Planning for Flu

A Review of the

Manitoba Health 2004 Influenza Immunization Program Planning Model

Marilyn McIvor

A project presented to the University of Manitoba in partial fulfillment of the requirements for the degree of Master of Nursing

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Planning for Flu: A Review of the Manitoba Health 2004 Influenza Immunization Program Planning Model

BY

Marilyn McIvor

A Thesis/Practicum submitted to the Faculty of Graduate Studies of The University of Manitoba in partial fulfillment of the requirement of the degree

Of

Master of Nursing

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Manitoba Health 2004 Influenza Immunization Program Planning Model By Marilyn McIvor

Abstract

The Manitoba Health 2004 influenza immunization program planning model was reviewed and an evidence-based model proposed for 2005. The investigator functioned as an immunization specialist in the Communicable Disease Control Unit, using a participant-observer research strategy. The variables in the 2004 model were compared with actual year-end data and in-house planning documents. Supporting literature was found for the framework of the model, the key variables to be considered, coverage rates, and vaccine wastage. The review showed that 72% of the influenza vaccine distributed in the province was administered and entered in the provincial database. The new infant immunization program achieved at least 40% coverage. It is expected that this improved model will have applicability with other vaccines and in other jurisdictions.

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1. Statement of the Problem

1.1 Introduction

In Manitoba, publicly funded immunization programs are co-coordinated by the Communicable Disease Control (CDC) Unit of Manitoba Health. In the spring of 2004, the CDC Unit made the decision to accept the National Advisory Committee on Immunization's (NACI) recommendation to expand the annual publicly-funded influenza immunization program to include infants aged 6 to 23 months and their close contacts. This meant that Manitoba Health would assume the responsibility for covering the major costs of the program including procuring the vaccine, delivering it to the immunization providers, and funding them to administer the injections.

Staff immunization specialists created a planning model which, for the purposes of this report, shall be called the 2004 model and is attached as Appendix C. This model was based on the best evidence available at the time. Its purpose was to quantify current expenses for the existing influenza program, assist in planning the program expansion, predict the additional costs and volumes of the new program and facilitate year-to-year comparisons. The 2004 model included the population numbers for each of the segmented target groups, the expected immunization coverage rates (percentage of the target group who get immunized), the volumes of vaccine required, the expected cost per dose of the vaccine and the vaccine administration costs. It utilized an Excel spread sheet format and provided guidance for decisions regarding the volume of vaccine to purchase and the expected scope of the program over the course of the 2004/2005 influenza immunization season. This type of planning model is useful for health care

professionals involved in vaccine program implementation since it lends structure and logic to planning discussions and allows for instant updates as the inputs change throughout the year.

There were many assumptions made in the variables used in the model. On-hand population data allowed for some degree of accuracy regarding the number of infants and people over aged 64. The number of pregnant women could be estimated from the number of births.

The high risk population (those who are at greater risk of complications from influenza) has traditionally been estimated by Manitoba Health as 11 percent of the total population. However, little was known about the size of the close contacts groups, expected coverage rates for infants, and the amount of vaccine for which there would be no accounting.

The 2004 model was found to be useful although inaccurate. It allowed for an overall view of the program, with Manitoba Health costs on one page. It was utilized when responding to specific questions from stakeholders. It was not utilized to guide decisions regarding the amount of vaccine to purchase because of the lack of supporting evidence. Historical usage trends were consulted, for purchasing purposes, rather than the model itself.

1.2 Purpose of the Study

The purpose of this study was to review the 2004 model and create a more evidence-based model for 2005. The predicted values in the 2004 model were compared with actual year-end data, data from relevant literature and in-house data to make recommendations for the 2005 model. The goal was to develop a more accurate model for Manitoba Health to utilize in planning for the 2005 influenza season. Ultimately, it is expected that this model will be useful with other vaccines and in other national jurisdictions.

1.3 Background

Influenza affects millions of Canadians every year (Public Health Agency of Canada, 2004). It is an acute viral infection of the respiratory tract spread from person-to-person by droplets and characterized by fever, headache, myalgia, prostration, coryza, sore throat and cough (American Public Health Association, 2004). It can prostrate those infected for 2 – 7 days and sequelae can be severe, including pneumonia and death, especially when contracted by people with an underlying medical condition (NACI, 2004). Large scale epidemics can evolve rapidly since the influenza virus is continually mutating and the whole population is regularly susceptible. World wide epidemics can occur with devastating effects, including 20% death rates (Kolata, 1999).

Prevention of Influenza.

Influenza is an example of an infection where there is little effective treatment. Some success has been shown with antiviral medication for treatment but they are expensive, have a number of side effects, must be taken within 48 hours of symptom onset, and merely lessen the number of sick days. The most important strategy for influenza control is by immunization. Research indicates hand washing and care with unprotected coughing and sneezing have a role in influenza prevention, as with all viruses (Manitoba Health, 2005). However, immunization is the *most* effective means to reduce the impact of influenza (Public Health Agency of Canada, 2005).

Certain population subgroups are more at risk of influenza complications. NACI provides guidance for Provincial and Territorial health ministries in determining who the highest risk groups are and, as such, who should be prioritized for immunization. Most provinces in Canada offer publicly funded influenza immunization to their high risk recipients based on the annual NACI recommendations.

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Immunization is the best method for prevention of influenza (Manitoba Health, 2004). Influenza vaccine has been established as effective both in randomized controlled trials and clinically (Fedson, 1993). Available economic estimates pooled into an analytical model show that influenza vaccination is an efficient intervention (Jefferson & Demicheli, 1998).

The influenza virus mutates and changes so it is recommended that Canadians get immunized every year for optimum protection (NACI, 2004). The new vaccine each year creates new immunity for the new strains and boosts old immunity to previous strains. The major strains are monitored and recorded as they move around the world and the World Health Organization (WHO) specifies the component strains for the vaccine every year. Vaccination is effective in the senior population in preventing hospital admission and death, and results in direct health care cost savings (NACI, 2004). A meta-analysis which pooled results of 20 observational studies on elderly people, reported that influenza vaccines were 56% effective in preventing respiratory illness, 53% effective in preventing pneumonia, 48% effective in preventing hospitalization and 68% effective in preventing death (Gross, Hermogenes, Sacks, Lau, & Levandowski, 1995).

Research has also demonstrated that the vaccine is both effective (44 – 83%) and safe in children (NACI, 2004). The vaccine has not been found to be effective in infants aged birth to six months (NACI, 2004), leaving them particularly vulnerable to the disease. It is for this reason that NACI recommended their household contacts be immunized; to protect susceptible children < 6 months old.

High risk groups.

For decades, the influenza immunization program has focused on seniors 65 years of age or older because of their increased risk of severe illness and death (NACI, 1993-2004). An infection with influenza virus is more likely to result in medical care with this population than

infections with other respiratory viruses, and influenza is the most common cause of respiratory tract illness leading to medical care by the elderly (Deguchi, Takasugi, & Nishimura, 2000). Emergency room visits and hospitalization rates for respiratory disease and chronic lung disease are significantly increased among seniors during influenza seasons (McBean & Hebert, 2004). It has been estimated that 80-90% of all pneumonia- and influenza- attributable deaths each year occur in the elderly (Menec, Black, MacWilliam, & Aoki, 2003). This Winnipeg study also found significant excess hospitalization, physician visit, and emergency room visit rates for influenza-associated respiratory illnesses especially among adults aged 65 and over (Menec, et al., 2003). The vaccine is made available to high risk target groups and their close contacts in order to protect them.

Influenza in Children.

Recent research indicates infants and toddlers also suffer disproportionately from influenza (Skowronski, 2005). They experience a high attack rate of 10-35% and have an increased risk of hospitalization (Peltola, Ziegler, and Ruuskanen, 2003) and physician or emergency room visits related to influenza (Menec, et al., 2003). They are more likely to use antibiotics for the treatment of complications such as acute otitis media and respiratory tract infections (Neuzil, Mellen, Wright, Mitchel, & Griggin, 2000). Approximately 12-40% of children with influenza illness develop acute otitis media (Heikkinen, Ruuskanen, Waris, Ziegler, Arola, & Halonen, 1991). Although mortality due to influenza in infants and toddlers is low (Thompson, Shay, Weintraub, Brammer, Cox, & Anderson, 2003), young children are equally susceptible to hospitalization for influenza as seniors (Neuzil, 2004). The vaccine is licensed for children over age 6 months only since it is less immunogenic in infants <6 months of age (NACI, 2004). The vaccine is "safe and well tolerated in healthy children" (NACI, 2004,

p.9) A recent Cochrane review reported that inactivated influenza vaccine efficacy was no better than placebo in children aged 2 years or younger (Jefferson, Smith, Demicheli, Hamden, Rivetti, & Di Pietrantonj, 2005). Research is ongoing in this area.
Influenza in Manitoba.

The Manitoba Influenza Surveillance System reports up to 250 lab confirmed cases per year (Manitoba Health, 2005). The first lab-confirmed case in Manitoba was reported on November 19, 2004 and there were a total of 217 cases over the 04/05 season. Over the last six seasons, there has been an average of 131 cases of influenza A and 54 cases of influenza B per year. Figures 1 and 2 illustrate influenza A and B trends over the last six seasons including the arrival of the virus in Manitoba in the fall, peaking in different months in different years, influenza A before influenza B, and how the virus usually stops circulating by April or May.

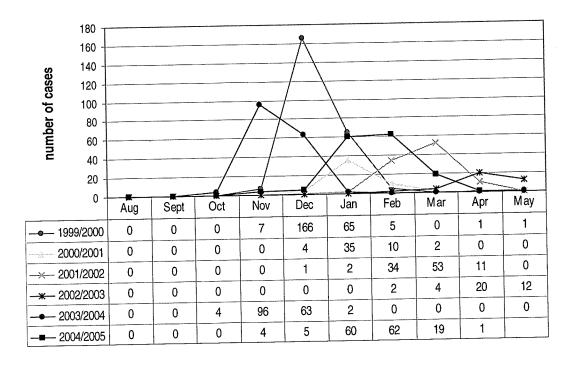


Figure 1: Influenza A: Number of Laboratory-Confirmed Cases, 1999/2000 – 2004/2005 in Manitoba (Manitoba Health, 2005)

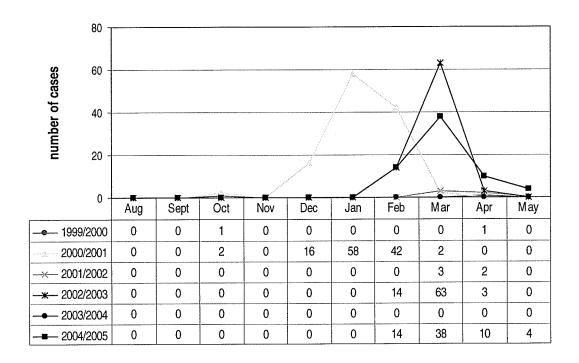


Figure 2: Influenza B: Number of Laboratory-Confirmed Cases, 1999/2000 – 2004/2005 in Manitoba (Manitoba Health, 2005)

These data are used as markers or indicators of influenza activity rather than actual influenza activity since not all people with influenza seek medical attention, and of those that do, not all are cultured for the virus (Manitoba Health, 2005). The number of Manitobans infected with influenza annually may be in the thousands. In 1993, it was estimated that up to 74,000 hospitalizations and 6,700 deaths each year in Canada were associated with influenza virus infection (CCDR, 1993). This illness not only has impacts on the people who are actually ill, bedridden, hospitalized, or die; it also has larger societal impacts on health care costs, hospitalization costs, and employee and school absenteeism.

Influenza immunization in Manitoba.

Manitoba Health has offered influenza immunization to selected target groups since the 1970s. As NACI's recommendations have evolved and expanded, so have Manitoba Health's.

Over the past 10 years there have been few significant changes beyond recommending the vaccine to people at highest risk of complications from influenza; people with chronic heart and lung disorders and people over aged 64 are at higher risk of complications from influenza such as pneumonia and death. In order to protect these groups, their close household or health care contacts are encouraged to be immunized.

New evidence was reported in the early 2000s that children's risk of hospitalization from influenza matched that of seniors'. Tragically, some young children died from influenza in British Columbia in the fall of 2003. In early 2004, NACI decided to recommend the vaccine for children aged 6 – 23 months and their close contacts. They made this recommendation informally in February, 2004 and formally in June of that year. Children develop influenza because they are exposed to the virus before they have developed immune memory. They usually develop an upper respiratory tract infection with fever but other common clinical presentations include lower respiratory tract infections (such as croup, bronchitis, or pneumonia), otitis media, diarrheal illness, and febrile seizures. Less common but severe complications can include myocarditis, pericarditis, toxic shock syndrome, transverse myelitis, encephalitis and Reye's syndrome. Children aged <2 years are at increased risk of influenza-related hospitalizations during influenza season, than older children (NACI, 2004). It is noteworthy that, although young children are at greater risk of influenza-related hospitalization, fortunately, their mortality rates are usually lower.

Manitoba Health staff entered into a planning phase in the spring of 2004 to prepare to implement this new NACI recommendation. A significant amount of capacity for the annual influenza immunization program already existed including vaccine procurement systems, communication systems with immunization providers province-wide, an annual immunization

promotion campaign, a biologics storage and distribution system, an immunization registry, and an established funding mechanism.

