
IMMUNIZING PREGNANT WOMEN IN THE COMMUNITY CLINIC SETTING

Review of the risk of adverse events, for vaccines recommended for pregnant women, which may occur and require management/intervention in a Public Health immunization clinic setting

Final

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August 2010

Key Messages:

- 1) There is no evidence to suggest that healthy pregnant women experience more or different adverse effects following immunization than their healthy non-pregnant counterparts.
- 2) There is strong evidence to support the practice of immunizing pregnant women with vaccines that have been recommended for them.
- 3) Immunization of pregnant women must be considered in the context of their risk of exposure to a vaccine preventable disease and the potential negative outcomes in the event that they contract the disease.
- 4) Pregnant women have an increased risk of morbidity and severe illness from influenza viruses, in particular pandemic flu viruses.
- 5) As there is no evidence of pregnancy related risk from immunization, pregnant women should be able to receive vaccines recommended for them at community based, public health immunization clinics that offer those vaccines.
- 6) Health care professionals follow a strong precautionary principle related to health care interventions for pregnant women, including immunization. They require explicit and clear information regarding safety for the pregnant woman and her baby in order to change their practice and effectively respond to questions from their clients.

Executive Summary:

During the H1N1 pandemic mass immunization campaign, pregnant women were identified as a vaccine priority group. Peel Public Health (PPH), according to standing medical directives, does not routinely immunize pregnant women in public health immunization clinics. This policy was discussed during the H1N1 pandemic and PPH decision makers determined that the available evidence should be reviewed before a change of practice was implemented. As such, a systematic review of high quality evidence was conducted to answer the following question: “Do pregnant women, for whom vaccine is approved/recommended, experience more or different adverse events following immunization than non-pregnant women?”.

This literature review was not designed to examine the licensing and manufacturer recommendations for the use of vaccine in pregnant women. A robust regulatory process exists in Canada to ensure vaccine safety. The scope of this review was focused only on potential adverse events that may occur in pregnant women that would require intervention/management by immunization clinic staff. Two professional practice guidelines on immunizing pregnant women were identified and critically appraised.

Both of the appraised guidelines were rated as strong or moderate evidence and support a change in practice. As such, the final recommendation of this literature review is that Peel Public Health offer pregnant women vaccines recommended for them at community based public health immunization clinics that offer those vaccines.

An Applicability and Transferability Workshop was held with program staff to discuss how a policy change to include pregnant women would be accepted in Peel and how it would impact our services. As a result it was proposed that the recommendation be implemented. The recommendation will require a change in PPH policy and practice. Medical directives will need to be updated and program policy and procedures will require modification in order for the new practice to be implemented in Fall 2010.

The majority of program staff is expected to be supportive of the change in practice. It is recognized that there is strong precautionary principle when considering interventions for pregnant women and that program staff will require the opportunity to understand the evidence used to support the decision for the policy change. In addition, program staff representatives who participated in the workshop expressed a need for good information on the risk/benefit of vaccine(s) that will be offered to pregnant women in the clinic setting in order for them to effectively answer the questions pregnant women will have.

Implementation of the recommended change in practice will be presented to all program staff during orientation sessions. All medical directives, policy and procedures will also be reviewed and updated. Data collection and evaluation measures will be implemented to track program impacts and service outcomes.

The Issue

In May 2009 the World Health Organization declared the H1N1 flu virus a Pandemic. In response, the Federal government contracted GlaxoSmithKline (GSK) to begin production of an H1N1 vaccine for Canada. Ontario received its first shipments of vaccine around Oct. 20th and Peel Public Health held the first H1N1 mass immunization clinic for priority groups on October 28th.

Priority groups were established nationally to ensure that those most at risk would have access to Pandemic flu vaccine first. Pregnant women were included in the priority groups. This presented a problem for Peel Public Health. The Medical Directive for administration of influenza vaccine stated that Peel Public Health nurses would not provide vaccine to “individuals who are pregnant, or think they may be pregnant”. These individuals were to be referred to their family physician for vaccination.

Although influenza vaccination has been recommended for pregnant women in past flu seasons, referring women to their family doctor had worked well in the past. During the H1N1 Pandemic, not all family physicians were able or willing to provide the vaccine to their patients. This meant that pregnant women in Peel, who wanted to be immunized with Pandemic flu vaccine, had few alternatives to ensure that they were protected.

Discussions regarding the Peel policy to not immunize pregnant women in PPH clinics revealed that the history of this policy decision was unclear. Although not servicing pregnant women was a serious concern it was important not to change the established medical directive during the pandemic H1N1 response when there was insufficient time

to conduct a thorough review of the issue. Peel Public Health addressed the service gap by implementing special clinics staffed with physicians to ensure that pregnant women, who chose to be vaccinated, could get access to the Pandemic flu vaccine.

