EVALUATION OF PANDEMIC H1N1 INTERVENTIONS IN CANADA

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ABSTRACT

Background: The first pandemic of the millennium was declared in June 2009. At that time, the pH1N1 virus was already in circulation in Canada and early reports from around the world indicated a potentially severe pandemic. The initial projections did not materialize but it was not clear whether this was due to the nature of the virus, or the success of public health initiatives. The objective of this analysis was to examine the effectiveness of the interventions used in Canada from both a health and economic point of view.

Methods and Findings: A mathematical model was fitted to the observed Canadian hospitalizations and deaths including the reported antiviral and vaccine interventions. In addition to the number of infections, hospitalizations, deaths and quality adjusted life years (QALYs) lost, the model also determined the indirect economic impact on GDP driven by absenteeism. The model yielded an attack rate of 15%. By turning off the interventions, the potential impact of the unmitigated pH1N1 pandemic was evaluated and found to have an attack rate of 28%. The interventions reduced hospitalizations by 55%, deaths by 74%, QALYs lost (3% discounted) by 69% and the GDP impact by 49%. In 2009 dollars, the net cost of the combined antiviral and vaccine intervention was $11,145 per QALY gained indicating that the interventions were very cost-effective. This includes costs saved from the reduced hospitalizations and doctor visits.

Conclusions: Without the reported use of antivirals and vaccine during 2009 in Canada, the analysis indicated that the pandemic impact of pH1N1 could have had an attack rate of 28%, twice the hospitalizations and GDP impacts, almost three times the hospitalization costs and QALYs lost; and almost four times the number of deaths. Such pandemic intervention policies were also very cost-effective with an incremental cost-effectiveness ratio of $11,145 per QALY gained.

INTRODUCTION

During the spring of 2009, a novel triple-reassortment H1N1 influenza virus combining human, avian and porcine segments was documented as a cause of severe systemic illness in California (1). Within months major outbreaks of influenza were reported in several North American locales (2). Shortly thereafter, epidemic cases were being reported in the Southern Hemisphere. On June 11, 2009, the World Health Organization declared the first influenza pandemic of the millennium (3). As of late June 2009, the pandemic model used in this study was generating a stable estimate of the potential pH1N1 attack rate of 24% and cumulative total Canadian death count of 796 (4). Early clinical reports suggested a high frequency of severe infectious illness in relatively young, working age adults (5). Following the declaration of the pandemic, an unprecedented public health initiative was launched with accelerated development of a vaccine and stockpiling of antivirals in anticipation of a major world-wide outbreak of illness in the Northern Hemisphere during the 2009/2010 influenza season.

In the early phase of the pandemic, some projections suggested the possibility of severe stress on national health care resources. Indeed, health care systems in some moderately resourced countries were seriously challenged with reports of deaths in some jurisdictions as a consequence of a saturated ICU capacity (Personal communication, Christopher Farmer, MD). Whether due to the intrinsic nature of the virus or the early public health response and preparation, the more dire projections in North America were not realized. Nonetheless, the pandemic clearly had an impact on hospital admissions and mortality and is estimated to have had a measurable impact on national GDP. This has led to the question of what may have happened with respect to the attack rate, the number of total cases and deaths and GDP impact had vaccine been unavailable or available antivirals ineffective.

A recent study looking at the cost-effectiveness of pH1N1 vaccination in Ontario indicated that the program was very cost-effective (6). This study goes beyond that study by considering antivirals in the model, extending the analysis to the rest of Canada, and examining the economic impact of the pandemic on the national GDP. In particular, the cost effectiveness of both antiviral and vaccine therapy is addressed.

METHODS

There are two key model aspects to this study. The first is the pandemic model and the second is the economic model.

PANDEMIC MODEL

The pandemic model was based upon the well-studied Susceptible-Exposed-Infectious-Recovered (SEIR) compartmental model (7). An SEIR model is dynamic and deemed acceptable for economic evaluations of immunization programmes by the World Health Organization (8). In a simple SEIR model, members of the susceptible population become ‘exposed’ (infected with the virus, but not yet infectious) at a rate proportional to the number of infectious individuals in the population and the rate of contact between individuals. After infection, people transition into the infectious state at a rate dependent upon the latent time of the virus. Finally, at a rate dependent upon the average infectious period and the case fatality rate, people either recover or die. In this model, asymptomatic cases were not distinguished and the infectious population referred to both symptomatic and asymptomatic cases.