NACI (2004)	guidelines for	dosage schedule	are as follows:
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Age	Dose (ml)	Number of doses		
6-35 months	0.25	1 or 2*		
3-8 years	0.50	1 or 2*		
> 9 years	0.50	1		

Table 1: Recommended influenza vaccine dosage, by age. (NACI, 2004)

Previously unvaccinated children < 9 years require two doses of the split-virus influenza vaccine with an interval of 4 weeks. The planning models include a line for number of doses because it can affect the total number of doses required to fully immunize a target group. For influenza planning, one dose is taken as sufficient. Some children require two doses but since they only require ½ a dose, this was noted in the model as 1 dose.

Manitoba participates in the National Vaccine Supply Working Group (VSWG) in collaboration with the other Provinces and Territories and with the support of Public Works and Government Services Canada (PWGSC). Manitoba purchased and shipped more vaccine to the immunization providers in the field every year for the last three, as illustrated below:

Year	Number of doses purchased from the manufacturer	Number of doses shipped to the field
2002	244,000	241,131
2003	295,250	273,310
2004	320,500	318,930

Table 2: Volumes of influenza vaccine purchased and shipped by Manitoba Health 02-04.

In 2004, Manitoba purchased the vaccine Fluviral®, supplied by ID Biomedical Pharmaceuticals. Sanofi Pasteur (formerly Aventis) also manufactured influenza vaccine and some other provinces decided to purchase their Vaxigrip® and/or Fluzone® due to a variety of factors including the amount of preservative, the way the product is supplied (i.e. vials versus prefilled syringes), price, and availability. Nationally, the prices were negotiated between the

manufacturers and the provinces by the VSWG and PWGSC, contracts were established, and the provinces were invoiced. The contracts are arranged so that there is a 10% flexibility factor, which means that the volume purchased can be 10% more or less than the contracted volume with no penalty. Manitoba initially purchased 275,000 doses and increased their purchase as the season progressed. Since there are 1.2 million Manitobans, this allowed for about 23% of the population to be immunized, with a priority on the high risk groups.

As in previous years, a letter was sent to 3700 immunization providers in September advising them of program details, eligibility criteria, and how to order the vaccine (see Appendix D). The vaccine was available for order from the Provincial Vaccine Warehouse by September 20, 2004 and shipped on an as-needed basis. The bulk of the vaccine was administered between October 15 and November 30th by public health nurses, primary care staff, occupational health staff, and private practitioners. This allowed for as many as possible of the high risk populations to be immunized before the influenza virus began to circulate.

Manitoba Health also has a role in promoting the uptake of influenza vaccine provincially. CDC Unit staff, in partnership with Communications Manitoba Services, has developed a provincial communications strategy to promote the awareness of the publicly funded vaccine for eligible high risk people. It includes promotional posters and brochures, fact sheets, bus shelter posters, radio and newspaper advertising. A media study commissioned in 2003 indicated the campaign was successful in communicating its main message and that a large percentage of eligible Manitobans were aware of their eligibility. The study indicated there was good awareness of the need for influenza vaccine in the targeted groups and was supporting evidence to maintain the campaign. It was decided that the promotional materials, radio advertising, transit shelter posters, newspaper advertising, and Health Links support would be

maintained; the television ads were discontinued. A financial estimates process was used to monitor and control these costs.

Influenza vaccine is delivered in Manitoba by Public Health Nurses (PHNs) in the eleven Regional Health Authorities (RHAs): Assiniboine, Brandon, Burntwood, Central, Churchill, Interlake, Norman, North Eastman, Parkland, South Eastman, and Winnipeg. Each RHA has its own Regional Immunization Coordinator, most of whose salary is paid by direct funding from the CDC Unit. Additionally, vaccine is delivered by nurses and doctors at the 64 First Nations Inuit Health Branch (FNIHB) Nursing Stations/Health Centres, 1000 doctors' offices/clinics, 138 Hospitals and Personal Care Homes, 14 Occupational Health departments, and nine Correctional facilities.

Vaccine is ordered on a Biologics Order Form from the Provincial Vaccine Warehouse in Winnipeg and shipped to the immunization provider under cold chain conditions (between 2° and 8° from the manufacturer to the eligible recipients). The vaccine is administered to the qualified recipient and data including the date, the type of vaccine, the lot number, and the provider is entered into the Manitoba Immunization Monitoring System (MIMS) using the Personal Health Information Number (PHIN). MIMS is a provincial mainframe database housed at Manitoba Health wherein all immunizations are to be recorded. When PHNs or other staff members of a RHA immunize, the data is entered into MIMS and the RHA is funded accordingly. When private physicians immunize and submit their billing data to the Manitoba Insured Benefits Branch, the data roll over into the MIMS database, as well. MIMS is capable of providing Manitobans with accurate and valid information regarding influenza vaccine usage for all doses that are entered therein.

In 2000/2001 Manitoba Health contracted the Manitoba Centre for Health Policy to investigate the impact of influenza-like illness on the Winnipeg health care system. It was becoming apparent that "the data to describe influenza vaccination coverage in Manitoba were inadequate" (Menec, Black, MacWilliam, Aoki, Peterson, & Friesen, 2001, p.79). At that time, Manitoba Health enhanced the ability of MIMS to track immunizations in all age groups and tied it to physician billing codes.

Since then, MIMS data has been used for funding the RHAs. In March of every year, a data run is executed that reports the number of doses of influenza vaccine that have been administered by each RHA and they are reimbursed \$7.00 per dose. Additionally, funding for Regional Immunization Co-coordinators and other immunization staff is disbursed annually. Physicians are paid \$6.00 per dose by the Insured Benefits Branch at Manitoba Health.

By the end of the 2003/04 influenza immunization season, 273,310 doses of influenza vaccine were shipped from the vaccine warehouse to immunization providers and 198,723 (73%) were captured in MIMS. The "unaccounted for" 74,587 (27%) doses were troubling and this project contributes to their analysis. The loss reflects vaccine expiring without being given, most likely due to immunization providers ordering more than they need for the season. A small amount of loss is probably due to cold chain breaks; when vaccine is exposed to temperatures outside of 2° - 8° it must be discarded. In addition, vaccine may be administered but no MIMS entry made. The exact analysis of this vaccine loss is largely beyond the scope of this study.

The 2004 model was developed in June of 2004 to plan the influenza immunization program and it laid out clearly and simply the major target groups, expected vaccine uptake, and the estimated major costs. Initially, when the decision was made to expand the influenza immunization program, policy analysts at Manitoba Health were aware that there was a

prototype model for a program such as this for the pneumococcal conjugate, meningococcal conjugate, and varicella immunization programs. It was determined that those models could be adapted and utilized for influenza program planning. Although there were gaps in evidence, some data was available to assist with planning.

There are different types of mathematical models in the literature that are used for immunization program planning. There are cost-effectiveness models that show that if 1000 Manitobans catch the flu every year and some are hospitalized, some miss work, and some end up with long term chronic illnesses, it will cost society and the health care system a measurable amount of money. These models will show that if there is an immunization program that also costs another measurable amount of money, it will be cost effective in reducing the costs of the unprevented disease in certain populations (Yassi, Kettner, Hammond, Cheang, and McGill, 1991). This case had already been made in Manitoba and on going funding was in place for the influenza immunization program.

There are also disease models that exist. For example, research is currently in progress that is looking at how influenza is circulated in Manitoba and whether it would be advantageous to immunize all the school aged children, rather than the seniors, in order to protect the seniors. This was not the type of model that was needed by CDC Unit staff.

The 2004 model included the target groups for this vaccine which were determined by a combination of what Manitoba Health had covered in previous years and what NACI recommended for 2004. Historically people with chronic illnesses, health care workers, and people aged 65 or over, their household contacts, and their caregivers were eligible for publicly funded vaccine. New additions included children aged six to 23 months, household contacts and childcare providers of children aged birth to 23 months, and pregnant women in their third

trimester who were expected to deliver between October 1, 2004 and March 31, 2005. Manitoba Health population data available at www.gov.mb.ca/health/population/ was used in combination with MIMS immunization coverage data to develop the 2004 model.

The model proved to be useful for organizing the planning but the values were known to be likely inaccurate at the beginning of the season. A valid model would predict the amount of vaccine required to purchase more accurately. In times of vaccine shortage, the target groups could be easily segmented as priorities change. Manitoba Health had a great deal of data on populations, quantity of vaccine purchased, and MIMS coverage rates but it had not been drawn together onto one page in a simple, yet comprehensive manner. There was no knowledge of similar models in the literature or being used by other provinces.

1.4 Context

This project was set in the context of a positive socio-political environment for immunization programs and a time of implementation of new programs. Vaccines and quality immunization programs are recognized as integral to the success of Canada's health care system. Immunization is generally accepted as the single most cost-effective health investment a government can make in the health of their population. Influenza is respected as a serious disease with extensive health and economic consequences that can be prevented with a safe, effective vaccine. With looming influenza pandemics and threats of other serious communicable diseases and biological warfare, Manitoba is experiencing a renewed interest in the capacity of Public Health to manage and deliver vaccines. The provincial government has a strong role in communicable disease prevention and the CDC Unit invests millions of dollars in vaccines every year.

On a national level, Canada's new National Immunization Strategy (NIS) represents a Federal/Provincial/Territorial (F/P/T) collaboration that has evolved since 1999 through the Deputy Ministers of Health's Advisory Committee on Population Health and Health Security. In June 2003, the Conference of Deputy Ministers of Health (CDMH) endorsed the *National Immunization Strategy* which provided the fundamentals for moving forward with a Canadian strategy on immunization. This triggered Federal funding of \$45 million over five years to "strengthen federal infrastructure and programs for addressing immunization issues" (Public Health Agency of Canada, 2005, p.2). Additionally, \$300 million was announced in March 2004 to be made available to the provinces by the federal government to support the implementation of new and recommended childhood and adolescent vaccines. Manitoba's share was \$12 million and this funding was used to introduce universal immunization programs with pneumococcal conjugate, meningococcal C conjugate, and varicella vaccines.

Manitoba Health moved quickly and announced the new vaccine programs publicly at the end of April 2004. Immunization was attracting a significant amount of media attention and was seen as being beneficial to the overall health of Manitobans. The decision was made to offer the three new vaccines starting September 1, 2004. Manitoba Health supported the RHAs' capacity to deliver the new vaccines in conjunction with the expansion of the influenza program by doubling their base funding for immunization staff. Planning models similar to the 2004 influenza model were utilized.

Finally, a positive socio-political context for this project is evidenced by the World Health Assembly adoption on May 24, 2005 of the Global Immunization Strategy for 2006-2014 which calls for 80% immunization coverage in all districts of all countries (WHO, 2004). This

strategy is aided by the Bill and Melinda Gates Foundation and demonstrates ongoing, world wide support for immunization.

This project will help Immunization Specialists at Manitoba Health to understand the costs of the largest immunization program in the province. The results of this project will contribute to the CDC Unit's knowledge base needed to plan better and make accurate, informed decisions regarding caring for all Manitobans to protect them from vaccine preventable diseases.

Evaluation involves the systematic and thorough review of programs and their supporting decisions. Evaluations do not need to be complicated, time intensive or overly extensive; they need to be achievable and target key indicators. The 2004 model is a brief, but important, program planning tool that sets direction for a large, expensive campaign. This evaluation of the model illuminated key shortcomings and has applicability to other immunization programs. "Program evaluation, an integral part of program planning, enables nurses and other health-care providers to make informed decisions regarding the efficacy of health care" (Johnson & Olseinski, 1994, p. 43).

Economic evaluations are particularly important as financial resources become more limited for health care provision. Important decisions must be made about where to spend an immunization budget and how to provide the best protection for the greatest number of people in the most cost-effective way. Consideration must be given to the concept that resources spent on one immunization program are being withheld from another. The first step to a cost-effectiveness analysis is a cost-description analysis such as this. Cost-description evaluations calculate the total resources used as interventions ('inputs'), and usually quantify these resources in terms of money. Ovretveit (1998) defines a cost-description economic evaluation as "measurement of the costs of one thing in a way which allows an explicit or implicit comparison of costs" (p.116).

This type of evaluation is often deemed "partial" since it does not implicitly compare the intervention with alternatives. However, it does lay the groundwork and invites comparison with other uses of the money. This project will be useful to promote comparison of the total resources used by different vaccine interventions and will allow policy analysts to understand their programs better.

1.5 Relevance

This project is addressing one key component of the National Immunization Strategy which encourages immunization program planning supported by immunization research. In order to facilitate evidenced-based decision making in all jurisdictions regarding immunization programs, research is encouraged on "models to predict the effect of the new program" (NIS, 2003). An improved planning model will assist Manitoba Health CDC Unit staff to manage the 2005 influenza immunization season. It is expected that the proposed 2005 model will be helpful in other Canadian jurisdictions in order to improve the accuracy of planning for the annual influenza immunization campaign. It can likely be applied to both smaller regional vaccination programs in Manitoba and in larger provincial programs. It could be useful nationally for planning at that level. Ultimately, it could have applicability in pandemic planning and in all parts of the world where influenza immunization is offered. Furthermore, the information this project will uncover will likely be useful in other new vaccine program implementations.

1.8 Problem summary

The problem was that the 2004 model was approximately 28% inaccurate, particularly in terms of the way the coverage and wastage variables influenced the amount of vaccine required to purchase. Further investigation was required to create an accurate 2005 planning model that described the major costs the CDC unit was responsible for and summarized how the cost of this

particular vaccine program impacted the CDC budget, and overall public health budget. Critical questions existed regarding vaccine use, coverage, and wastage variables. A thorough review was necessary to analyze the 2004 model against recent literature, compare the model with actual year-end and existing in-house data with proxy value, and create a more evidence based model for 2005.

