An Incremental Economic Evaluation of Targeted and Universal Influenza Vaccination in Pregnant Women

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ABSTRACT

Objective: Pregnancy is associated with increased influenza hospitalizations and physician visits (events) in healthy women and those with co-morbidities. Annual influenza immunization is recommended for all pregnant women. Although vaccination is expected to reduce influenza-related events, the economic implications are unclear. We developed an economic model to estimate the cost-effectiveness (CE) of different vaccination strategies in Nova Scotia.

Methods: A decision tree characterized the one-year costs and consequences of targeted (pregnant women with co-morbidities only) and universal (all pregnant women) vaccination strategies relative to a no-vaccination strategy. Baseline event probabilities, vaccine effectiveness, costs and quality-of-life weights were derived from individual-level Nova Scotia administrative databases, health system sources and published reports. Sensitivity analyses tested the impact of varying key parameters, including vaccine effectiveness and mode of delivery.

Results: Targeted vaccination was cost-saving relative to no vaccination when delivered by public health clinics (PHC) or routine family practitioner (FP) visit. Cost per quality-adjusted life year gained by universal vaccination relative to targeted strategy was <\$40,000 when delivered by PHC or routine FP visit. Net cost of universal vaccination by PHC or a routine FP visit was <\$10 per pregnant woman.

Conclusion: Universal vaccination of pregnant women appears cost-effective when delivered by PHC or as part of a routine FP prenatal visit. Targeted vaccination of pregnant women with co-morbidities can be cost-saving, but the possibility of higher vaccine uptake with a universal compared to a targeted strategy must be considered in addition to costs in program planning.

Key words: Influenza, human; vaccination; pregnancy; cost-benefit analysis

La traduction du résumé se trouve à la fin de l'article.

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A recent population-based study in Nova Scotia demonstrated that women at all stages of pregnancy are at increased risk of serious respiratory illness during influenza season, even in the absence of pre-existing co-morbid conditions known to increase the risk of influenza-associated morbidity.¹ The rate of hospitalization observed in this study among healthy pregnant women exposed to influenza season during their third trimester (65/100,000) was comparable to observed rates among American adults aged 15-44 years with co-morbid medical conditions (56-110/100,000),² a group for whom annual influenza immunization is already recommended.³ However, while the US Advisory Committee on Immunization Practices³ and the Canadian National Advisory Committee on Immunization⁴ both recommend annual influenza immunization for all pregnant women, uptake in Nova Scotia is low (<3%).⁵

Inactivated influenza vaccine has a long record of use in pregnant women and is considered safe in all stages of pregnancy.^{6,7} Influenza vaccination in pregnant women may help prevent influenza-related physician and hospital utilization, but the economic implications of such a policy are unclear. We developed an economic model to estimate the incremental cost-effectiveness of targeted and universal vaccination strategies relative to a no-vaccination strategy in pregnant women in Nova Scotia, Canada.

METHODS

The evaluation compared targeted vaccination of pregnant women with one or more co-morbidities, universal vaccination of all preg-

nant women, and no-vaccination strategies. The evaluation was performed in Excel (Microsoft; Redmond, Washington) using Palisade Decision Tools (Palisade; Newfield, New York) to construct the decision tree (Figure 1) and to perform the probabilistic sensitivity analysis. The decision tree characterized costs and consequences over a one-year horizon, including the acquisition and administration costs of vaccination and the costs and quality-of-life consequences of influenza-related events and vaccination-related adverse effects. As all events in the evaluation occurred within one year, neither costs nor outcomes were discounted. The research project was approved by the Capital District Health Authority Research Ethics Board.

Event rates

Baseline event rates were derived from an analysis of a population-based cohort of 134,188 pregnancies extracted from health admin-

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Figure 1. Model schematic

istrative databases in Nova Scotia, covering the period 1990-2003 by Dodds et al.¹ These rates were consistent with a Canada-wide study using different data and methods.⁸ The Dodds study stratified women into two subgroups: those with no co-morbidities and those with one or more co-morbidities, including pre-existing diabetes, respiratory disease (including asthma), heart disease, renal disorder or anaemia. Event rates were calculated as the number of physician visits or hospital admissions for an influenza-related diagnosis (Table 1, adapted from Neuzil et al.⁹) concurrent with a pregnancy code, divided by the number of women in the stratified cohort.