The basic SEIR model was extended to include age groups, antiviral use, vaccination and hospitalizations. Contact rates between age groups were based on an extensive study of 8 European countries (9). Antiviral use incorporated into the model consisted only of antiviral treatment for those who are hospitalized and antiviral treatment for the public. In this analysis, post-exposure or pre-exposure prophylaxis was not considered. In addition, the model took into account the existing immunity to pH1N1 observed in the elderly (10; 11). Finally, a seasonal dependence for contact rates was introduced to account for the decline in the first wave during the summer of 2009. The detailed equations for the model can be found in Supplementary Appendix A.

The pH1N1 base model consisted of the best-fit match of the observed hospitalizations, mortalities and early confirmed cases to the infectious disease model. During the fitting procedure, both vaccines and antivirals were incorporated into the model as reported across Canada. Ontario age-dependent hospitalization and mortality reports were used to determine the age-profile of the case hospitalization rate and the case fatality rate. Vaccine doses ordered amounted to 50.4 million of which 29% were used. Provincial antiviral prescription data was obtained from Brogan Inc which indicated a total of 325 thousand prescriptions were filled in 2009, of which almost 70% were filled in October and November. A complete list of data used in the model can be found in Supplementary Appendix B.

The fitting procedure consisted of fitting Ontario aggregate age-independent results to determine an initial estimate of the average pH1N1 parameters. Based upon the initial average results from Ontario, age-dependence was added to the hospitalization and mortality rates and the Ontario fit was repeated. Finally, using the age-dependent hospitalization and mortality rates from Ontario, the model was fit to the rest of the regions using their age-independent hospitalizations and mortalities.

In order to model the observed antiviral use, the model determined the fraction of population that would seek antiviral treatment when they become ill. Given the relatively low or non-existent prophylactic use of antivirals in Canada during 2009, prophylaxis use was not considered during the fitting procedure. It was assumed that vaccines become widely available at the end of October 2009 and become effective by providing full protection in 2 weeks time. Estimates of the total fraction of the population vaccinated were available from provincial ministries of health, but detailed information about who actually received vaccinations was not available. Therefore, it was assumed that the age and sex distribution of those who received vaccinations was similar to the seasonal vaccination distributions. This does not necessarily agree with the suggested vaccination priority lists from the Public Health Agency of Canada, but was the best estimate available. In addition, a reduction in contacts during the summer months was incorporated into the fits to drive the two wave behaviour.

For the Ontario fitting procedure there were a total of 20 parameters including: the initial number of infections; the confirmation rate (fraction of total cases positively identified); the infectiousness; the average infectious duration; the fraction of the population over 55 who were immune; the summer contact rate adjustment for adults and children; the fraction of population eligible for antiviral treatment; the age-dependent hospitalization rate in 6 age-groups; and the age-dependent mortality rate in 6 age-groups. For remaining regions, 7 parameters were fit which were: the initial number of infections; the hospitalization rate adjustment; the mortality rate adjustment; the overall contact rate adjustment; the summer contact rate adjustment for adults and children; and the fraction of population eligible for antiviral treatment.

Once the base model was calibrated to the Canadian observations, it was possible to remove the antiviral and vaccination interventions to determine their effects on the evolution of the pandemic. The three scenarios investigated were a “No Intervention” scenario where neither antivirals nor vaccines were used in the model; an “Antiviral Use Only” scenario where only antivirals were used at same levels seen during the pH1N1 pandemic; and

a “Vaccination Only” scenario where vaccines became available at the same time as observed, and had the same uptake as in 2009.

In addition to the actual numbers of hospitalizations and deaths, Quality Adjusted Life Years (QALYs) provides an additional measure of the impact of the pandemic. The QALYs lost for each morbidity case and mortality were taken from Sander *et al.* (12).

ECONOMIC MODEL

A macroeconomic structural simulation model is coupled with the infectious disease model. The economic model is a version of the Klein Model (13; 14; 15; 16; 17; 18) and includes simulations of the labour force by industry and employment status, wages, economic production (GDP), income and consumption taxation rates by government type, corporate profits, and demand for health care services and products.