2. Review of the Literature

The literature on influenza infection and its prevention is extensive. This summary will include information relevant to an evaluation of the Manitoba Health influenza immunization program planning model including the framework of the model, the key variables to be considered, coverage rates, and the literature regarding wastage of vaccine.

2.1 Framework of the Model

The 2004 model utilized an Excel spreadsheet framework that allowed for an ata-glance view of the entire program and the ability to make changes to variables and have them apply throughout. The literature revealed similar frameworks were utilized in other jurisdictions. Moore, Bigham, and Patrick (2003) from the British Columbia Centre for Disease Control (BCCDC) published a planning model for the introduction of their pneumococcal conjugate vaccine. Using a mathematical spreadsheet format, similar to the Manitoba Health influenza planning model for 2004, the BCCDC pneumococcal conjugate planning model included a number of important assumptions such as; the schedule of the vaccines would be integrated into the existing routine infant immunization program without a "catch-up" component, annual costs were estimated, based on in-house data from the previous year, and a coverage rate of 90% was assumed "approximating the average for infant immunization programs in BC over the past decade" (p. 2). Moore, et al. (2003) planned for 5% vaccine wastage, and estimated 60% of immunizations would be delivered by PHNs and 40% by physicians in their offices, which reflected their provincial averages. They also factored in additional costs such as surgical supplies, promotional material, clerical support, regional and provincial

surveillance and program evaluation costs. They also assumed 10 nursing minutes per dose and a nurse to clerical staff ratio of 3:1. The overall framework as a spreadsheet matched the 2004 model used in Manitoba very closely and served to validate it.

The World Health Organization (WHO, 2002) Department of Vaccines and Biologicals also published guidelines for estimating costs of introducing new vaccines into a national immunization system, including guidelines for estimating the overall costs of introducing the vaccine and maintaining sufficient coverage. The WHO provided a formula for calculating the number of doses required as:

n = i x b x d x (1/(1-w)) x (1 + r), where
n = number of doses required
i = immunization coverage rate
b = birth cohort
d = number of doses per fully immunized child
w = wastage rate (%) (suggested at 30%)

r = reserve stock (%) (usually set at 25%)

The total vaccine costs per year (c) are then estimated as $c = p \times n$, where p = p price of the new vaccine per dose, including shipping and handling, and n = number of doses required. In subsequent years, the reserve stock (r) should be excluded and any vaccine in stock should be extracted from the number of estimated doses as follows:

 $n = i \times b \times d \times (1/(1-w)) - s$, where s = number of vaccine doses in stock. These calculations are incorporated into the spreadsheet for the 2005 model. Both the BCCDC and the WHO frameworks served to validate the overall design of the 2004

model. The two frameworks are integrated by applying the WHO formulae to the Excel spreadsheet in the 2005 model.

2.2 Key variables

It was important to identify the key variables that needed to be included in the program planning model and the literature was searched for suggestions for what other researchers had included. The 2004 model included the populations of the risk groups, coverage, wastage, and cost of vaccine, number of doses required, vaccine administration costs and promotion costs.

A significant amount of research has been done on the cost-effectiveness and cost-benefit of influenza vaccine in a variety of settings. These studies were designed to compare the total costs of the immunization program with the effectiveness of the program at achieving established goals. This project was not a cost-effectiveness or cost-benefit analysis; that has been proven elsewhere. However, it was useful to examine that literature since those studies start by assembling the total costs of the program which has relevance for this project.

An investigation into the effectiveness and cost benefit of immunizing Health Care Workers (HCWs) against influenza determined that the total savings in absenteeism was \$59.70 per employee (including paid sick time), less the total costs to immunize at \$20.47 per employee, which resulted in a net benefit of \$39.23 per employee vaccinated in the influenza epidemic year studied (Yassi, Kettner, Hammond, Cheang, & McGill, 1991). This current project is interested in the ways those researchers calculated the program costs in their project. Direct costs associated with vaccine administration included:

costs of materials for each vaccination, (\$2.25 for the vaccine and \$0.25 for the needle, syringe, swabs, etc.) totaling \$2.50 as well as an estimated 20 minutes of the occupational health nurse's time for each vaccinated employee (including preparation, travel within the hospital, charting and filing), representing a cost of \$5.87 (1/3 hour x \$17.60/h) per vaccinated employee (Yassi et al., 1991, p.104).

Yassi et al. (1991) also included a promotion budget (\$5.27 per vaccinated HCW), lost time attributable to adverse vaccine reactions (\$1.58 per vaccinated HCW), and lost time from work duties for the HCW to receive the vaccine (\$5.25 per vaccinated HCW).

Campbell and Rumley (1997) reported on their investigation of the costeffectiveness of the influenza vaccine in a healthy, working-age population in six North
Carolina textile plants. They concluded that the "cost per saved lost workday" was
US\$22.36, for a company savings of US\$2.58 per dollar invested in the program. They
included such costs in their calculations as vaccines, syringes, and alcohol preps at
US\$3.50 per dose. They paid the nurses US\$15.38 per hour and budgeted one hour per
vaccinated employee including time to contact them, administer vaccine and complete all
paperwork. They also costed employee time to come to get immunized, fill out
paperwork, and receive the vaccine at 30 minutes per employee. They found no lost work
time because of vaccine side effects. (This is consistent with NACI statements that side
effects are rare.)

White, Lavoie, and Nettleman researched cost savings attributable to influenza vaccination of school-aged children. The total costs they investigated included "direct costs for vaccination, physician visits, and treatment" (1991, p.1). Indirect costs were "in the form of lost productivity when working parents stayed home to care for ill children or to take children to an office for vaccination" (White, et al., 1991, p.1). They demonstrated large savings per child vaccinated (US\$35) if they were administered the vaccine in a

group-based setting such as by PHNs in schools. Smaller savings were generated (US\$4) if the parent had to take time off work and take their child to a doctor for immunization.

In 2000, Cohen and Nettleman reported that "vaccinating preschool children is economically advantageous" (Cohen & Nettleman, 2000, p.973). They took a societal approach and included factors such as the time parents missed from work to have their children immunized, or to care for an ill child. Their cost calculations included the costs of the vaccine, supplies, personnel, and administrative expenses at US\$10 per dose.

Also in 2000, the Centers for Disease Control Atlanta (CDCAtlanta) funded a randomized controlled trial investigating the effectiveness and cost benefit of influenza vaccination of healthy working adults at Ford Motor Co. (Bridges, Thompson, Meltzer, Reeve, Talamonti, Cox, Lilac, Hall, Klimov, & Fukuda, 2000). They determined that even when the influenza strains in the vaccine and the strains that are actually circulating in the community are well matched there may not be an overall economic benefit to immunizing healthy working adults. Their study found that when there was a good match between vaccine and circulating influenza, as happened in 1998-1999, there was a net cost of US\$13.93 per vaccine recipient. The costs they took into consideration when making their calculations included: vaccine and supplies at US\$2.66, 15 minutes of the nurses' time at US\$29.37/hour for wages and benefits, and 30 minutes per vaccine of time lost from work to get vaccinated for a total cost of US\$24.70 per person vaccinated.

In 2001, Dr. K. Nichol from Minneapolis, with funding from influenza vaccine manufacturers, reported that influenza vaccination of healthy working adults was "on average cost saving" (Nichol, 2001, p.749). Her cost calculations included US\$10/dose for vaccine, supplies and administration, and US\$0.64/dose for the cost of treatment of

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potential side effects. This calculation was based on the cost of 1 physician office visit per 100 persons vaccinated at US\$69.51 per visit. As well, she included indirect costs of vaccination at US\$4.58 (for 30 minutes of work time lost while getting vaccinated) and of potential side effects at US\$1.47 (for 2 days per 100 persons vaccinated of work time lost due to a side effect) for a total cost of vaccination of US\$16.69 per person.

Parlevliet, de Borgie, Frijstein, and Guchelaar (2002) analyzed the cost-benefit of vaccination against influenza of the employees of a Dutch medical centre. They concluded there was an overall economic benefit to immunization, especially of medical residents. The inputs they included were costs of vaccination, promotion, and loss of productivity.

A 2002 report from Lee, Matchar, Clements, Juber, Hamilton and Peterson on the economic analysis of influenza vaccination and antiviral treatment for healthy working adults in North Carolina utilized some of the preceding research to compare the relative health values of contemporary treatment strategies. They included vaccine costs and administration costs but excluded the cost of side effects. "Because side effects rarely occur with use of influenza vaccine...the probabilities for these variables were not included" (p.227).

Lastly, an economic evaluation in Taiwan (Wang, Lee, Chen, & Chen, 2005, p.1973) comments that "economic evaluation of influenza vaccination... is paramount". They included the following in their costs of vaccine model: vaccine cost, cost caused by severe vaccine side-effect, traveling fee and production loss due to vaccination. Their vaccination cost was calculated to be US\$7.54 with drug cost (US\$4.32) + consultation cost (US\$2.88) + administration cost (US\$0.34). They counted side effects at US\$0.104

per dose based on one outpatient treatment (US\$11.53) x rate of side-effect due to vaccine (1.8%). They also factored in production loss costs which they only attributed to care givers since they assumed the productivity of a person aged 65 years as null. They calculated production value per hour = average gross national product per person (US\$12,970)/ [average monthly working hours for employer (182 h) x 12 months] = US\$5.94. They included a traveling fee of US\$1 for accompanying the family for their vaccination.

This project reviewed the literature on cost-effectiveness and cost-benefit of influenza immunization to determine typical costs that might be included in the 2005 model. There are a variety of possibilities (summarized below) including vaccine purchase costs, surgical supplies, nurses' time, promotions, cost of side effects, and loss of productivity.

Researcher	Vaccine costs	Surgical supplies	Nurses' time	Promotion	Cost of Side Effects	Loss of productivity
Yassi, et al.	X	X	X	X	X	X
Campbell & Rumley	X	X	X		X	X
White, Lavoie, & Nettleman	X	X	X	X		X
Cohen & Nettleman	X	X	X			X
Bridges, et al.	X	X	X			X
Nichol	X	X	X		X	X
Parleviet, et al	X	X	X	X		X
Lee, et al Wang, et al	X		X		X	X

Table 3: Summary of key variables literature

It can be seen from the literature on cost-effectiveness and cost-benefit of influenza immunization that there are some costs which could be added to the 2005

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model including cost of treatment of side effects, immunization supplies, and societal costs for people to take the time to get immunized rather than being productive. The WHO also recommended costing considerations for other items such as waste management, an expansion of the vaccine storage and distribution system, personnel training, disease surveillance and monitoring, redesign and reprinting of immunization forms and stationary, and social mobilization/immunization promotion.

This project concluded no change in the variables from the 2004 Model was necessary. The 2005 Model included the costs that the CDC Unit was directly accountable for; the cost of the vaccine, the administration payments to the RHAs, and the program promotion costs. It was not useful to include other, broader costs of the immunization program.

2.3 Immunization coverage

Coverage refers to the percentage of the target group that is actually immunized or "covered" by the vaccine. It varies, depending on the vaccine and the population it is offered to. National goals aim for coverage for 80-95% of the population, depending on the target group. These goals are rarely achieved in any jurisdiction, yet. It is not prudent to purchase vaccine to "cover" that whole population, if the actual coverage achieved is less. If accurate coverage rates can be predicted, it is more likely that accurate forecasting of volumes of vaccine to purchase can occur.

The literature reveals evidence about immunization coverage rates that has helpful proxy or transferable value in planning immunization programs. Historically, influenza coverage rates have increased in seniors from the 40% reported in 1993 (Duclos & Hatcher, 1993) to the 68% in 2003 (Manitoba Health, 2004). In 1996, Macdonald,

Roberecki, and Cosway reported at least 48% coverage of seniors in the Manitoba Interlake region (not accounting for Interlake seniors who traveled to Winnipeg for their vaccine).

Canadian national influenza immunization coverage data indicate an average of 69% of seniors, 38% of high risk people, and 55% of health care workers were immunized (Squires, 2001). The National Population Health Survey reported that 33.8% of Canadian's aged 18-64 years with at least one chronic condition received an influenza shot in 1996/97 and this climbed to 47.2% in the 2000/01 Canadian Community Health Survey (Johansen, Nguyen, & Mao, 2004).

Ontario's universal program produced a childhood coverage rate of 25% when 208 parents of children presenting in the Emergency Room (ER) of Children's Hospital of Eastern Ontario were surveyed (Grant et al, 2003). This study is limited in that it may not represent parents of children in the general population who do not seek care at an ER. Ontario school aged children's coverage was as high as 54% in some schools (Cronsberry, Tamblyn, Smith, & Nevin, 2004). Perth District Health Unit in Ontario found varying rates of coverage in health care workers depending on their setting: hospital based HCWs were 50% immunized, long term care facility HCWs were 47% immunized and home care workers were 40% immunized. Similarly, high risk client coverage varied by setting: in long term care facilities, 93% of the residents were immunized; while 86% of home care clients were covered (Tamblyn, Gaylor, & Smith, 1997). A Toronto study found a coverage rate of 51% among house staff (Lester, McGeer, and Tomlinson, 2003).

CDC Atlanta reported American influenza coverage rates of 6% for children (Santibez, 2004), 70% for seniors, and 34% for high risk adults (Bardenheier, Wortley, and Euler, 2004). American Medicare beneficiaries >65 reported 67 – 70% coverage over 1991-2002 (Adler & Winston, 2004). Weycker et al. (2004) estimated 5% coverage for young children, 60% for high risk adults <65 years of age, and 68% for adults >65.