The evaluation also included a risk of Guillain-Barré syndrome (GBS) following influenza vaccination or an influenza event with or without vaccination. GBS risk in the absence of vaccination or an influenza event, risk following vaccination and risk following an influenza event were represented as ranges derived from published literature reviews.^{10,11} Pregnant women receiving vaccination and experiencing an influenza event were assigned the higher of the two risks.

The effectiveness of vaccination was taken from a single randomized prospective study of laboratory-confirmed influenza in pregnant women with and without vaccination.¹² The severity and duration of an influenza event was assumed to be the same whether or not a woman was vaccinated.

Costs

The cost of vaccine acquisition was based on costs to the Nova Scotia Department of Health and Wellness.* Family practitioner (FP) delivery costs were based on the 2010 Nova Scotia fee schedule. Public health delivery costs were based on the average cost per vaccination at clinics conducted by the Department of Health and Wellness* and were consistent with previously published Canadian costs.¹³ The cost of influenza-related physician utilization was derived from the 2005/06 Nova Scotia physician claims database. Hospital costs were derived from the 2006/07 Ontario Case Cost Initiative database. The annual cost of GBS was taken from a US evaluation of influenza vaccination.¹⁴ Costs were adjusted to 2010 Canadian dollars based on the consumer price index, health component.¹⁵ The evaluation took a health system payer perspective as this was felt to be most relevant to public health authorities considering an immunization strategy.

Quality of life

As there was no mortality observed in the study cohort, the key outcome in the evaluation was the quality-of-life improvement due to influenza-related events prevented. Baseline utility (no

* Personal Communication. D Vaughan, Nova Scotia Dept. of Health Promotion & Protection, 2009. July 27, 2010).

Table 1. Influenza-related Respiratory Diagnoses

Disease	ICD-9	ICD-10
Viral pneumonia	480	J12
Pneumonia due to adenovirus	480.0	J12.0
Pneumonia due to respiratory syncytial virus	480.1	J12.1
Pneumonia due to parainfluenza virus	480.2	J12.2
Pneumonia due to other virus, not classified elsewhere	480.8	J12.8
Viral pneumonia, unspecified	480.9	J12.9
Pneumococcal and other bacterial pneumonia	481,482	J13, J15
Pneumonia due to other specified organism	483	J16.8
Pneumonia in infectious diseases classified elsewhere	484	J17
Bronchopneumonia, organism unspecified	485	J18.0
Pneumonia, organism unspecified	486	J18.9
Influenza	487	J10, J11
With pneumonia	487.0	J10.0, J11.0
With other respiratory manifestations	487.1	J10.1, J11.1
With other manifestations	487.8	J10.8, J11.8
Acute nasopharyngitis	460	J00
Acute sinusitis	461	J01
Acute pharyngitis	462	J02
Acute tonsillitis	463	J03
Acute laryngitis and tracheitis	464	J04
Acute upper respiratory infections of multiple sites	465	J06
Acute bronchitis and bronchiolitis	466	J20, J21
Bronchitis, not specified as acute or chronic	490	J22
Chronic bronchitis	491	J42
Acute myocarditis	422	I40
Heart failure	428	I50

Adapted from Neuzil et al., 1998 (see ref. 9).