Two different types of economic impacts were considered in this study. The first was the direct cost associated with vaccine and antiviral interventions. Direct health cost types included: GP visits ($38.02 per visit), emergency department visits ($58.66 per visit), and hospitalization costs ($6,972 per hospitalization). All unit cost estimates were taken from Sander *et al*. (12) and converted into 2010 dollars using a deflator of 2.8% provided by the Conference Board of Canada (19). The second type of economic impact considered was the indirect impact due to lost economic output (GDP) driven by employee absenteeism. Using the friction cost method (20), the approach allowed for both employed, unemployment and other realistic circumstances to exist in productivity cost calculations by distinguishing between a friction period, in which productivity loss occurs and a further period where a sick worker has been replaced (21). The impact of absenteeism on output was conducted using an aggregate production function with an output-hours elasticity of 0.6 for the period of absence (22). The relationship between infections and total absenteeism was estimated from a Statistics Canada study (23) of the number of work hours lost due to pH1N1 during November 2009.

The key measure of the cost effectiveness of an intervention is the incremental cost-effectiveness ratio (ICER) defined as the net cost/benefit per QALY Gained. The ICER numerator comprises the cost of intervention (excluding distribution costs) and the incremental change to health care costs. The ICER denominator is the QALYs saved through the intervention. According to the World Health Organization recommendations, an intervention is generally considered very cost-effective if the ICER is less than the GDP per capita which, for Canada, is approximately $50,000 per QALY gained (8; 24). Distribution costs that maintain an intervention’s cost-effectiveness can then be calculated.

The sustainability of the health care system funding is an important issue in Canada. Hence, the protection of the community’s productive capacity is also an important outcome that can complement traditional cost-effectiveness measures. As a societal measure of production, changes in GDP due to absence from work are provided as a relative measure of each intervention’s ability to protect productive capacity.

RESULTS

The fitting procedure matched the observed hospitalizations and mortalities in Canada well with root-mean-squared deviations below 0.06 for all provinces and below 0.1 for the territories. In general, the more populous the region, the better the model was able to fit the data. As of May 1st 2010, there were 8,678 reported hospitalizations due to pH1N1 in Canada and the model yielded 8,636. There were 428 observed deaths and the model produced 425. Figure 1 compares the reported cumulative hospitalizations and mortalities to the model fit. Supplementary Appendix C shows the results for each province. Figure 2 shows the case fatality and

hospitalization rates estimated from the fits, while Figure 3 presents the estimated age-dependent attack rate. The analysis estimated that the pH1N1 attack rate was 15%, 12,680 QALYs were lost (discount rate 3%), direct health care costs amounted to $57 million; and the indirect economic production impact due to pandemic-induced absenteeism amounted to $1.6 billion or 0.1% of GDP.

Without the reported use of antivirals and vaccine during 2009, the analysis indicated that the pandemic impact of pH1N1 could have had an attack rate of 28%, twice the hospitalizations and GDP impacts, almost three times the hospitalization costs and QALYs lost; and almost four times the number of deaths assuming that available ICU resources suffice for the increased number of critically ill patients (25).

Table 1 summarizes the key life and economic impacts of the pandemic under: (a) observed interventions; (b) no interventions; (c) a scenario with only antivirals (used at the same rate as in 2009); and (d) a scenario with vaccine only. Figure 4 show the modelled infectious population under each of the intervention scenarios. The total direct healthcare cost due to doctor visits, emergency department visits, and hospitalization under each scenario is shown in Table 2. Table 3 summarizes the costs associated with vaccines and antivirals. The net cost of any intervention is the cost required for the intervention minus any savings in direct healthcare costs that may arise. At a 3% discount rate, the cost per QALY gained for the observed interventions jointly was estimated to be $11,145/QALY. This is significantly below the threshold for cost-effectiveness of $50,000 indicating that the interventions in 2009 were very cost-effective. Table 4 presents the complete cost-effectiveness analysis for all scenarios and at undiscounted and 5% discount rates.

DISCUSSION

During pH1N1, there was a relatively low use of antivirals as treatment intervention (6.2% of those who were ill were treated), and of the 50.4 million vaccine doses ordered, only 29% were used. (Refer to Supplementary Appendix A for the reported provincial vaccination rates.) Notwithstanding the limited use of antivirals for treatment only and the limited uptake of vaccine, both interventions are considered very cost-effective.

The combined use of antivirals and vaccine resulted in a synergistic reduction in the number of hospitalizations. Used on their own without vaccines, antivirals would have prevented 7.6% of the hospitalizations. Vaccines on their own without antivirals would prevent 85.4% of the hospitalizations. The remaining balance of 7.0% is reflective of the synergistic use of both antivirals and vaccines together. In terms of deaths, antivirals would have independently accounted for 55.1% of the cases saved and vaccines for 65.0%. The excess of 20.1% is reflective of the common ability of both interventions to prevent death. This synergistic coupling of antivirals and vaccines arises since the use of antivirals tends to slow the pandemic resulting in fewer infections prior to vaccine availability and highlights the importance of both in pandemic planning.