Canadian national childhood data indicate that 74% of two year olds have had four doses of tetanus vaccine; 93% have had two doses (McWha et al, 2002). This was useful information for its proxy value since coverage rates for two doses of the new influenza for infants program was not likely to exceed coverage rates for two doses of the long-established tetanus immunization program. BCCDC planned for 90% coverage for their pneumococcal conjugate vaccine based upon the average for infant immunization programs in B.C. over the past decade (Moore, et al, 2003). This is likely a high assumption since information regarding an established vaccine program is not necessarily completely transferable to a new program implementation. Figure 4 provides a summary of this coverage data in selected populations. This table illustrates the lack of literature on influenza immunization coverage rates in siblings, parents, child care providers, and pregnant women but provides good evidence for other coverage assumptions for the 2005 model.

Source	Infants	Siblings	Parents	Child care	Preg ♀	High Risk adults	HCWs	>64	House contacts
Squires						38	55	69	
et al.									
CCHS						47			
Ontario ER	25								
Ontario	54								
School									
Perth						86-93	47-50		
Toronto							51		
CDC	6					34		70	
Atlanta									
CDC								69	
Medicare									
Cdn	74								
Tetanus									
BC	90								
planning									
Weycker	5					60	68		
et al	<u>a</u> .		<u></u>	<u> </u>	<u> </u>			<u> </u>	

Table 4: Influenza immunization coverage in selected populations as percentage

The WHO (2002) recommends coverage rates be set as targets based on the current coverage rates and predicted changes in service. The best predictor of 2005 coverage is likely to be 2004 coverage as reported by MIMS. It is most useful for coverage rate prediction for infants, adult high risk groups, and the >65 group. However, there are some inadequacies in what MIMS data can describe in the Health Care Worker category and this literature was utilized to support the decision to plan for 50% coverage in HCWs in the 2005 model.

MIMS is able to capture Health Care Worker coverage when the person entering the data describes them as such. This revealed 19,199 doses administered to HCWs in 2003 and 20,270 doses in 2004. When physicians immunize and bill for immunization,

the data automatically transfers into MIMS but not the risk group. Therefore, it is not possible to distinguish physician delivered immunization to HCWs. Further research is required to determine the denominator in this population.

2.4 Unaccounted

Unaccounted vaccine is that which is known to be shipped to the immunization providers, but not recorded in MIMS as a dose administered. To a degree, it represents vaccine that has been purchased but not utilized; a waste of resources. Rates are affected by the number of doses in a vial, the size of the immunization session, cold chain failures, and the number of vials discarded due to expiry (WHO, 2002). The WHO guidelines (2002) suggest calculating the wastage factor (f) as follows: $f = (b + c - d) \times e/n$

Where b = number of usable vials in stock at start of year

c = number of vials issued from store for use during year

d = number of usable vials in stock at end of year

e = number of doses per vial

n = number of doses administered.

The wastage factor is then converted to a percentage wastage rate, W, as follows:

$$W = 100 - (100/f)$$
.

This literature is applied to Manitoba data in the Results section.

The Manitoba Interlake study from 1996 indicated that there were 7,260 doses of vaccine distributed to the region. Of these 5,643 (77%) were recorded as given. Thus, there were 1,617 doses (23%) that were distributed but not accounted for (Macdonald et al, 1996). McRobert (1998) reported in a BC study that the cost of wasted vaccine comprised 3.3% of their annual provincial vaccine budget. The WHO (2003) estimates as

high as 50% wastage in developing countries. An Indonesian study reported 36% wastage with home delivery of heat stable Hepatitis B vaccine (Sutanto, Suarnawa, Nelson, Stewart, & Indijati Soewarso, 1999). An Egyptian study of house-to-house oral polio campaigns reported up to 41% wastage (Linkins, Mansour, Wassif, Hassan, & Patriarca, 1993). A CDC Atlanta study showed wastage rates from 1 to 5% upon polling 64 public-sector state and local health department immunization programs (Setia, Mainzer, Washington, Coil, Snyder, & Weniger, 2002). Moore et al. (2003), reporting on their modeling of the costs and effects of a universal infant immunization program using conjugated pneumococcal vaccine at the BCCDC, state that there was an assumption of 5% vaccine wastage.

In summary, large variations in wastage (3.3 – 50%) are discussed in the literature. Wastage is likely to be less common in a developed country like Canada with reliable electrical power and highly qualified immunization providers, but the literature from the developing countries still has some value to this project. Again, the best predictor of wastage in 2005 is probably wastage in 2004 since there were few extenuating circumstances in 2004 that would have caused excessive wastage of vaccine. Year end MIMS actual data is reported in the Results section and used in conjunction with the literature described above to inform the 2005 model

2.5 Summary

There was significant information found in published literature to inform an accurate influenza program planning model for 2005. The framework utilizing an excel spreadsheet and the WHO formulae is supported by the literature as appropriate. The key variables should include cost of vaccine, payments to RHAs and doctors for

administration and supplies, and promotion. Immunization coverage predictions in HCWs in the 2005 model were informed by the literature. Large volumes of unaccounted for vaccine were found to be common world-wide, and must be planned for.

3. Methodology

3.1 Introduction

This project used a data gathering/analysis approach to review the 2004 influenza immunization model against year end data and made recommendations for an improved 2005 model. The project took place in the Manitoba Health Communicable Disease Control Unit (CDC Unit) over the spring of 2005. This chapter will outline the steps taken in project planning, data collection, data analysis, and application of findings to the new model. Issues regarding validity and ethics are also addressed.

3.2 Project Design

This project reviewed the 2004 model for accuracy against the literature, actual year end data, and in-house information. During the practicum, from April until June, 2005, the investigator functioned as a policy analyst/immunization specialist. Throughout the experience, the investigator worked in partnership with CDC Unit staff to retrieve 2004 immunization data from MIMS, analyze it, validate it and use it to fund the RHAs. The investigator used this year-end MIMS coverage data for this project so that this review could occur easily in subsequent years and would not require a special data cut. The design permitted access to in-house data and systems, participation in overall planning, and continual evaluation and feedback from CDC Unit staff. This allowed for the development of processes and creation of capacity within the CDC unit to apply this model and its evaluation to other immunization programs. This arrangement increased the likelihood of the success of the project due to the staff rapport and relationships of mutual trust and respect. This project was defined as useful and important by the team, with applicability for future accurate planning and evaluation of immunization programs.

3.3 Setting

The CDC Unit of Manitoba Health is responsible for the control of communicable diseases through surveillance, immunization, and provincial guideline development. Staff manage a large vaccine budget and procure and supply publicly funded vaccine for all of Manitoba's RHAs, immunizing doctors, and FNIHB staff. The Unit is complemented with a manager, four immunization specialists, a medical advisor, and an epidemiologist. It is directed by the Public Health Branch and works with the Finance department and Decision Support Services. The department is also supported by 3 administrative support staff, two students, and three surveillance clerks.

3.4 Project Planning

Site Access.

Negotiations for site access began more than a year before the start date of the project. A letter requesting access was sent to the Manager of the CDC Unit at Manitoba Health. (Appendix E). A four page proposal outlining the rationale for the project, the objectives, and methodology was developed and submitted to Manitoba Health for approval (Appendix F). The proposal was reviewed and approved by the Manager of the CDC Unit.

An Advisory Committee was established in the Unit to oversee the project.

Committee members included: a Communicable Disease Specialist, an Immunization

Specialist, an Immunization Program Consultant, finance staff, decision support staff, and the CDC Unit manager, medical advisor, and the Director of Public Health. This committee met with the investigator during the project planning phase and regularly throughout the project to review any problems and to monitor the student's performance.

The team was informed of the investigator's role and questions were addressed. Team members reviewed the report and provided feedback and assistance.

Role Preparation.

For six months prior to the start of the project, the investigator reviewed the background to the problem, narrowed down the problem statement and reviewed the relevant literature. Aligning with Stimpson's (1992) role descriptions the investigator functioned as a policy analyst, utilizing analytic and communication skills, backed by health expertise, to look at health care as it occurs both within and without traditional care-providing institutions. Nurse analytical skills were used to identify related factors and forecast future outcomes in order to provide information to decisions makers. *Data Access*.

Publishable 2004 MIMS immunization coverage data was accessed via the CDC Unit usual processes. The standard annual request data was used for this project for ease of comparability in future years. The age breakdowns for the coverage data was redefined to provide results for Manitobans age 0-2, 3-17, 18-65, and > 65. These were designed to best align with the target group age breakdowns and comply with national standards. Special data request documentation was unnecessary. The project did not require approval by the Health Information Privacy Committee (HIPC) since it investigated aggregate data only and not individual health records.

3.5 Research Methodology

This project incorporated a summative evaluation approach to create recommendations for future programming. The 2004 model was evaluated for design and accuracy of the major variables. These data were then utilized to predict the 2005 model

more accurately. The investigator reviewed the MHIIPM2004 against the available, actual year-end data. The design allowed for access to in-house systems, participating in overall program planning and evaluation.

The project methodology included a literature search, a search for existing inhouse data, and a review of actual, year-end results. In order to validate the 2004 model, the researcher determined the amount of vaccine purchased by reviewing financial statements and invoices, the amount shipped to the immunization providers by reviewing shipping reports from the Provincial Vaccine Warehouse, and the funding provided to the RHAs for influenza vaccine administration. A "harvest" of unused vaccine was undertaken to inform the analysis of vaccine not entered in MIMS. A letter was sent to all the immunization providers in the province requesting them to return their unused vaccine to the warehouse.

An analysis was undertaken to review existing data about quantities of vaccine shipped from the biologics warehouse to immunization providers. Shipping reports were reviewed in order to quantify doses shipped to the field versus doses administered and entered in MIMS. The 2004 year-end MIMS coverage data were compared with the predicted coverage values in the 2004 model. The data from the <65 columns in the model were aggregated and compared with MIMS data. Actual year-end funding data were compared with the predicted funding values in the model. The Insured Benefits Branch was approached for the data regarding payments to doctors for influenza immunization. This helped to validate the MIMS data, as well.

Concurrently, a review was undertaken of in-house documentation to uncover useful electronic or paper information relevant to this project. Like many health care

environments, staff turnover can dilute the corporate memory of Manitoba Health.

Electronic and paper files spanning the last eight years were reviewed and useful documentation was summarized in *Results*. These data are presented as three spreadsheets so that actual data and predicted data align and can be compared at a glance.

3.6 Data Collection

The literature was reviewed on an on going basis and inserted in the review section using the presented framework. MIMS data were used to compare the predicted values with the actual, year end coverage information. In house financial data were reviewed and inserted in the actual 2004 model and used to predict 2005 values.

Decisions were made with the CDC Unit manager regarding sharing in house financial data. In house planning data were utilized to update the 2004 model.

3.7 Data Analysis

MIMS coverage data were obtained, reviewed and validated. They were inserted in the 2004 actual model and the 2005 model wherever appropriate. The literature data were inserted in the models and referenced. The actual funding of the RHAs and the doctors was used to validate the model. Predicted variables were studied in relation to actual data and revisions made, as appropriate.

3.8 Ethical Considerations

This project was described verbally to the Unit Manager in September 2004 and approved in principle. It was important to respect the confidentiality of the negotiated prices of the vaccines with the vaccine manufacturers. As a result, the price was presented as \$10.00 per dose which represents an inflated price. The CDC Unit Epidemiologist deemed it unnecessary to seek approval from the Health Information

Privacy Committee since no personal health data was used. The data were publishable aggregate MIMS data, in-house financial data, and the published Manitoba Health Population Report. Prior to and during the project implementation, meetings were held with the staff of the CDC Unit to inform them of the purpose and methodology of this practicum project. Staff was informed of the investigator's role and questions were addressed. A letter was sent to the Ethics review committee at the University of Manitoba describing the project and the methodology (see Appendix G). Comments were returned that since the project was using aggregate, public data there was no need for a full ethical review (see Appendix H). Two sets of three planning model spreadsheets were created to present the results; the public set used the arbitrary price of \$10.00 per dose of vaccine, the in-house set used the actual prices. Each set included the 2004 planning model, the 2004 year end actual model, and the 2005 model. A brief, confidential, in-house report was submitted to the CDC Unit.

3.9 Limitations

The Manitoba Immunization Monitoring System has limitations in terms of data entry. "Immunization records are derived from physician billing claims and from manual entry of public health provided immunizations" (Manitoba Health, 2003, p.1) Not all Manitoba immunizers have access to MIMS or the resources to enter data so there may be more influenza vaccine administered than is captured in the database.

There are limitations with the First Nations Inuit Health Branch (FNIHB) data. This population represents about 7% of the Provincial population (Manitoba Health Population Report, 2003). The FNIHB versus non-FNIHB population differentiation relies on the entry of an identifying code which FNIHB estimates about 64% of their

population self-identify at the time of their enrollment for Manitoba Health benefits. This coding issue is not especially critical to this project since we are looking at aggregate data for the entire province. It does become relevant, however, when we differentiate between the payments made for administration costs since Manitoba Health funds the Regional Health Authorities to deliver influenza vaccine (\$7.00) and the doctors (\$6.00) but not the FNIHB nurses delivering vaccines on reserves. They use the provincial supply of vaccine but are not funded to administer it.

Additionally, Provincial audits indicate there are gaps between immunizations administered to FNIHB clients and documented on paper records and those data entered into MIMS. This may be related to difficulties with access to MIMS terminals, lack of training, or lack of staff time for data entry. As with the rest of the province, coverage rates may be higher than those generated from MIMS data.