Table 2. Model Inputs

Deterministic Parameters	Expected Value					Source
Vaccine acquisition cost	\$3.64					13
Vaccine delivery costs						
FP office visit	\$29.64					NS Fee Schedule
Tray fee	\$3.42					NS Fee Schedule
Injection fee	\$13.68					NS Fee Schedule
Public health clinic, cost per vaccination	\$6.75					13
Probabilistic Parameters	Expected Value	Std Dev or Range	Distribution	Lower 95% CI	Upper 95% CI	Source
Proportion of pregnant women with ≥ 1 co-morbidity	0.101	0.001	Beta	0.099	0.102	1
Baseline probability of physician event, 0 co-morbidities	0.21	0.001	Beta	0.24	0.24	1
Baseline probability of physician event, ≥ 1 co-morbidity	0.28	0.004	Beta	0.33	0.34	1
Expected cost of physician event	\$31.82	\$4.70	Log Normal	\$23.70	\$41.70	PHRU
Baseline probability of hospital event, 0 co-morbidities	0.003	0.000	Beta	0.002	0.003	1
Baseline probability of hospital event, ≥ 1 co-morbidity	0.014	0.001	Beta	0.012	0.016	1
Expected LOS per influenza-related event	2.97	2.64	Log Normal	0.44	10.24	OCCI
Expected cost of hospital event	\$4,464	\$5,995	Log Normal	\$315	\$17,773	OCCI
Relative risk of an event with vaccination (vaccine effectiveness)	0.64	0.11	Beta/Beta	0.45	0.90	12
Baseline utility weight	0.95	1.00-0.90	Triangle	0.91	0.99	17
Relative utility weight, influenza*	0.58	0.97-0.77	Triangle	0.50	0.66	18
Relative utility weight, Guillain-Barré Syndrome*	0.25	0.10-0.40	Triangle	0.13	0.37	Assumption
Guillain-Barré Syndrome per 100,000 No Vaccination (1)	1.90	0.4-4.0	Triangle	0.68	3.50	10
Guillain-Barré Syndrome per 100,000 Vaccination	0.54	0-1.07	Uniform	0.27	10.43	11
Relative risk of GBS Influenza Event (2)	15.32	8.09	Beta	6.80	38.20	11
Guillain-Barré Syndrome per 100,000 Influenza	29.10	21.28	Derived from (1) & (2)	7.90	87.30	
Annual Cost, Guillain-Barré Syndrome	\$135,464	\$30,000	Log Normal	\$92,237	\$189,539	15

* Health-related utility is calculated assuming a multiplicative utility function, where the utility associated with any particular state is the product of baseline utility and specific health state utility (e.g., the health-related utility associated with influenza is $0.95 \times 0.58 = 0.551$). The utility penalty associated with influenza is calculated as the difference between baseline utility and the multiplicative utility associated with influenza, weighted by influenza duration (i.e., $(0.551 - 0.95) \times (2.97/365) = -0.003$).

LOS=length of stay; PHRU=Population Health Research Unit, Dalhousie University; OCCI=Ontario Case Cost Initiative

influenza) was 0.95, reflecting the average utility of all individuals more than 12 years of age with no chronic conditions.¹⁶ Utility weights for influenza-related illnesses were derived from a Canadian study by O'Brien et al.¹⁷ As we were unable to find estimates of the utility associated with GBS, we assumed a conservative weight of 0.25.

Economic analysis

The evaluation was conducted as an incremental cost-effectiveness analysis, comparing each vaccination strategy to the next best alter-

native. Key economic outcomes were the net cost of vaccination (vaccination costs less event costs avoided), net quality-adjusted life years (QALYs) gained and the incremental cost per QALY gained. Estimating cost-effectiveness in terms of cost per QALY gained facilitates economic comparisons across different programs and diseases. All costs and outcomes were reported on the basis of the average annual cohort of pregnant women, calculated as the total number of pregnancies observed over 1990-2003 divided by the number of years of observation.¹ Reflecting a decision-making perspective, all conclusions were based on expected values.¹⁸

Table 3. Results

	Women Vaccinated	Cohort Cost	Incremental Cost (95% CI)	Total Cohort QALYs	Incremental QALYs (95% CI)	Cost per QALY	Gained Budget Impact*
No Vaccination	0	\$344,878	—	9,492.23	—	—	—
Targeted Strategy	1002	\$335,392	-\$9,485 (-\$65,993-\$14,177)	9,492.55	0.32 (0.06-0.88)	Dominant	-\$9,485
Universal Vaccination	10,000	\$426,536	\$91,143 (-\$22,546-\$152,454)	9,494.83	2.28 (0.44-6.18)	\$39,942	\$81,658

* Budget impact is relative to a no-vaccination strategy and may therefore be less than incremental cost.
QALY=quality-adjusted life year.

Sensitivity analysis

The base-case scenario assumed all vaccinations were delivered by a family practitioner (FP) as part of a routine visit, but sensitivity analyses considered alternative modes of delivery (extra FP visit, public health clinic). Threshold analyses were conducted on key parameters to identify the threshold values necessary to meet specific cost-effectiveness targets. One-way sensitivity analyses were conducted on other key parameters. Probabilistic sensitivity analysis was used to incorporate uncertainty into the economic evaluation.^{19,20} Parameter point estimates, standard deviation and probability distributions are shown in Table 2. Uncertainty was expressed in terms of confidence intervals around point estimates.