COST EFFECTIVENESS

Under all intervention scenarios and discount rate assumptions, the use of vaccines and antivirals at the levels observed during 2009 was very cost-effective. Due to the absence of reliable data, distribution and other overhead costs were not incorporated into the cost effectiveness measures. While the inclusion of such costs would reduce the cost-effectiveness, the exclusion is not expected to change the general conclusions of the cost-effectiveness analysis. Assuming a $50,000 per QALY gained threshold, the distribution costs of antivirals would have to exceed $650 million ($1,000 per prescription), and the distribution costs for vaccines would have to exceed $613 million ($42 per dose) before their cost effectiveness measures would begin to be questioned.

The scenario with antivirals only yielded a somewhat interesting outcome. Once health care costs saved were taken into account, rather than a net cost per QALY, antivirals resulted in a net savings of $1,077 for each QALY gained. That is, antiviral use essentially had paid for itself in terms of health care costs saved. This is largely driven by the reduction in hospitalization costs due to faster recovery when antivirals are used for treatment. While the cost-effectiveness of antivirals on their own is superior to that of vaccine use (in this case), the addition of vaccines significantly reduces the number of hospitalizations and mortalities reflecting its superior performance in volume terms under the condition that vaccine intervention arrives prior to a major pandemic peak.

The general consensus was that pH1N1 was a mild pandemic in terms of the absolute number of hospitalizations and mortalities with some regions reporting fewer deaths than during a regular flu season (26; 27). However, due to the higher mortality rate among younger people, the QALYs lost were significantly higher than during a typical flu season.

While the interventions were cost-effective under the pH1N1 pandemic, the questions arises as to whether the interventions would remain cost-effective under a more severe pandemic, or if the observed cost-effectiveness was an artefact of the relatively mild nature of the 2009 pandemic. In order test the cost-effectiveness of the used interventions against a more severe pandemic, the case fatality rate was increased by approximately an order of magnitude to 0.16% while maintaining the same age distribution and overall attack rate. With no interventions, there would be over 11,000 deaths and over 57,000 hospitalizations. Interventions at the same level used during 2009 would reduce hospitalizations and mortalities by 56% and 70% respectively. With a savings of $109/QALY gained (discount rate of 3%), the interventions become more cost-effective than during the pH1N1 pandemic in 2009.

THE SIGNIFICANCE OF TWO WAVES

The fact that the pH1N1 struck Canada in two waves with a relatively quiescent summer period provided a considerable length of time for vaccine production and dissemination in preparation for the expected fall resurgence. In contrast, if the pandemic had struck in a single wave, it would largely have been over by the time vaccines were available. Figure 5, which plots the number of infectious individuals in Canada if a pandemic had started in early fall, highlights the timing issue. The timing of the fall pandemic is such that the cumulative number of infections by September 1st is the same as on May 1st in the base case. In such a situation, the 6 month delay between initial virus sequencing and vaccine availability results in vaccines being available well after the pandemic has peaked. The role of antivirals is more important in situations where the pandemic strikes quickly and vaccines were not readily available.

SENSITIVITY TO VACCINE TIMING DATA

There was considerable uncertainty in the actual rollout of vaccination and the fit results are sensitive to the vaccination timing. To test this sensitivity, instead of using October 30th, 2009 as the vaccine start date, it was assumed that vaccines were available 2 weeks later (mid-November) and the base model was re-fit under this assumption. Note that this was not simply taking the “No Intervention” pandemic from the previous section and applying vaccination at different times. This involved completely re-parameterizing the pandemic. Figure 6 shows the significant impact that shifting the vaccine rollout has on the conclusions. The impact of vaccines was significantly reduced as they now arrive after the pandemic has naturally peaked. This was expected since the model must fit the observed levelling off of the hospitalizations and mortality in November without the aid of vaccines. As a result, the impact of vaccines is reduced considerably. The ICER of the observed intervention in this

case is $35,928 per QALY gained (at a 3% discount) which is still cost-effective. For undiscounted QALYs and QALYs discounted at 5%, the ICER is $18,660/QALY and $47,380/QALY respectively.