The coverage rates by age have some limitations that become important when analyzing the coverage for a new program such as this. MIMS reports children as age 2 until the day before they turn 3. The MIMS report entitled Influenza/Pneumococcal Immunization Coverage report by First Nations Status January 1 – December 31, 2004 refers to all children 0-2 years old. This refers to children age 6 months to one day less than 3 years old, so more accurately, represents $2\frac{1}{2}$ cohorts of infants. This explains the population denominator at 34,028, when the birth cohort is 14,009, since $2\frac{1}{2}$ times the cohort equals the denominator. However, only the children age 6-23 months were eligible for public health provided influenza vaccine. The reported coverage rate of 40.3% is therefore likely higher.

MIMS data is only as valid as the entries. The CDC unit has conducted audits of MIMS over the last few years and found that if a person immunized and charted the vaccine and entered it in MIMS, there was reliable data found in MIMS. However, if someone immunizes and does not bill for it or enter it in MIMS, this does not get captured. This may happen in some settings. Immunizers are instructed to complete an Influenza Immunization Surveillance form and send it to their local health authority for data entry but it is unknown at this time how well this happens. Immunization coverage data can be partially validated by Statistics Canada's National Population Health Survey influenza data which indicates that "almost two thirds of Canadian seniors have been immunized against the flu" (2001, p.1). Similarly, Manitoba Health's Comparable Health Indicators report (2004) states that for indicator 69-HLT, 56% of the >65 population received an influenza immunization within 2003. This is lower than the reported MIMS rate of 68% for 2003, likely due to research methodology.

Validity of shipping data from the Vaccine Warehouse has not been formally assessed in this project. However, they adhere to the national standard operating procedures and offer state-of-the-art inventory management systems including detailed reports. The investigator received detailed monthly vaccine distribution reports and reviewed them for face validity.

The Finance department information included the actual values spent on vaccine and were validated by reviewing the invoices for the product and confirming them against the packing slips for vaccine received at the warehouse. The actual year-end funding provided to the RHAs for vaccine administration was validated by comparing the

MIMS data cut with information provided by the RHAs regarding the number of doses given. They were found to be within 2% overall.

An attempt was made to validate the amount of funding provided to the physicians by Manitoba Health. The 2004 actual model reports a calculation rather than an actual value. The investigation is in progress.

3.10 Summary

This project examined the literature, existing in-house data, and actual year end values to improve the influenza planning model for 2005. The participant/observer methodology allowed for a summative analysis and evaluation of year end data. The design permitted the researcher to be able to access key, relevant information. There are limitations to the ability of the CDC unit to monitor influenza immunization but this project contributes to the evidence.

4. Results

There were a number of ways the 2004 planning model was improved. This chapter describes the results of the analysis regarding the framework of the model and key variables with special emphasis on coverage and wastage. The proportion administered by doctors or Public Health Nurses, administration costs, formatting and wording are also presented. The literature review provided helpful information which was summarized previously. The search for relevant in-house documentation revealed helpful information described below. The results are primarily presented in the Appendices I and J as Excel spreadsheets indicating actual 2004 results and the projections for 2005.

4.1 In-house relevant documentation

The review of relevant in-house documentation revealed important and useful tools for improving the 2004 planning model. The first outlined Manitoba's portion of a project wherein Thomas, Stephens, and Associates were commissioned to investigate the size of the NACI influenza groups across Canada. Their investigations determined that, in 1999, Manitoba Groups size totaled 637,600 as outlined in Appendix K. These data, calculated in-house in 1998, were used to validate the 2005 model. With identified assumptions, the total number of Manitobans in the high risk categories worked out to 637,600 people in the 1998 calculation and 599,950 in the 2005 model. This represents an acceptable 6% difference.

The second useful file described Manitoba's 2001 calculations regarding estimated populations of selected target groups, coverage assumptions, a wastage factor and the total number of doses of vaccine required. It validates the design, a portion of the key variables included in the planning model, and the concept of a wastage factor. The

calculations are available in Appendix L and lend validity to the predicted population of the HCW target group. The in-house file from the CDC unit calculation of 2001 identifies 13,702 HCWs in Manitoba. This project doubled the 2004 HCW population of the Winnipeg Regional Health Authority (11,936). The 2005 model used this information to predict a HCW population of 23,872.

Lastly, an important National Immunization Strategy document from October 2002, *Immunization Program Options for New Candidate Vaccines: Varicella, Conjugate pneumococcal, Conjugate meningococcal, Acellular pertussis* was located at the CDC Unit that outlined the underlying assumptions used for the economic analysis of those programs. It discussed vaccine wastage rates of 5 – 25% which is described further in section 4.6.

With staff turnover, useful in-house planning documents can become difficult to track. This project reviewed old files and found information that was used in the 2005 model to validate the total number of people in the target group as close to 599,950, predict the HCW population at 23,872, and the wastage between 5 and 25%.

4.2 Framework of the Model

The framework was determined to be valid to provide the CDC unit staff with the key information that needed to be tracked on a year-to-year basis to best inform program planning. The Excel spreadsheet was brief and concise and allowed for instant updating. Consideration was given to inserting additional lines in the 2005 model layout to include influenza prorated centralized immunization specialist costs, regional co-ordination costs, and storage and distribution costs. It could be estimated that 1.0 FTE of the CDC Unit staff is dedicated to the influenza immunization program. This work load shifts

throughout the year and across staff members but likely works out to 1.0 FTE. The CDC Unit also funds the Regional Health Authorities for 12.9 FTE per year for immunization staff. It would be difficult to determine the proportion of that directly related to influenza vaccine. Of the funding the CDC Unit provides to the RHAs for vaccine administration, 50% is for influenza. This excludes major immunization programs that the CDC unit does not fund on a "per dose administered and entered in MIMS basis" such as Pentacel®, Quadracel®, and MMR. It would also be influenced by the differing rates of reimbursement for different vaccines i.e. Adacel is at \$3.75 per dose and Hepatitis B is at \$12.00. Of the total CDC Unit vaccine budget, influenza represents 14%. If that figure is used, the influenza portion of the RHA immunization staff payment could be calculated on an annual basis and inserted in the model.

Influenza is not an expensive vaccine but involves large volumes which are significant for the storage and distribution budget. This cost could also be calculated using the above 14% and inserted in the model. This additional detail might be inserted into a future planning model after being reviewed and validated by the CDC Unit staff in partnership with the Finance Department of Manitoba Health. The values are estimates only for consideration. The actual value is less important than the framework for variables to consider in planning.

A simple change in the 2005 model framework was to total the segments horizontally as well as vertically. With this simple change, important information such as the total population of the target groups, total doses required, total vaccine costs, and total administration costs was more readily available.

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4.3 Key Variables

Although the literature described additional variables including surgical supplies, clerical support, surveillance, and evaluation, the 2005 model provides the CDC unit with the key variables it needs to track and plan for. The CDC Unit funds the RHA a flat rate of \$7.00 per dose that is intended to augment their costs for staff time, surgical supplies, and clerical support to deliver the program. Influenza surveillance is extensive in Manitoba and is carried out in partnership with the Public Health Agency of Canada through the national Fluwatch program. This provincial influenza surveillance program is funded as part of the overall CDC Unit budget and is not accounted for in this model. Similarly, evaluation is a core function of the CDC Unit and funded as part of the overall operating budget of the unit and does not need to be itemized in this model.

4.4 Population of the risk groups

The size of the population of some of the risk groups is incremental from the size of the birth cohort. The Manitoba Health Population Report 2004 indicates there were 14,009 one year olds in 2004 (Manitoba Health, 2004b). This number was utilized in the new model and referenced. This includes all First Nations children and indicates a decline in the number of births per year in Manitoba. The size of the infant target group represents a cohort and a half since the universal influenza vaccine was offered to children aged 6-23 months. This calculation is reflected in the Excel formula as $14,009 \times 1.5 = 21,013$. Siblings were assumed to be at least one for every child aged 0-23 months (double the cohort x one). Each child was assumed to have two parents (double the cohort times two). Each child was assumed to have one child care provider. Assumptions on the 2005 are indicated with underlining as per the legend. For the

purposes of planning this program, the infants aged six to 23 months were assumed to have two parents, one sibling, and one caregiver each.

To calculate the number of pregnant women in their third trimester and expected to deliver during influenza season:

 $P = \{ \text{Birth cohort} \div 3 \text{ (for third trimester)} \} \div (6/12) \text{ (for influenza season)}$ Where P = pregnant women needing influenza vaccine

Birth cohort = number of babies expected to be born that year

Third trimester = the last three months of pregnancy

Influenza season = October 1 - March 31 or 6 months

Health Care worker population was calculated as twice the number of the WRHA employed workers or $11,936 \times 2 = 23,872$. Since half the population of Manitoba lives in Winnipeg, half in rural areas, it follows logically that the WRHA HCW population doubled could be a good guideline for the number in the entire province. It is recognized there is more tertiary care in Winnipeg, but this is seen to be balanced for the core staffing required for rural populations. This is likely a low estimate; more research is required in this area. Also, HCWs can be loosely defined. There are likely many more HCWs who do not work for a health authority but would be immunized as a HCW.

Household contacts of seniors who are not over 65 themselves will be arbitrarily assumed to be 33% of the seniors' cohort. Caregivers of seniors (who are not HCWs or seniors themselves) will be assumed to be one each, similar to the proportions for infants.

To calculate the number of high risk people in the under 65 population the population of this group from the Manitoba Health Population Report was used less the sum of the previous target groups. The population is 1,010,991 minus the total number of

people under 65 who are high risk for influenza or are close contacts. To calculate these, the sum of the following is subtracted:

Infants 6 – 23 months	21,014
Siblings of infants 0 - 23 months	28,018
Parents of infants 0 – 23 months	56,036
Caregivers of infants 0 – 23 months	28,018
Pregnant women in third trimester	2,335
Health Care Workers	23,872
Caregivers of seniors	158,676
Household contacts of seniors	52,892
Total:	370,861

Table 5: Estimated populations of target groups

The size of the group of high risk for influenza Manitobans < 65 not yet addressed is 1,010,991, less the 370,861 discussed above or 633,507 people. Manitoba Health calculates the high risk population as 11% of the general population less than age 65, or 11% of 633,507 = 69,685. Summing these values, we determine there are 441,275 Manitobans under 65 who are likely eligible for free vaccine. Additionally, all Manitobans age 65 or over (158,676) are deemed to be high risk. Thus, the total number of Manitobans identified as high risk and eligible for Public Health influenza vaccine is 599,951 or 51% of the total population. These values are inserted in the 2005 model.

In total, the model informs us there are 599,950 Manitobans in the target groups, or 51% of the total population. This is partially validated by in house calculations from 2001 (see Appendix K) which total 637,600 people.

4.5 Coverage

The 2004 MIMS coverage data includes information about influenza immunization delivered between January 1 and December 31, 2004. This data was "cut" April 1, 2005 thus allowing for 3 months of data entry to occur regarding service dates prior to December 31, 2004. That is, if an immunization provider administered an

influenza vaccine on December 31, 2004 and either billed the Insured Benefits Branch or entered it in MIMS directly before March 31, 2005, it would appear in this data run. This data excluded influenza immunization provided between January 1 and May 31, 2005. These dates are still within the 2004-2005 season, vaccine was still recommended, and would have been effective but only 30 doses were shipped to the field at that time, so it is likely that little vaccine was actually given. The decision was made to use the coverage cut to allow for easy reproducibility of this analysis next year.

The data indicate the following:

Age	0 - 2	3 - 17	18 - 64	<65 high	All <65	65+	Total
group	years	years	years	risk*		years	
Flu doses given 2003	n/a	n/a	n/a	17,289	91,163	105,806	196,969
Population				110,297	1,003,219	156,565	1,159,784
Coverage rate				15.7%	9%	68%	17%
Flu doses given 2004	13,729	15,880	96,159	20,507	125,768	103,542	229,310
Population	34,028	242,598	729,398	110,670	1,006,024	163,643	1,169,667
Coverage rate	40%	7%	13.2%	18.5%	13%	63%	20%
Change in coverage				+ 3%	+ 4%	- 5%	+ 3%

Figure 6: MIMS 2004 coverage data

*defined as 11%

A significant finding of this review is that 40% of the children aged 0-2 were immunized. It is possible that this value is actually closer to 67% since MIMS defines a two year old as aged two until the day before they turn three. Thus, when MIMS refers to children aged 0-2, it actually refers to children aged birth to one day less than age three, or three birth cohorts. As well, when MIMS draws it population data on June 1 and reports on immunization as of December 31, it may be dropping half of a cohort. This

could explain the population reported by MIMS as 34, 028 which looks like 2 ½ cohorts. Lastly, if we assume very few children aged 24 – 36 months were immunized, it is possible that the number of infants aged 6 – 23 months immunized against influenza was closer to 67%. The CDC unit expected 20% coverage of this group in 2004. To predict for 2005 it would be expected that this would likely increase to 80% since, coverage typically increases in the second year of a new program. It would be unlikely to exceed 86%, which is the coverage rate for two year olds with one dose of measles – a good proxy. The 2005 model will use 80% as the expected coverage rate for infants and plan for a purchase of that volume of vaccine.

4.6 Unaccounted for:

The literature review described the WHO guidelines (2002) for calculating the wastage factor (f). The wastage factor is then converted to a percentage wastage rate, W, as follows:

$$W = 100 - (100/f)$$
.