RESULTS

The average annual cohort of pregnant women was 10,316, but for simplicity this was rounded to 10,000. Relative to a no-vaccination strategy, a targeted vaccination strategy for pregnant women with at least one co-morbidity delivered as part of a routine FP visit was cost-saving. Relative to the targeted strategy, the universal strategy had an incremental cost-effectiveness of \$39,942 per QALY gained. The expected budget impact of the targeted strategy was -\$9,485, while the universal strategy had a net budget impact of \$81,658 relative to the no-vaccination strategy. Results and associated 95% confidence intervals are shown in Table 3.

Threshold analysis on vaccine effectiveness showed that the targeted strategy would be economically dominant (cost saving, improved outcomes) over no vaccination with a vaccine effectiveness (i.e., relative risk) less than 0.76 and would meet a \$50,000 per QALY gained threshold with an effectiveness less than 0.84. A universal strategy would meet a \$50,000 threshold with an effectiveness less than 0.68 and a \$100,000 threshold with an effectiveness less than 0.80.

One-way sensitivity analysis on mode of delivery suggests that the targeted strategy would remain dominant relative to the no-vaccination strategy when delivered by public health clinics, while the universal strategy would be strongly cost-effective, bordering on dominant, relative to the targeted strategy. If vaccination required an additional FP visit, the targeted vaccination strategy would lose its dominance and have a cost-effectiveness of \$62,796, while the cost-effectiveness of the universal strategy would increase to more than \$150,000. Other one-way sensitivity analyses are shown in Figure 2, sorted by their impact on the cost-effectiveness of a universal strategy. The targeted strategy remained dominant across all ranges.

DISCUSSION

Two recent evaluations of universal influenza vaccination in pregnant women compared to a “no vaccination” strategy have found

Figure 2. One-way Sensitivity Analysis (Universal Strategy) ± 50% change from Reference Scenario

universal strategies to be economically attractive. Roberts et al.¹⁴ reported universal vaccination of all pregnant women was dominant relative to no vaccination, while Beigi et al.²¹ reported a universal vaccination strategy ranged from dominant to strongly cost-effective relative to no vaccination, depending on prevalence and mortality assumptions. However, we suggest that comparison of a universal strategy to a no-vaccination alternative risks overstating the benefit of the universal strategy, since it is generally accepted that targeted programs (influenza immunization of pregnant women with risk factors for complicated influenza) are already standard practice. Our analysis is unique in conducting an incremental comparison of the costs and benefits of a universal strategy relative to both a targeted and a no-vaccination strategy. It is methodologically more appropriate to consider the incremental costs and benefits of a universal strategy relative to a targeted strategy rather than the dominated no-vaccination comparator.²²

The use of a population-based cohort was a strength of our analysis. This dataset included 134,188 pregnancies over 14 years and allowed us to track individual-level physician and hospital utilization. It was not possible to reliably identify and exclude vaccinated women from the cohort when calculating baseline event rates, but since only 2.6% of pregnant women in Nova Scotia were vaccinated over the period covered by our data,⁵ this is unlikely to have influenced our estimates. The inclusion of vaccinated women would likely underestimate the baseline risk of an influenza-related event and result in a more conservative estimate of benefit from vaccination. Also, although illnesses attributed to influenza were not laboratory-confirmed in this study, our incidence rates are consistent with estimates from another study with a different design.⁸

Evidence around the precise risk reduction associated with influenza vaccination in pregnant women is limited. In the only prospective randomized controlled trial, Zaman et al.¹² reported a

relative risk (RR) of 0.64 for laboratory-confirmed influenza in vaccinated pregnant women. Their estimate is similar to a comprehensive Cochrane review of vaccine effectiveness in healthy adults that found a RR of 0.77 (95% CI 0.69-0.86) for clinically-defined influenza and an RR of 0.65 (95% CI 0.34-1.22) for influenza-related hospitalizations.²³ A 2010 review by Jefferson et al.²⁴ reported lower effectiveness but excluded all industry-funded studies. Sensitivity analysis on this critical parameter suggests that a targeted strategy would be dominant or strongly cost-effective, and a universal strategy would meet a \$100,000 per QALY gained threshold, at all these RR point estimates, although a universal strategy would not be cost-effective at the upper extremes of the 95% confidence intervals.