The importance of reliable vaccination data to accurately determine the actual pH1N1 trajectory is clearly visible. Unfortunately, only limited estimates of aggregate vaccination rates were available and therefore assumptions were required. If more detailed vaccination data become available, it may be worthwhile to repeat the analysis though the conclusion that the antiviral and vaccination interventions were cost-effective is likely to remain.

CONCLUSION

Our analysis demonstrates that the mildness of the 2009 influenza pandemic is substantially attributable to the early and aggressive dissemination of vaccine (particularly to high risk groups) and to the targeted use of antiviral therapy for symptomatic patients (especially those requiring hospitalization). Substantially higher attack rates, hospitalization rates and mortality were likely to have occurred had a situation occurred where vaccine and antiviral therapy were either unavailable or ineffective. Contrary to public perception, it is the public heath response in Canada more so than any lack of virulence of the pathogen that was substantially responsible for the manageable impact of the pandemic H1N1 experience. Further, this analysis suggests that both antivirals therapy and vaccine deployment were highly cost-effective in minimizing attack rate, hospitalization and mortality in the Canadian environment.

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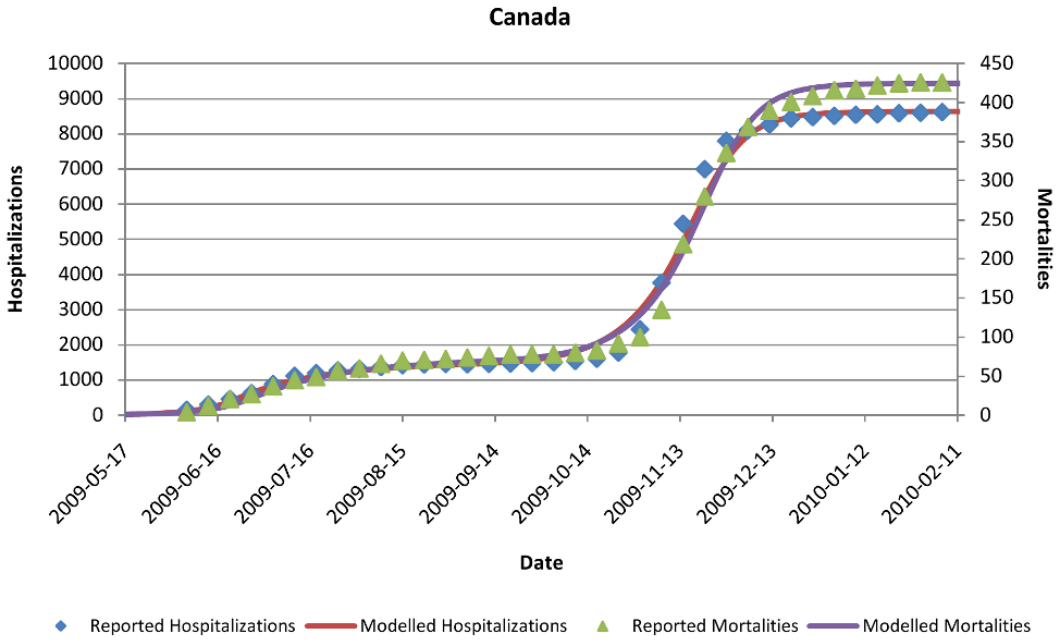

Figure 1: Comparison of reported and modeled hospitalizations.

The comparison of reported and modeled hospitalizations (left-hand axis) and mortality (right-hand axis) in Canada

