,3	58,4 ; 64,1
Ensemble 50 ans et plus	42,8	39,9 ; 45,6	45,7	43,4 ; 48,1	44,3	42,5 ; 46,2
Ensemble 60 ans ou plus[‡]	56,2	52,3 ; 60,0	57,0	53,9 ; 60,0	56,6	54,2 ; 59,0

* Moins de 1 % des participants ont refusé de répondre à cette question ou ont répondu *Ne sait pas*.

[†] Couvertures vaccinales statistiquement différentes par groupe d'âge ($p < 0,001$).

[‡] Groupe ciblé par le programme gratuit de vaccination contre la grippe saisonnière au Québec.

Nearly 50% of 24-59 month old children hospitalized with influenza have underlying condition

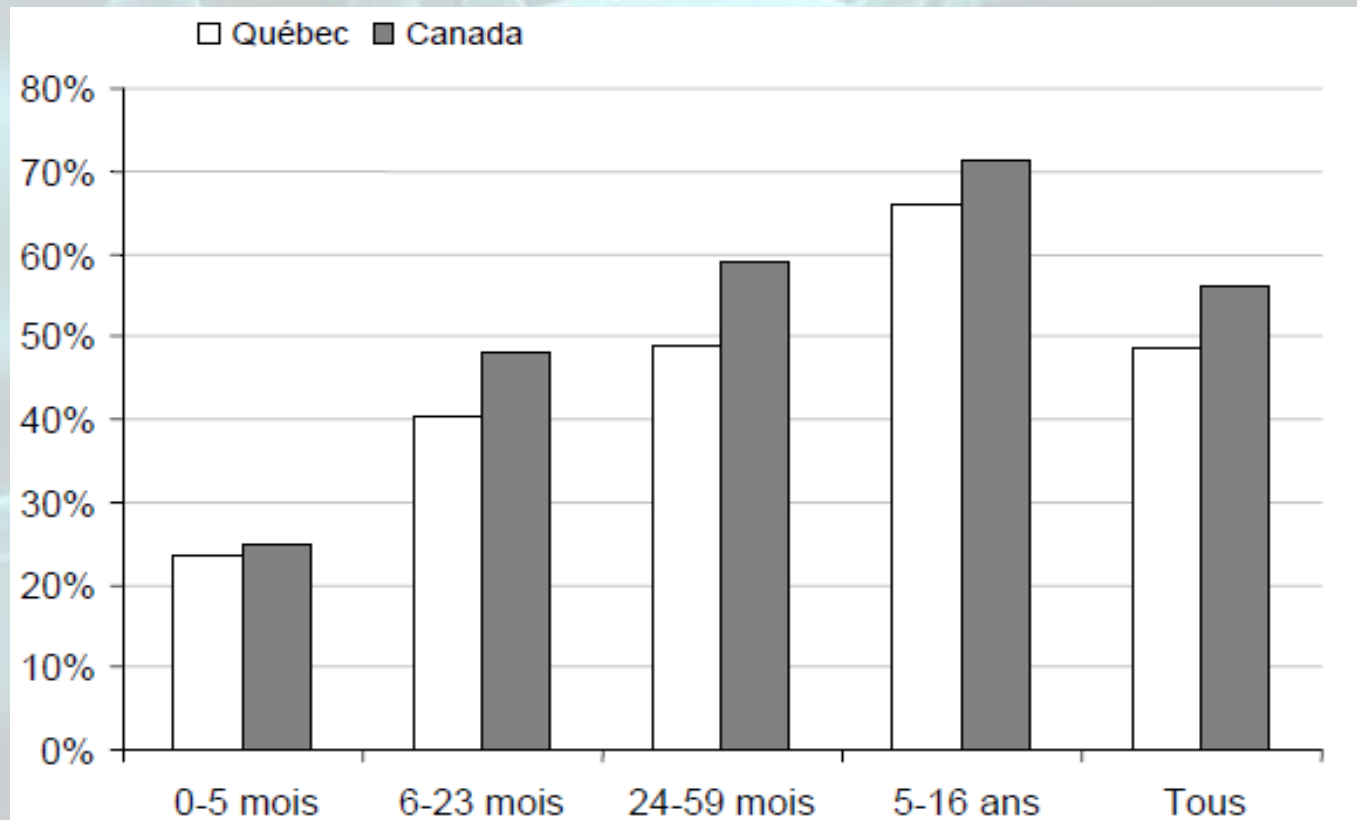


Figure 1 Proportion de maladies sous-jacentes parmi les enfants hospitalisés avec influenza dans les hôpitaux du réseau IMPACT, 2009-2012

Analysis

- Should exclude children with underlying conditions already covered by the program
- Hospitalizations 2009-2012:
 - Mean annual number: 154 hospitalizations
 - Rate: 0.6/1000 children or 1 per 1613 children
- Deaths: 0.15/100 000 or 1 death/3 years

ICU admission and deaths among healthy children in Quebec

- IMPACT:
 - 7% of hospitalized children were admitted to ICU (2009-2012)
 - 2 deaths in healthy children between Sept 2004 and August 2012

Cost of immunization vs cost of disease

Tableau 3 Coûts par événement prévenu en fonction du scénario utilisé et ratio coût immunisation/coût maladie en fonction du scénario utilisé

Événement dû à l'influenza	Coût moyen actuel par événement, \$ CAN	Coût par événement prévenu lors de l'implémentation d'un programme de vaccination contre l'influenza, \$ CAN		Ratio coût immunisation/coût maladie	
		Première année du programme*	Années suivantes du programme**	Première année du programme*	Années suivantes du programme**
Consultation en externe	98	621	345	6	4
Visite aux urgences	140	2 560	1 422	18	10
Hospitalisation	924	99 100	55 055	107	60
Décès	ND	40,53 millions	22,41 millions	ND	ND


* Première année du programme si 80 % des enfants avaient besoin de 2 doses.

** Années suivantes du programme si tous les enfants avaient déjà reçu un vaccin contre l'influenza.

ND : non disponible.

Cost per QALY \geq 180 000\$

Influenza vaccine coverage in Quebec

- Children 6-23 months : <20%
 - Adults with chronic disease: ~ 25% to 40 %
 - Individuals 60 years and older: ~ 45% to 61%
 - Far from the 80% target
- 

Opportunity cost

- The cost of dedicating resources to one intervention is the loss of these resources to do another intervention
- Adding this group of children to the list of « high-risk individuals » may impact on the vaccine coverage in other groups of high-risk patients

Recommendation

- The addition of healthy 24-59 month old children will be expensive and will mostly impact outcomes not targeted by the public health program.
- Great problems of the current program to reach individuals at substantially higher risk of hospitalization and death
- Need to concentrate public health efforts on these individuals rather than diluting its resources on low-risk individuals.
- The CIQ does not recommend adding healthy 24-59 month old children to the program

Conclusion

- Science can help predict the impact of recommendations. Good science will permit to better know the « return on investment »
- A recommendation can have a scientific basis but adopting a recommendation is not science.
 - It is an action taken to manage risk that will require resources
 - Risk management is driven by professional, social or personal values.
- NACI's recommendations focus on disease burden and vaccine efficacy and safety whereas provinces need a broader analysis
- Values then play on different set of issues