The risk of GBS following influenza vaccination is uncertain, but clinical evidence suggests that vaccination is protective against GBS, supporting vaccination strategies.¹¹ Owing to the protective benefit associated with vaccination, the relative cost-effectiveness of both the targeted and universal strategies improve as either the baseline risk of GBS or the associated costs increase. As such, our one-year horizon presents a conservative estimate of the broader benefits of vaccination. Our estimates also exclude savings related to prevented complications related to the child or the pregnancy itself – even though a recent case-control study estimated influenza vaccination was 91.5% effective at preventing influenza-related hospitalization within the first 6 months of life²⁵ – as well as the value of lost productivity and the social and emotional costs associated with illness in pregnancy. It is also worth noting that although our estimates of budget impact are relative to a no-vaccination alternative, Nova Scotia does have an ad hoc vaccination program. The budget impact of moving to a universal strategy, therefore, would likely be less than our estimates suggest.

Our analysis suggests that a strategy of targeted vaccination in pregnant women with at least one co-morbidity could be economically dominant, and that a strategy of universal vaccination of all pregnant women could be cost-effective relative to a targeted strategy. It also shows that a universal strategy could be delivered with a reasonable budget impact by public health clinics or by FPs as part of a routine office visit. Precise cost-effectiveness will vary by jurisdiction, but sensitivity analysis suggests that our results are robust across a range of costs and risks. Both strategies have potential advantages and disadvantages. For example, targeted strategies may be associated with less vaccine uptake than universal strategies, while universal strategies will have greater costs. The economically preferred strategy must be considered within the context of affordability, potential coverage rates and the overall health benefit.

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RÉSUMÉ

Objectif : La grossesse est associée à des hausses de certains événements liés à la grippe (hospitalisations et visites chez le médecin) chez les femmes en bonne santé comme chez les femmes atteintes de comorbidités. On recommande le vaccin annuel contre la grippe à toutes les femmes enceintes. On sait que la vaccination réduit les événements liés à la grippe, mais ses répercussions économiques ne sont pas claires. Nous avons élaboré un modèle économique pour estimer le rapport coût-efficacité de diverses stratégies de vaccination en Nouvelle-Écosse.

Méthode : Au moyen d'un arbre de décision, nous avons caractérisé les coûts et les conséquences sur un an de stratégies de vaccination ciblées (seulement les femmes enceintes avec des comorbidités) et universelles (toutes les femmes enceintes) comparativement à une stratégie de non-vaccination. Les probabilités de base de survenue des événements, l'efficacité du vaccin, les coûts et la pondération selon la qualité de vie ont été dérivés de bases de données administratives par personne de Nouvelle-Écosse, de sources du système de santé et de rapports publiés. Des analyses de sensibilité ont permis de tester l'incidence de divers paramètres clés, dont l'efficacité du vaccin et son mode d'administration.

Résultats : La vaccination ciblée était plus économique que l'absence de vaccination lorsqu'elle était administrée dans les cliniques de santé publique (CSP) ou lors d'une visite ordinaire chez le médecin de famille (MF). Comparativement à la stratégie ciblée, le coût de la vaccination universelle, par année de survie ajustée pour la qualité de vie, était de <40 000 \$ lorsque le vaccin était administré dans une CSP ou par le MF. Le coût net de la vaccination universelle dans une CSP ou par le MF était de <10 \$ par femme enceinte.

Conclusion : La vaccination universelle des femmes enceintes semble rentable lorsque le vaccin est administré dans une CSP ou lors d'une visite prénatale ordinaire chez le MF. La vaccination ciblée des femmes enceintes présentant des comorbidités peut être rentable, mais en plus des coûts de planification de programme, il faut tenir compte de la possibilité d'une plus grande acceptation du vaccin avec une stratégie universelle comparativement à une stratégie ciblée.

Mots clés : grippe humaine; vaccination; grossesse; analyse coût-bénéfice

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