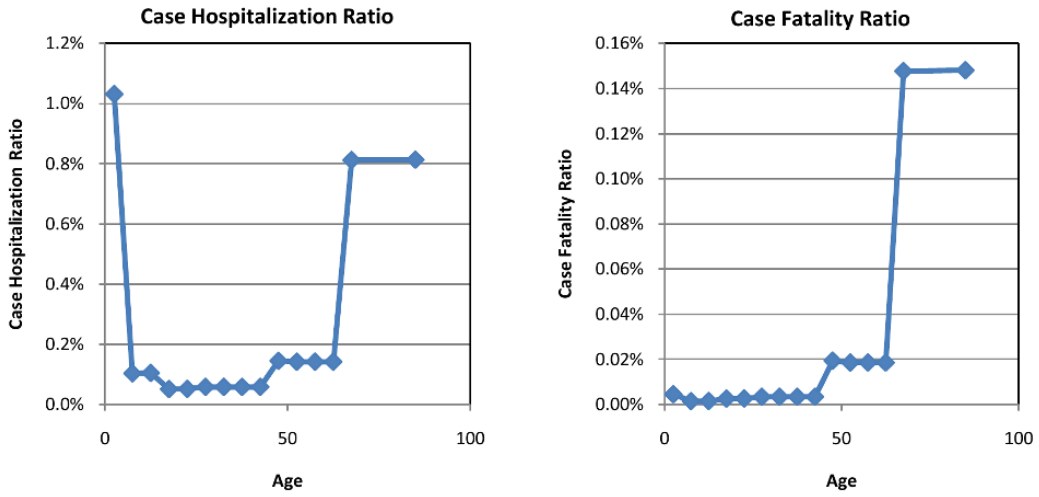

Figure 2: Case hospitalization ratio and case mortality ratio.

Case hospitalization ratio (left) and case mortality ratio (right) for H1N1 in Ontario based upon the fitting procedure

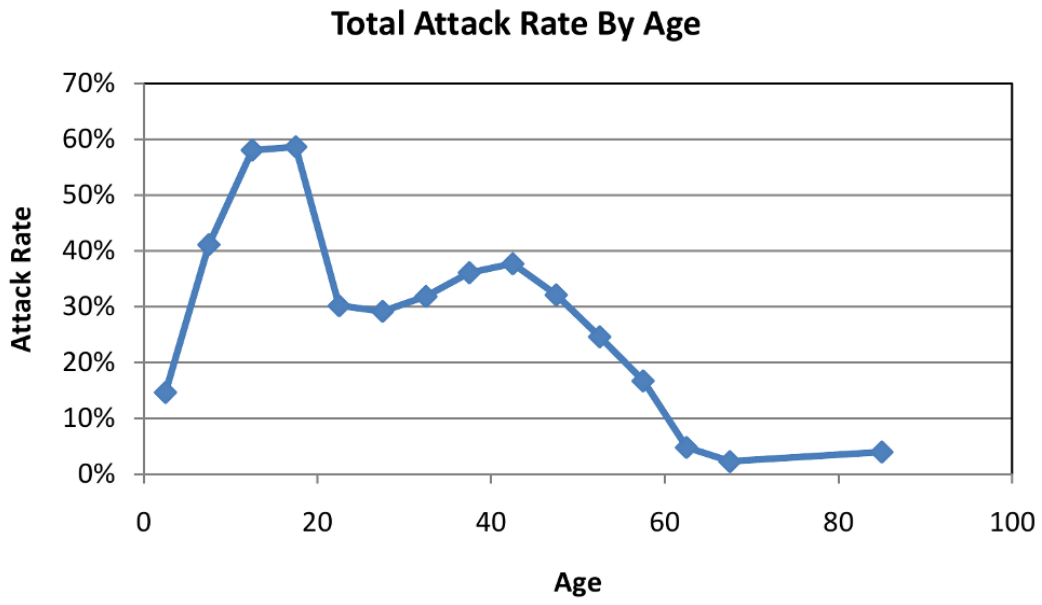

Figure 3: Age-dependent attack rate.

Age-dependent attack rate based upon the fit and contact rates from Mossong *et al*. (2008) (9)