Applying this to Manitoba data f=318,930/229,310 or 1.39. This is converted to a percentage wastage factor, W, as 100-100/1.39=28%. The predicted volume of unaccounted for vaccine must increase to 28% to explain the difference between the 318,930 doses of vaccine shipped to immunization providers in the 2004/05 season and the 229,310 doses entered in MIMS.

The WHO (2002) Guidelines also discuss a reserve stock of 25% for new programs. This literature has relevance to this project since the influenza immunization program is like a new program being introduced every year. There is no year-to-year

carry-over of vaccine; it expires after 8-10 months, depending on the lot number, and demand drops off after Christmas. New doses must be given every year.

The literature described wastage rates of 3 – 50%. The Canadian National Immunization Strategy document employed a wastage rate of 5% but referred the reader to the GAVI standard. "The country would aim for a maximum wastage rate of 25% for the first year with a plan to gradually reduce it to 15% by the third year. For vaccine in single or two-dose vials the maximum wastage allowance is 5%" (p.13). Most of the influenza vaccine for 2005 will be supplied as a multi-dose vial which can lead to increased wastage. The 04/05 harvest of unused vaccine resulted in 20,039 doses (9%) being returned to the vaccine warehouse. It is estimated that reported cold chain breaks might account for about 800 doses of influenza vaccine per year.

The 2005 model was most informed by actual unaccounted vaccine at 28% from 2004, supported by the literature as to be expected. This validates the fact that this volume of unaccounted for vaccine is less likely to be data entry gaps. It will be divided as 10% unaccounted for and 18% reserve stock, arbitrarily. These could be summed and considered together but keeping them independent establishes a useful framework for their analysis and for planning other vaccine programs that have a decreasing need for reserve stock.

4.7 Price per dose

The price of the vaccine varies between \$4 - 24 per dose in the literature (Weycker et al., 2004; White, Lavoie, & Nettleman, 1999; Cohen & Nettleman, 2000). This project arbitrarily chose \$10.00 per dose in order to respect the confidentiality of the Vaccine Supply Working Group's negotiated contracts through PWSC with the vaccine

manufacturers. The 2004 price was thought to be established during the planning phase of this project but increased twice during the season due to the cost of clinical trials and extra demand for vaccine. Small clinical trials were required by the Biologics and General Therapeutics Directorate (BGTD) as a licensing requirement. Since influenza vaccine is grown anew every year, the process is licensed rather than the vaccine itself. This necessitated small clinical trials once the vaccine was produced and the manufacturers passed on the costs of these to PWSC as a price increase part way through the 04/05 season.

The price was also established for the amount of vaccine for which the provinces had contracted. When the provinces determined that they wished to purchase more vaccine late in the season, as demand peaked due to problems with the US supply and media interest, the manufacturer released new uncommitted vaccine and made it available to the provinces, but at an increased price. The 2005 price will be calculated once final purchases are committed. This project will use \$10.00 per dose.

4.8 Proportion Administered by Doctors versus PHNs

In 2004, doctors administered 123,596 of the total 229,310 doses and PHNs delivered 66,867 doses. These proportions represent 54% and 29%, respectively. In 2003, the proportions were 53% and 29%. The 2005 model, informed by these actual values, will use these percentages to determine the proportions delivered by doctors and PHNs instead of the 70% and 30% in the 2004 model. This will correct the underestimation of the vaccine administration costs in 2004.

These values will not total 100%; the remaining 2.5% are provided by FNIHB staff and 14% by "other" providers. Since Manitoba Health does not fund the

administration of vaccine provided by these groups, they do not need to be reflected in the 2005 model.

4.10 Summary

The major results of the review of the 2004 model are described above and incorporated in the appended 2005 model (Appendix J). This table summarizes the most significant results:

Major	2004	2004	variance	2005	Comments
Differences	planned	"actual"		proposed	
Compliance	.20	.40	100% low	.80	New target group
infants					success
Total doses	181,719	320,500	43% low	371,248	More accurate
required					model
Wastage	10%	28%	60% low	28%	WHO, GAVI,
					actual data
Doctors'	\$763,219	\$742,964	3% low	\$917,424	Overall
costs					underestimated
RHA costs	\$381,609	\$563,913	32% low	\$581,360	As above
Overall	\$3,243,736	\$4,603,133	40% low	\$4,721,941	As above

Figure 6: results summary

Key findings include the 40% coverage rate in infants, the proportion of vaccines provided by PHNs versus immunizing physicians, and the significant amount of unaccounted for vaccine. The 2005 model called for 189,658 more doses than the 2004 model.

5. Discussion

Immunization specialists will continue to be required to plan programs within an environment of uncertainty. Unknowns will remain, but efforts can be made to minimize them. Analyses such as the one undertaken by this project will contribute to evidence for program planning but it will always be difficult to accurately predict all the variables.

The actual values are important, but the framework for which variables and how to consider them is important, too.

A significant amount of uncertainty remains in the cost-effectiveness and cost-benefit analyses in the literature because of the wide range of assumptions and variables. Jefferson and Demicheli (2002) commented that "published economic evaluations of influenza vaccination are not of great help" (p.255) owing to the variability of assumptions of the likely incidence and effectiveness of the vaccines underlying the models and the variability of compliance of the population in accepting the vaccine. They recognize the complexity of the decision to undertake an immunization program and, in particular, feel spending resources on vaccinations of healthy adults remains "somewhat of a gamble" (p.248). Notwithstanding this discussion, the case for immunization of high risk groups has already been made in Manitoba.

Some of the changes to the model because of this review are logical because of the increase in volumes. The unaccounted for vaccine is important. It begs the question of whether that will happen every year, even though it was consistent for 2003 and 2004. What could have increased wastage in those years that makes the 28% invalid for 2005? The 2003 influenza season was early (see Figure 1) and demand for vaccine was high. A MIMS-generated reminder letter was sent to all Manitobans aged 63 and over regarding their pneumococcal immunization. It encouraged them to get their "pneumo" shot at the same time as their "flu" shot and likely effected an increase in influenza immunization in the fall of 2003. In the fall of 2004, there was a problem with the US supply of influenza vaccine that was described in the media and this increased demand in Manitoba. In response, the CDC unit participated in the national plan and prioritized the eligibility

criteria for one month. This allowed for the high risk people to be immunized before their close contacts but may have left some missed opportunities for immunization. It is possible that the 2005 season will bring even greater demand for vaccine as a result.

Some recommendations for future analysis include:

- Surveying the RHAs, the colleges, and the workforce planning department of
 Manitoba Health to determine the number of HCWs more accurately.
- Surveying the associations of childcare providers to determine their numbers more accurately.
- Investigating Manitoba population and demographic data to validate the
 assumptions about the number of household contacts and child care providers the
 infants and seniors actually have.
- Reviewing the adverse event data on influenza vaccines to determine a per dose cost.
- Reviewing the cold chain breaks involving influenza vaccine to quantify that more accurately.
- Investigation of storage and distribution of vaccines to determine the portion that could be allocated to the flu program. I.e. The number of flu shipments in relation to the number of total shipments to be apportioned to the costs of the program.

In terms of unaccounted for vaccine, there are many actions currently being undertaken to improve data entry into MIMS. Training of data entry staff is ongoing.

Most immunization providers' funding is tied to their entry of the data in MIMS. Efforts are underway to establish MIMS terminals in hospitals and other sites where

immunization is being administered and data is not being directly entered into MIMS. Per dose funding includes \$0.15 for data entry only, if applicable.

In the upcoming influenza season, strict shipping guidelines will be in place.

Vaccine will not be shipped on demand to immunization providers. In 2004, consumer demand spiked, influenced by the media advising of supply issues and the scare of a pandemic. Intense demand is likely in early October and strict shipping guidelines will assist with supply management.

Steps are being taken to ensure immunizers are receiving the types of information, training and education they need to provide quality immunization programs.

Certification of immunizers may assist in ensuring they are aware of and adhere to eligibility criteria and shipping guidelines.

Inventory management systems are being reviewed to improve vaccine supply management. Currently, immunizers order one months' supply of vaccine at a time.

New systems could provide for "just in time" delivery to many sites, permitting less reserve stock to be kept on hand and potentially wasted. Systems for maintaining corporate memory are continually being improved at Manitoba Health and this project highlights the importance them.

6. Conclusion

This project reviewed the predicted values in the Manitoba Health influenza immunization program planning model for 2004 in relation to relevant literature and actual, year-end data. In-house documentation was systematically searched and useful information was retrieved. The goal was to develop a new model for 2005 that was more evidence based and, therefore, more accurate. The public version of the 2005 model is attached as Appendix J and utilizes an arbitrary price of \$10.00 per dose of vaccine. It was necessary to create an arbitrary public version of the model in order to respect the confidentiality of the negotiated prices of the vaccines.

Both the BCCDC and the WHO planning frameworks served to validate the overall design of the 2004 model. The two frameworks are integrated by incorporating the formulae from the WHO into the spreadsheet in the 2005 model. The literature on cost-effectiveness and cost-benefit of influenza immunization was reviewed to determine typical costs that might be included in the 2005 model. A variety of possibilities were considered including cost of side effects, and loss of productivity. The main variables were not changed as a result of the review, but maintained at population, coverage, wastage, and vaccine administration costs.

In total, the model informs us there are 599,950 Manitobans in the eligible target groups for public health influenza vaccine or 51% of the general population. The literature review regarding immunization coverage informed the decision to plan for 50% coverage for HCWs in 2005. The program total cost increased significantly and a more likely volume of vaccine was called for.

The 2005 model could be further improved as actual year end data becomes available in the literature regarding coverage of pregnant women, especially from CDC Atlanta.

Planning for 2005 will include a reserve stock (18%) and wastage (10%). The volume of unaccounted for vaccine is a key finding of this project. Manitoba shipped 318,500 doses to the immunization providers and 229,310 were documented in MIMS as administered. What has national significance is that Manitoba funds its immunization providers on a "per dose administered and entered in MIMS" basis. Therefore, excellent data entry is expected since it is tied to funding. Even within the context of this funding system, there was a significant proportion of unaccounted for vaccine. Recommendations were described to decrease this, such as more restrictive ordering procedures and shipping guidelines. Further analysis is recommended.

A significant finding of this review is that at least 40% of the children aged 0-2 were immunized against influenza in the inaugural year of their eligibility for public health provided vaccine. It is expected this will increase to 80% in 2005. The CDC unit expected 20% coverage of this group in 2004 since it was the first year of the program and the immunization providers were initiating pneumococcal conjugate, varicella and meningococcal C conjugate programs concurrently. The success of this implementation speaks to the capacity of Manitoba's public health system to implement new immunization programs, given the appropriate time and resources, including policy support, to plan. This may have important relevance if an influenza pandemic appears or another unforeseen public health emergency.

This project assisted in the development of processes and creation of capacity within the CDC unit to apply this model and its evaluation to other immunization programs. The project helped CDC unit staff to work as a team and understand their programs better and will assist in moving forward with the national immunization agenda. The findings will assist other influenza program planners in other provinces and territories to plan for at least 40% coverage of infants and to plan for 28% unaccounted for vaccine. The findings of this project will have applicability with the implementation of other vaccines and in other national jurisdictions. This process and the framework for the models have now been established and can be utilized in the future with other programs.

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8. Appendices

Appendix A: Definition of Terms

Administration The actual injecting of the vaccine by the provider into the

client, funded \$6-7 dollars per dose.

Coverage The percentage of the target group immunized or "covered" by

the vaccine.

Funding model The Excel spreadsheet designed by CDC Unit staff to plan the

influenza immunization program and its total costs.

Population risk group The number of people in the group targeted to receive the

vaccine.

Price per dose The price Manitoba Health will pay for the vaccine.

Promotion/Health Links The value the CDC Unit will pay for print costs for

promotional materials, radio advertising costs, transit shelter

posters, newspaper advertising costs, and Health Links/Info

Santé support.

Proxy value When one number informs the choice of another number

because of the situational similarities of its use.

Reserve stock The vaccine held on hand by immunization providers and the

provincial warehouse in reserve for expected clients.

Sibling A brother or sister of an eligible child and assumed to be a

household contact.