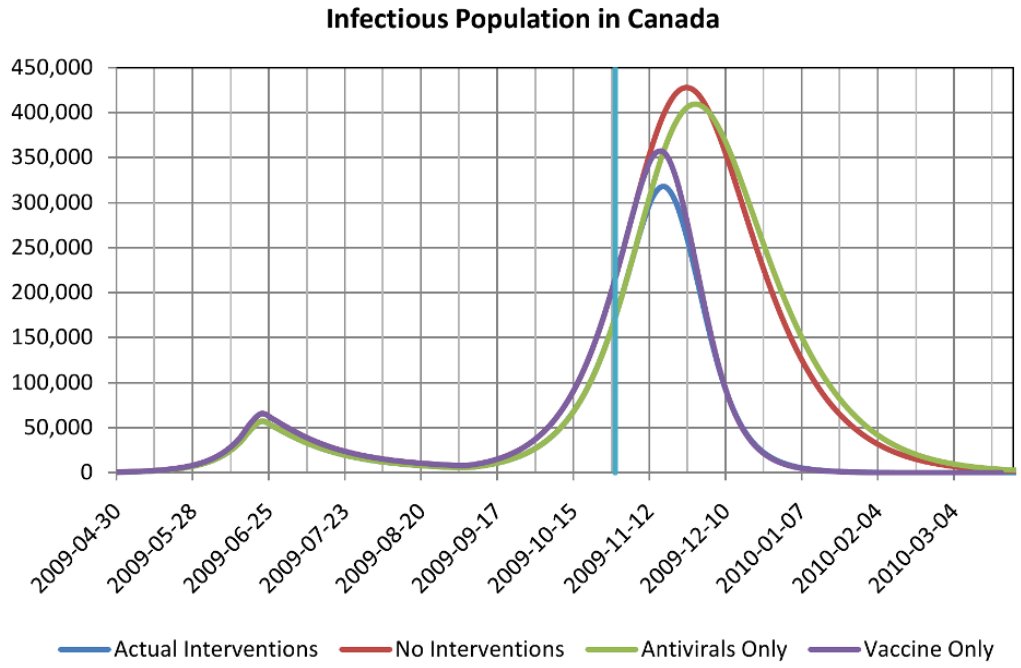

Figure 4: The infectious population in Canada under different intervention scenarios.

The infectious population in Canada under the actual antiviral and vaccine interventions and under scenarios where antivirals and/or vaccines are removed. The vertical line indicates when vaccines become available.

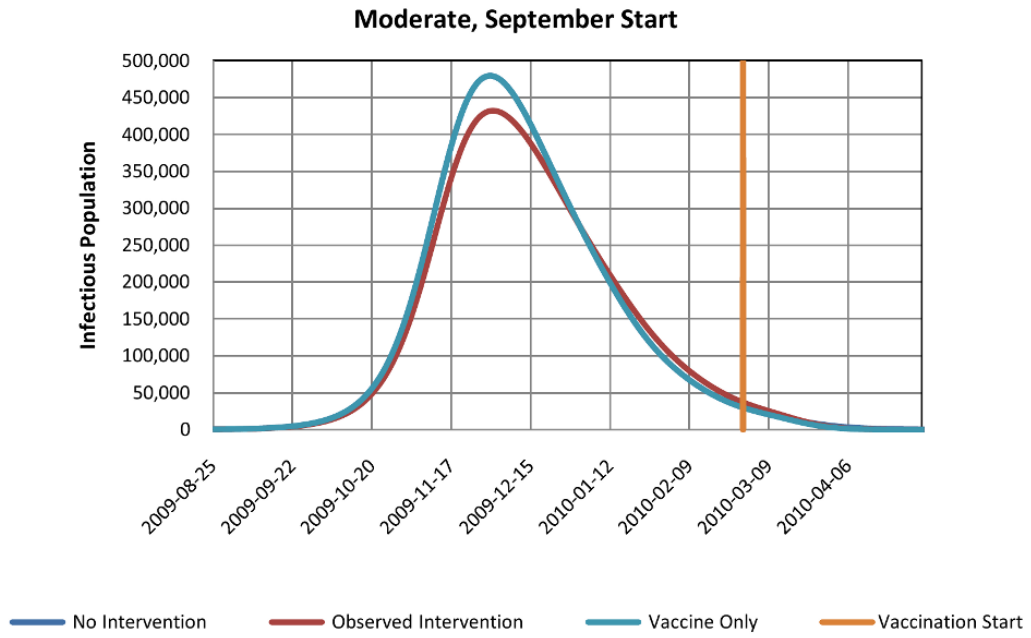

Figure 5: The infectious population in Canada under a moderate pandemic with a single wave peaking in the fall.

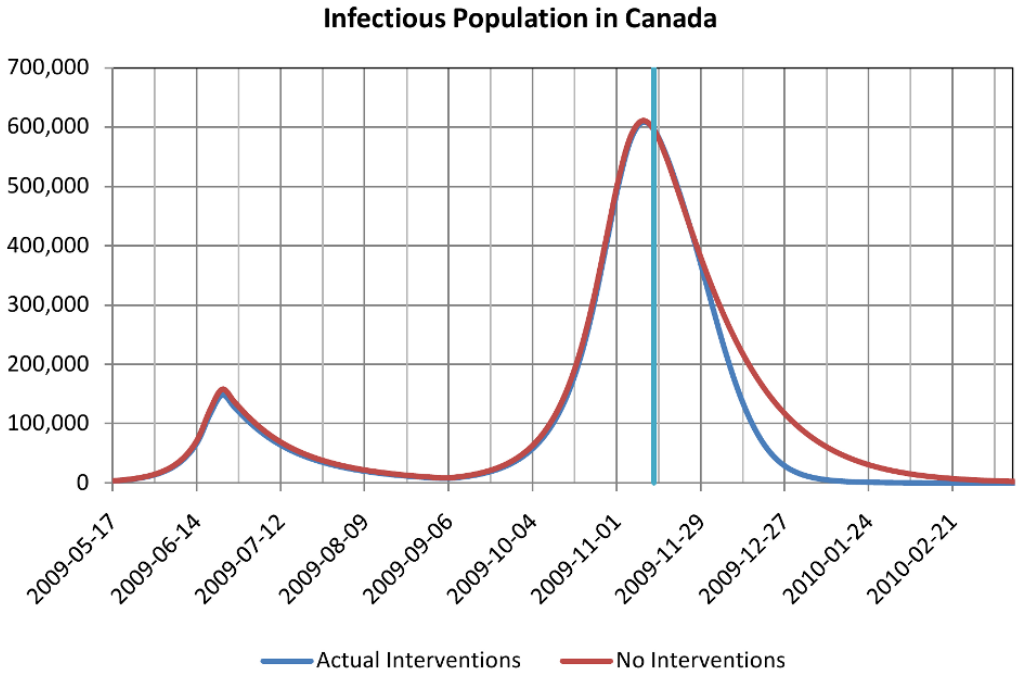

Figure 6: Infectious population in Canada if vaccines started mid-November

Infectious population in Canada if vaccines started mid-November

Table 1: Life and economic impacts of pH1N1 in Canada

Scenario	Attack Rate		Hospitalizations		Mortalities		Annualized Lost GDP ($m)	
As observed (modelled results)	15%	(-46%)	8,636	(-55%)	425	(-74%)	$1,660	(-49%)
Reported vaccine use only	17%	(-39%)	10,196	(-47%)	853	(-48%)	$1,945	(-41%)
Reported Antiviral use only	27%	(-4%)	18,543	(-4%)	975	(-41%)	$3,106	(-5%)
No antiviral or vaccine use	28%		19,353		1,649		$3,280	

The life and economic impacts of pH1N1 in Canada. The values in brackets show the percentage change from the no intervention scenario.

Table 2: Breakdown of healthcare costs

Scenario	Office Visits		Emergency Department Visits		Hospitalizations		Direct Healthcare Costs ($m)
	Unit Cost	Total ($m)	Unit Cost	Total ($m)	Unit Cost	Total ($m)	Total ($m)
As observed (modelled results)	$38	$9	$59	$4	$5,229	$45	$58
Reported vaccine use only	$38	$11	$59	$4	$6,972	$71	$87
Antiviral use only	$38	$20	$59	$8	$5,229	$97	$125
No antiviral or vaccine use	$38	$21	$59	$8	$6,972	$135	$164

The breakdown of healthcare costs associated with pH1N1 in Canada under the observed scenario and the different intervention scenarios.

Table 3: Total economic costs

Scenario	Direct Healthcare Costs ($m)	Cost of Vaccine Used ($m)	Cost of Vaccine Not Used ($m)	Cost of Antivirals Used ($m)
As observed (modelled results)	$58	$117	$286	$12
Reported vaccine use only	$87	$117	$286	-
Antiviral use only	$125	-	-	$25
No antiviral or vaccine use	$164	-	-	-

Economic costs associated with pH1N1 in Canada under the observed scenario and the different intervention scenarios.

Table 4: Quality Adjusted Life Years lost

Scenario	Undiscounted		Discounted at 3%		Discounted at 5%	
QALYs Lost						
As observed (modelled results)	21,080	(-71%)	12,680	(-69%)	10,491	(-67%)
Reported vaccine use only	38,853	(-46%)	21,619	(-47%)	17,129	(-47%)
Antiviral use only	45,669	(-36%)	27,675	(-32%)	22,976	(-29%)
No antiviral or vaccine use	71,658		40,410		32,256	
ICER ($/QALY Gained)						
As observed (modelled results)	$6,111		$11,145		$14,200	
Reported vaccine use only	$9,919		$17,317		$21,512	
Antiviral use only	-$528		-$1,077		-$1,478	

QALYs lost under each scenario and the ICER including the cost of vaccine unused but excluding distribution and other overhead costs. The values in brackets show the percentage change from the no intervention scenario.