Target groups The groups identified by the National Advisory Committee on

Immunization (NACI) and ratified by Manitoba Health as eligible for publicly-funded influenza vaccine

Unaccounted for

See wastage

Wastage

An assessment of the percentage of vaccine that will expire without being administered, be lost in a cold chain break or through mishandling, or somehow not be captured in MIMS as a dose administered

Appendix B: List of Acronyms

BCCDC British Columbia Centre for Disease Control

CDC Communicable Disease Control

CDMH Conference of Deputy Ministers of Health

CIC Canadian Immunization Committee

ER Emergency Room

FNIHB First Nations Inuit Health Branch

GAVI Global Alliance for Vaccines and Immunization

HCW Health Care Worker

HIPC Health Information Privacy Committee

MIMS Manitoba Immunization Monitoring System

NIS National Immunization Strategy

PCH Personal Care Home

PHAC Public Health Agency of Canada

PHIN Personal Health Information Number

PHN Public Health Nurse

RHA Regional Health Authority

WHO World Health Organization

WRHA Winnipeg Regional Health Authority

Appendix C: The 2004 Influenza Immunization Planning Model (public)

See attached Excel spread sheet

Manitoba Health - Public Health Branch Influenza Program for 2004/5

PUBLIC

Jun-04

Doses are given at 6 - 23 months between October 15 & March 31 Household contacts and caregivers of children 0 - 23 months and seniors pregnant women in 3rd tri if delivering October to March High risk due to chronic illness children and adults at 11% health care workers people 65 or over

		household	household	child care	pregnant	high risk	health care		household	caregivers	
Program Area	child	contacts	contact	providers	women	at 11%	workers	>64	contacts	of seniors	totals
<u>Vaccine</u>		1 sibling	2 parents						of seniors		
Population Risk Group	22,500	30,000	60,000	10,000	2,500	110,177	20,000	158,489	50,000	50,000	513,666
Compliance (%) (see note)	0.20	0.20	0.10	0.10	0.10	0.15	0.30	0.70	0.20	0.20	
No. of Doses	2	2	1	1	1	1	1	1	1	1	
Total Doses Required	9,000	12,000	6,000	1,000	250	16,527	6,000	110,942	10,000	10,000	181,719
Wastage (%)	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	
Cost (\$) per Dose - see note	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	
Total Vaccine Cost (\$)	99,000.00	132,000.00	66,000.00	11,000.00	2,750.00	181,792.05	66,000.00	1,220,365.30	110,000.00	110,000.00	
<u>Adminstration</u>											
Proportion Admin'd by Docs (%)	0.70	0.70	0.70	0.70	0.70	0.70	0.70	0.70	0.70	0.70	
Admin Cost (\$) per Dose	6.00	6.00	6.00	6.00	6.00	6.00	6.00	6.00	6.00	6.00	
Total Doc Admin Costs (\$)	37,800.00	50,400.00	25,200.00	4,200.00	1,050.00	69,411.51	25,200.00	465,957.66	42,000.00	42,000.00	\$ 763,219.17
Proportion Admin'd by PHN (%)	0.30	0.30	0.30	0.30	0.30	0.30	0.30	0.30	0.30	0.30	
Admin Cost (\$) per Dose	7.00	7.00	7.00	7.00	7.00	7.00	7.00	7.00	7.00	7.00	
Screening Costs (\$)	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
Total PHN Admin Costs (\$)	18,900.00	25,200.00	12,600.00	2,100.00	525.00	34,705.76	12,600.00	232,978.83	21,000.00	21,000.00	\$ 381,609.59
Promotion/Health Links		mm in a									
Promotion Costs (\$)	100,000.00				···						
Grand Total (\$)	255,700.00	207,600.00	103,800.00	17,300.00	4,325.00	285,909.32	103,800.00	1,919,301.79	173,000.00	173,000.00	
Total for Year (\$)	3,243,736.11										

note- Provinces and territories are under contractual agreement with the vaccine manufacturers to maintain the confidentiality of the cost per dose. This \$10 used is not the actual amount paid by Manitoba Health.

Appendix D: The 2004 Influenza Immunization program letter

September 7, 2004

Dear Immunization Provider:

RE: 2004-2004 INFLUENZA AND PNEUMOCOCCAL POLYSACCHARIDE IMMUNIZATION PROGRAMS

- Eligibility Criteria: New this year, children aged 6 23 months and their close contacts are eligible for publicly funded influenza vaccine. Previously unvaccinated children require two doses of the vaccine with an interval of at least 4 weeks. See Appendix A for eligibility criteria. Additional information is provided in the 2004 National Advisory Committee on Immunization (NACI) Statement on Influenza Vaccination available at: www.hc-sc.gc.ca/pphb-dgspsp/publicat/ccdr-rmtc/index.html. Copies of the statement may be ordered from the Materials Distribution Agency (MDA) warehouse using the enclosed order form.
- 2. Influenza Vaccine: Vaccine will be supplied by I.D. BioMedical (Shire Biologics) in a 4 ml vial that yields at least 10 adult doses of 0.4 ml each. See Appendix B for vaccine ordering information. The 2004-2004 vaccine contains: A/New Caledonia/20/99 (H1N1), A/Wyoming/3/2003 (H3N2) and B/Jiangsu/10/2003 virus antigens. Vaccines must be stored at 2°C to 8°C to maintain potency. Refrigerator temperature should be monitored daily. Please discard remaining influenza vaccine from the 2003-2004 season in a sharps container.
- 3. <u>Vaccine Administration</u>: Influenza vaccine administration can begin as soon as vaccine is received. A media launch is planned for mid-October 2004. The national goal for influenza immunization is to immunize at least 90% of the eligible recipients. Data from Manitoba Immunization Monitoring System (MIMS) indicate that 68% of Manitobans aged ≥64 were immunized against influenza in the 2003-2004 season.
- 4. Pneumococcal Polysaccharide 23 Vaccine (PPV23): A limited supply is available from the provincial vaccine warehouse. This vaccine should be prioritized for individuals most at risk of invasive pneumococcal disease. (See Appendix C). The healthy ≥64 year old population can be offered the vaccine once the provincial stock is replenished in early October. This year Manitoba Health will not send a "pneumococcal reminder letter" to eligible Manitobans. Data from MIMS indicate that 61% of Manitoba seniors are immunized.

- 5. <u>Print Resources</u>: Samples of influenza and pneumococcal immunization promotional items are enclosed. Additional copies are available from MDA.
- 6. <u>Informed consent</u>: Sample Fact Sheets are enclosed to assist with informed consent. Consent may be documented in the client's chart or on a 2004-2005 Influenza and Pneumococcal Surveillance Form, sample enclosed.
- 7. Immunizations in MIMS and Insured Benefits billing:
 - Physicians' billing data is transferred into MIMS automatically.
 - Regional Health Authority (RHA) immunization providers are requested to complete the 2004-2005 Influenza and Pneumococcal Surveillance Form for every dose administered and return it to their public health office by mid-December 2004 for entry into MIMS. This enables public health staff to monitor and evaluate regional immunization programs.
- 8. <u>Simultaneous administration with other vaccines</u>: It is recommended to administer all vaccine doses for which a child or adult is eligible at the time of each visit. When more than one vaccine is required, they should be administered at the same visit, at different anatomic sites in separate syringes.
- 9. <u>Vaccine Associated Adverse Events</u>: Health professionals are requested to report vaccine related adverse events by completing a *Report of a Vaccine Associated Adverse Event* form (sample enclosed) and forwarding it to their local Medical Officer of Health. This report is reviewed by the provincial Communicable Disease Control Unit and forwarded to Health Canada for entering into the national database.
- 10. Ocular Respiratory Syndrome (ORS) Information: Included with this mailing is information about ORS and influenza immunization. See Appendix F.

Appendices include:

- A: Eligibility Criteria for Publicly Funded Vaccine
- **B:** Vaccine Ordering Information
- C: Individuals most at risk of Invasive Pneumococcal Disease
- D: Physician Reimbursement and Tray fees
- E: Influenza Surveillance Program
- F: Ocular Respiratory Syndrome (ORS) Information

Further information is available at:

- Communicable Disease Control, Manitoba Health, Health Professionals protected Web Site: www.cdcinfo.mb.ca
- Communicable Disease Control, Public Health Branch, Manitoba Health

- For the general public: www.gov.mb.ca/health/publichealth/cdc
- NACI Recommendations for Use of Pneumococcal 23-valent Polysaccharide Vaccine During Shortage in the Canada Communicable Disease Report (CCDR) https://www.hc-sc.gc.ca/pphb-dgspsp/publicat/ccdr-rmtc/04vol30/acs-dcc-4/index.html
- Canadian Immunization Guide (2002) www.hc-sc.gc.ca/pphb-dgspsp/publicat/cig-gci/index.html
- Canadian Coalition for Immunization & Awareness and Promotion www.immunize.cpha.ca and www.influenza.cpha.ca
- Product inserts

Thank you for your attention and assistance. Sincerely,

Marilyn McIvor, B.N., B.Sc. Immunization Program Specialist Communicable Disease Control Unit

Persons recommended by Manitoba Health to receive Influenza vaccine and for whom vaccine is available at no cost: (New categories are in italics)

a) People at high risk

- Children aged 6 23 months
- Adults ≥ 65 years of age.
- Adults and children with chronic cardiac or pulmonary disorders (including bronchopulmonary dysplasia, cystic fibrosis and asthma) severe enough to require regular medical follow-up
- People of any age who are residents of personal care homes or other chronic care facilities.
- Adults and children with chronic conditions, such as diabetes mellitus and other
 metabolic diseases, cancer, immunodeficiency, immunosuppression (due to
 underlying disease and/or therapy), renal disease, anemia, hemoglobinopathy,
 inflammatory bowel disease, celiac disease, multiple sclerosis, rheumatoid arthritis,
 lupus, alcoholism, etc.
- Children and adolescents (age 6 months to 18 years) with conditions treated for long periods with acetylsalicylic acid.

b) People capable of transmitting influenza to those at high risk

- Household contacts of children < 6 months of age, (who are at high risk of complications from influenza but for whom there is currently no licensed vaccine)
- Household contacts of children 6 to 23 months whether or not they have been immunized.
- Pregnant women in their third trimester expected to deliver between October 1 and March 31.
- Those providing regular child care to children aged 0 to 23 months, whether in or out
 of the home.
- Health-care workers, volunteers and other personnel in settings where care is
 provided for those at high risk noted above. This would include employees in
 hospitals, physicians' offices, personal care homes, seniors' recreation centres, home
 care employees, and first responders (police officers, firefighters, ambulance
 workers).
- Household contacts of people at high risk of influenza complications including family, relatives or friends of persons in chronic care institutions who visit frequently.
- Household contacts of people 65 years of age and over.

Note: Recommended to receive influenza vaccine but Manitoba Health does not provide funded vaccine:

Persons in these groups must purchase the vaccine and pay for its administration themselves. Arrangements for vaccine acquisition can be made with local pharmacies. There is no mechanism for persons to buy vaccine from Manitoba Health.

- Providers of essential community services.
- Healthy persons aged 2 to 64 years of age; e.g. teachers and office workers.

Appendix E: Permission to Access Request Letter:

April 21, 2005

Ms Kathy Mestery, Manager Communicable Disease Control Unit Public Health Branch Manitoba Health 300 Carlton St. Winnipeg, Manitoba

Dear Ms. Mestery,

As we have discussed, I am writing to request access to the CDC Unit at Manitoba Health, for the purpose of conducting a practicum experience. This practicum will be undertaken in partial fulfillment of the requirements for the degree of Master of Nursing at the University of Manitoba. The proposed project will take place over two months commencing April 20, 2005. This project will be conducted in the manner outlined in the attached proposal.

Thank you very much for considering this request. If you have any questions, please feel free to contact me.

Sincerely,

Marilyn McIvor Provincial Immunization Specialist Manitoba Health

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Appendix F: Proposal to Manitoba Health:

April 21, 2005

A Review of Manitoba's 2004 Influenza Immunization Program Planning Model

Project Summary:

Between April 24 and June 20, 2005 the investigator will review the major variables of the Manitoba Health Influenza Immunization Program Planning 2004 (MHIIPP2004) model and create a revised model for the 2005 season. The predicted values in the 2004 model will be compared with: (a) actual in-house year end data; (b) data from relevant literature; and (c) publishable data from other jurisdictions. This project will result in a more accurate, evidenced-based model for Manitoba Health to utilize in planning for the 2005 influenza season. Ultimately, it is expected that the improved model will have applicability in other jurisdictions and with other vaccines.

Project Setting:

This project will be carried out in the CDC Unit of the Public Health Branch at Manitoba Health. This is a provincial government setting with responsibilities regarding policy development, program evaluation, and vaccine procurement and distribution to support immunization services in Manitoba. The Unit manages the procurement, warehousing and distribution of the provincial publicly funded vaccines, manages the Manitoba Immunization Monitoring System, and works collaboratively with Infectious Disease experts and Regional Health Authority staff to design, implement and evaluate provincial immunization programs. The investigator will be requesting published and publishable aggregate immunization data to evaluate immunization coverage. In-house

financial and warehouse data will be used to reconcile the planned model variables with the actual model variables such as total costs and vaccine wastage volumes. The prices of influenza vaccine are negotiated nationally and are confidential. This project will arbitrarily use \$4.00 per dose since published prices in the literature vary from \$2.00 – 20.00 per dose.

Project Objectives:

The purpose of this project is to examine the following questions:

- 1. how accurate were the predicted values of the variables in the 2004
 Manitoba Health Influenza Immunization Program Planning Model?
- 2. what should the predicted values of the variables in the 2005 model be?

 Definition of the Manitoba Health Influenza Immunization Planning Model 2004

 (MHIIPPM2004) the model is the Excel spreadsheet from June 2004 which included the population of the target groups, the expected immunization coverage rates, wastage, cost of the vaccine, and other variables and summed to a total.

Purpose of a Practicum:

As a final step in obtaining a Master of Nursing Degree, the practicum is designed to provide an opportunity for the student to implement and evaluate a program in an area of interest. The project is undertaken by the student who is expected to use appropriate scholarly methods to solve problems identified in practice. The primary focus is the practical application of knowledge and there is an expectation of a scholarly written concluding document.

Rationale for the Project:

Planning for new immunization programs has become more complicated over the last decade as prices and volumes and types of vaccines all increase. This project is important to undertake in order to increase the ability of the Communicable Disease Control (CDC) unit to plan for and manage immunization programs. Although there will always be an element of uncertainty while planning and implementing new programs, this work will help to mitigate it. This project will look back at the 2004 expanded influenza program roll out, and will assist in the review of the expanded 2004 pneumococcal conjugate, meningococcal C conjugate, and varicella programs. As well, it will establish a framework for creating useful and accurate models for all the immunization programs at Manitoba Health. This work will be useful to predict the 2005 influenza program in Manitoba and will likely have applicability in other jurisdictions.

The literature yields some information useful for immunization program planning.

This project will involve a more thorough examination of the literature than current CDC staffing resources permit. This information will inform the entire planning process for CDC unit staff in the future.

There is very little evidence in current literature at the level of detail needed to accurately plan for an influenza immunization program in Manitoba. Because the CDC Unit is informed by the Manitoba Immunization Monitoring System (MIMS), Manitoba is in an excellent position to conduct this type of review and share it with the other jurisdictions which are without a provincial database.

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Project participant:

This project is being submitted for consideration by Marilyn McIvor, BN, BSc. Ms. McIvor is currently on leave from her position as Public Health Nursing Team

Leader – Sea to Sky, Vancouver Coastal Health Authority. Ms. McIvor has been employed on a part time basis in the CDC Unit at Manitoba Health as a Provincial Immunization Specialist since January 2004. She had been attending the University of Manitoba full time since September, 2003 completing her Master's in Nursing.

Critical Path

Phase 1: Project Planning

October 2004 – April 24, 2005

Establish advisory committee Request access to practicum setting

Phase 2: Project Implementation

April 24 – May 14, 2005

Retrieve and analyze year end MIMS, warehouse, and funding data

May 16 – May 31, 2005

Compare actual year end data with 2004 model projections

June 1 - 10, 2005

Create 2005 model recommendations

Phase 3: Project Documentation

June 11 - 20, 2005

Complete scholarly written project summary

Phase 4: Project Communication

June 21 - 30, 2005

Communicate with Manitoba Health CDC Unit staff and other jurisdictions as feasible. Publish as feasible.

Appendix G: Letter to Ethics

May 2, 2005

Dear Margaret Bowman,

Please find attached a brief summary of my proposed practicum project. I am planning to undertake this project in order to fulfill the requirements of my Master's in Nursing at the University of Manitoba. I am currently employed part-time at the Communicable Disease Control unit of Manitoba Health as an immunization specialist. In my capacity of Master's student I am interested in reviewing the planning model Manitoba Health used last year in preparation for the influenza immunization campaign. Specifically, I wish to compare the major variables of the model about immunization coverage rates (i.e. how many people accepted the vaccine) and vaccine wastage rates against the actual year end values that are becoming available now.

It is my understanding that since I will not be using individual, personal data, there will be no need to go through Ethics approval. This immunization coverage data will be at the aggregate level and publishable. I refer you to the internet site http://www.gov.mb.ca/health/publichealth/cdc/vpd.html where you can find the 2003 data. The 2004 data will be available in-house soon and will be publicly available on this web site over the next few months.

Other data to be analyzed includes in-house financial and vaccine warehouse and shipment data which does not reflect individual, personal vaccine usage in any way. Dr. Carole Beaudoin at Manitoba Health has already advised me there is no need for me to seek approval for the access of my project data through the Health Information Privacy Committee since it is aggregate level data only. Carole has also agreed to sit on my Practicum committee as an external member. Drs. Janet Beaton and Benita Cohen have agreed to sit as internal members.

Please confirm my understanding at your earliest convenience. I am available to speak with you anytime:

Sincerely,

Marilyn McIvor, B.N., B.Sc.

Appendix H: Comment from Ethics

If I understand this project correctly, it would not need ethical review because all of the information will be received from an outside authority and would include no data collection by the researcher. I am assuming from the request that the data are in the public domain.

If this is not true, then a second look will need to be taken, and we will need more information from the researcher.

I. The 2004 Actuals model (public)

See attached excel spreadsheet

Manitoba Health - Public Health Branch Influenza Program for 2004/5

Public

ACTUALS

Marilyn McIvor June 29, 2005

Doses are given at 6 - 23 months between October 15 & March 31 Household contacts and caregivers of children 0 - 23 months and seniors

pregnant women in 3rd tri if delivering October to March

High risk due to chronic illness children and adults at 11%

health care workers

bold denotes actual value

people 65 or over

	T		household	household	child care	pregnant	high risk	health care		household	caregivers	totals	
Program Area		child	contacts	contact	providers	women	at 11%	workers	>64	contacts	of seniors		actual
Vaccine			1 sibling	2 parents						of seniors			
Population Risk Group		22,500	30,000	60,000	10,000	2,500	110,670	20,000	163,643	50,000	50,000	519,313	
Compliance (%)		0.40	0.20	0.10	0.10	0.10	0.19	0.30	0.63	0.20	0.20		
No. of Doses		1	1	1	1	1	1	1	1	1	1		
Total Doses Required		9,000	6,000	6,000	1,000	250	20,474	6,000	103,586	10,000	10,000	172,310	200 500
Doses Purchased													320,500
Doses administered							20,507		103,542				229,310
Unaccounted for		0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	•	28%
Cost (\$) per Dose - see note	\$	10.00 \$	10.00 \$	10.00 \$	10.00	\$ 10.00 \$	10.00 \$	10.00 \$	10.00 \$	10.00 \$	10.00	\$	10.00
Total Vaccine Cost (\$)		99,000.00	66,000.00	66,000.00	11,000.00	2,750.00	225,213.45	66,000.00	1,139,446.21	110,000.00	110,000.00	\$	3,205,000.00
Adminstration							0.54	0.54	0.54	0.54	0.54		0.54
Proportion Admin'd by Docs (%)		0.54	0.54	0.54	0.54	0.54	0.54		6.00 \$	6.00 \$		\$	6.00
Admin Cost (\$) per Dose	\$	6.00 \$	6.00 \$	6.00 \$	6.00		6.00 \$	6.00 \$	335,618.70 \$			\$	742,964.40
Total Doc Admin Costs (\$)	\$	29,160.00 \$	19,440.00 \$	19,440.00 \$	3,240.00	\$ 810.00 \$	66,335.60 \$	19,440.00 \$	335,618.70 \$	32,400.00 \$	32,400.00	Ψ	7-12,001.10
Proportion Admin'd by PHN (%)		0.29	0.29	0.29	0.29	0.29	0.29	0.29	0.29	0.29	0.29		0.29
1 ' ' ' '	\$	7.00 \$	7.00 \$	7.00 \$	7.00		7.00 \$	7.00 \$	7.00 \$	7.00 \$	7.00	\$	7.00
Admin Cost (\$) per Dose Total PHN Admin Costs (\$)	\$	18.270.00 \$	12.180.00 \$		2,030.00	·	41,562.12 \$	12,180.00 \$	210,279.62 \$	20,300.00 \$	20,300.00	\$	563,913.00
Total PHIV Admini Costs (4)		10,210.00 Φ	12,100.00	12,100100			· · · · · · · · · · · · · · · · · · ·						
Proportion Admin'd by FNIHB		0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03		0.25
Proportion Admin's by Other		0.14	0.14	0.14	0.14	0.14	0.14	0.14	0.14	0.14	0.14		0.14
Proportion Admin's by Other		0.14	0.14	•									
Promotion/Health Links												œ.	91,256.00
Promotion Costs (\$)	\$	91,256.00										\$	91,256.00
													4 000 400 40
Total (\$)	\$	237,686.00 \$	97,620.00 \$	97,620.00 \$	16,270.00	\$ 4,067.50 \$	333,111.17 \$	97,620.00 \$	1,685,344.53 \$	162,700.00 \$	162,700.00	\$	4,603,133.40
Grand Total for Year (\$)	\$	2,894,739.20											

note- Provinces and territories are under contractual agreement with the vaccine manufacturers to maintain the confidentiality of the cost per dose. This \$10 used is not the actual amount paid by Manitoba Health.

Appendix J: The 2005 model (public)

See attached excel spreadsheet

Manitoba Health - Public Health Branch Influenza Program for 2005/6

PUBLIC

Marilyn McIvor July 3, 2005

bold denotes actual, referenceable data

italics indicate supported by literature or in-house historical data

underlining indicates estimated data

size of birth cohort	14,009				plan for 10% growth over	all						
l	child	siblings (1)	parents (2)	child care providers (1)	pregnant women in 3rd tri	health care	caregivers	house/contacts	high risk			T07410
Target group	aged 6 - 23 months	of child 0-23 mo	of child 0-23 mo	of child aged 0 -23 mo	with EDC in flu season	workers	of seniors	of seniors	at 11%	>64	other	TOTALS
Vaccine								50.000	70.444	158,676		599,950
Population	21,014	28,018	56,036	28,018	2,335	23,872	<u>158,676</u>	52,892	70,414	0.70		000,000
Coverage (%)	0.80	0.50	0.30	0.30	<u>0.50</u>	0.50	0.40	0.50	0.19	0.70		
Doses required per vacinee	1	1	1	1	1	1:	1	7	40.007	111,073		283,156
Doses Required for aggregate	16,811	14,009	<u>16,811</u>	<u>8,405</u>	<u>1,167</u>	11,936	63,470	<u>26,446</u>	13,027	0.10		200,100
Unaccounted for	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10		
Reserve stock	0.18	0.18	0.18	0.18	0.18	0.18	0.18	0.18	0.18			371,248
Total Doses required for aggregate	22,041	<u>18,367</u>	22,041	<u>11,020</u>	<u>1,531</u>	<u>15,649</u>	83,217	34,674	17,079	145,629		37 1,240
Cost per Dose - see note	\$ 10.00	\$ 10.00	\$ 10.00			\$ 10.00						\$ 3,114,711.67
Total Vaccine Cost (\$)	\$ 184,918.80	\$ 154,099.00	\$ 184,918.80	\$ 92,459.40	<u>\$ 12,841.58</u>	\$ 131,296.00	\$ 698,174.40	\$ 290,906.00	\$ 143,292.49	\$ 1,221,805.20		\$ 3,114,711.07
Administration Proportion Admin'd by Docs (%) Admin Cost (\$) per Dose	0.54 \$ 6.00	0.54 \$ 6.00	L				\$ 6.00	\$ 6.00		\$ 6.00		\$ 917,424.17
Total Doc Admin Costs (\$)	\$ 54,466.99	\$ 45,389.16	\$ 54,466.99	\$ 27,233.50	\$ 3,782.43	\$ 38,672.64	\$ 205,644.10	\$ 85,685.04	\$ 42,206.15	\$ 359,877.17		φ 311,424.11
Proportion Admin'd by PHN (%) Admin Cost (\$) per Dose	0.29 \$ 7.00	0.29 \$ 7.00	1	0.29 \$ 7.00			\$ 7.00	\$ 7.00		\$ 7.00		\$ 574,805.88
Total PHN Admin Costs	\$ 34,125.92	\$ 28,438.27	\$ 34,125.92	\$ 17,062.96	\$ 2,369.86	\$ 24,230.08	\$ 128,844.91	\$ 53,685.38	\$ 26,443.98	\$ 225,478.60		\$ 574,605.66
Proportion administered by FNIHB proportion administered by other	\$ 0.03 0.14		\$ 0.03 0.14		\$ 0.03 0.14	1		1 '	\$ 0.03 0.14		\$ 95,000.00	\$ 95,000.00
Promotion/Health Links							 	-		 	\$ 20,000.00	<u> </u>
AIM study	1	ı										
Total	\$ 273,511.72	\$ 227,926.43	\$ 273,511.72	\$ 136,755.86	\$ 18,993.87	\$ 194,198.72	\$ 1,032,663.41	\$ 430,276.42	\$ 211,942.62	\$ 1,807,160.96	\$ 115,000.00	<u>\$ 4,721,941.72</u>

Total for Year (\$) assumptions:

1. birth cohort is from the Manitoba Health Population Report 2004

4,721,941.72

- 2. assume one sibling per child
- 3. assume two parents per child
- 4. assume one caregiver per child
- 5. assume one caregiver per senior
- 6. assume 1/3 household contact per senior
- 7. plan for one dose per infant since they will need 0.25 ml

note- Provinces and territories are under contractual agreement with the vaccine manufacturers to maintain the confidentiality of the cost per dose. This \$10 used is not the actual amount paid by Manitoba Health.

definitions:

1. coverage: the percent of the target group immunized

2. unaccounted for: vaccine shipped but not entered in MIMS as administered

3. reserve stock: extra vaccine ordered by providers to meet demand

Appendix K: NACI defined groups, 1998

NACI-defined group	Manitoba
Health care workers age 20 -64	21,100
High-risk conditions	22,400
Age 0-19	
High-risk conditions	144,600
Age 20-64	
High-risk conditions	92,900
Age 65+	
Age 65+ living independently	39,900
Persons in long term care (all ages)	8,400
Household contacts of persons with conditions	283,000
Infants < 1 yr of age	24,200
Total	637,600

Appendix L: Influenza vaccine required, 2001

Population group	Estimated number of	Estimated vaccine	Estimated number of doses	
	persons	coverage as %	required	
Residents of personal care	9,000	84	7,640	
homes or other chronic care				
facilities				
People aged 6 months to 64 with	109,248	40	43,703	
high-risk conditions				
Persons > 64 not in chronic care	147,644	70	103,348	
Health Care Workers/volunteers	4,000	20	1,000	
in long term care facilities				
Health Care Workers/volunteers	4,000	20	1,000	
in hospitals		,,,,,,		
Health Care Workers/volunteers	4,000	20	1,000	
in the community				
Ambulance staff/paramedics	1,702	70	1,191	
Household contacts of people	10,000	20	4,000	
with high-risk conditions				
Total			163,902	
Wastage @ 11%	1	1.4. (H D. 20)	180,293	

In house influenza vaccine purchase planning template. (Horne, D, 2001)