Subsequently, the Manager of Vaccine Preventable Diseases proposed that a formal literature review be conducted to gather evidence to inform future practice.

The Context

Discussions with staff regarding the subjects that impact decision making, related to immunization clinic practice, resulted in the development of a conceptual model (see Appendix A). The model demonstrates that the assessment of risk is a key issue and must be addressed explicitly. In order to make responsible decisions at the program level and at the nursing level, we must have the knowledge, skills and tools to assess and understand the risk related to immunizing pregnant women.

In performing immunizations the nurse must always make the final decision whether to immunize or not immunize, based on an assessment of the patient and their medical history. A lack of evidence or information about the true risks can lead to either an exaggerated perception of risk or unidentified risk. If the sense of risk is exaggerated there may be reluctance to immunize, and eligible clients could be turned away. If a real risk remains unidentified a negative outcome could ensue, potentially causing harm. Having the best available evidence will provide information related to the risks for pregnant women who are immunized in the clinic setting. This will allow us to determine whether the risks are different for pregnant women and whether this risk is

manageable in a clinic setting. These decisions will inform any requirement to make policy changes.

Determining whether to change our policy started with examining the origins of our practice of not immunizing pregnant women in a Public Health immunization clinic setting. This policy is informed by the historical evolution of the Universal Influenza Immunization Program (UIIP).

The UIIP was mandated by the Ministry of Health and Long Term Care (MOHLTC) for implementation in Ontario for the 2000 flu season. The model for delivering seasonal flu vaccine to the public through the UIIP grew out of the existing model used in school based Hepatitis B clinics which had been offered since 1994. The processes were expanded and adjusted to suit larger clinic settings but the underlying model remained consistent. Under these procedures individuals are asked the question "is there any chance that you could be pregnant?". A positive response to this question will result in no administration of vaccine and the individual is directed to her family physician for vaccination.

The VPD Manager has gone to some length to uncover what evidence or rationale was used when this medical directive was first established. Only informal staff recall is available and suggests the supporting argument was based on a belief that PPH should refer pregnant women to their family doctor for vaccination as a way to encourage pregnant women to maintain their relationship with the family doctor throughout their pregnancy. Additionally, it is generally assumed that pregnant women are cautious

about taking medications during pregnancy and referring them to their family doctor for vaccination provided a forum for pregnant women to discuss their options and concerns.

The practice of refusing to vaccinate pregnant women in PPH clinics went largely unchallenged in the past. Vaccines routinely offered in clinic settings, primarily seasonal influenza vaccine, were readily available through family physicians and walk-in clinics. However, this was not the case for H1N1 flu vaccine.

Public Health was the primary provider of H1N1 flu vaccine to the public through mass immunization clinics. Although the MOHLTC had indicated that physicians would also be vaccine providers, logistics related to reporting and billing were not thoroughly developed in time to support Public Health vaccination efforts in the early days when public concern and demand was highest.

Despite the efforts of PPH to clearly communicate with the public that pregnant women would not be vaccinated at mass immunization clinics, and efforts to pre-screen women standing in line, some pregnant women still attended the clinics with the expectation that they would receive the vaccine. The impact of this is best illustrated by the following anecdote.

An Anecdote

At one of the early H1N1 clinics targeting high priority groups, a pregnant woman and her husband waited in line for about 6 hours to receive the H1N1 vaccine. The nurse, upon reviewing the assessment questions, informed the woman that because she was

pregnant she could not be immunized at the clinic. However, public messages from the MOHLTC strongly recommended that pregnant women get the H1N1 pandemic flu vaccine.

PPH's inability to vaccinate this woman caused considerable confusion and anxiety. She had attended the clinic based on the recommendations of the MOHLTC. She and her husband were angry and concerned for the woman's personal health and the health of her fetus. They challenged PPH's refusal to vaccinate pregnant women. The clinic supervisor and the Medical Officer of Health, who happened to be on location at the clinic during this incident, spoke to the couple to explain PPH's policy.

The couple both missed a day of work to ensure that they, and their unborn child, were protected from the pandemic flu virus. The couple were residents of Toronto but they both worked in the Region of Peel. They decided to attend a Peel clinic as it was closer to their places of work. Ironically, had they attended a Toronto mass immunization clinic, the woman would have been immunized.

Many PPH staff who were working at the clinic, and who were aware of the incident, still have a strong emotional reaction to this woman's situation. They were empathetic to the woman and understood her legitimate fear. Many of the nurses would have preferred to administer the vaccine to this pregnant woman rather than turn her away.

The unique circumstances of running mass immunization during an influenza pandemic brought to light the need to critically evaluate our standard practice of not immunizing

pregnant women. Additionally, surrounding health units were vaccinating pregnant women at their mass immunization clinics and MOHLTC public messages encouraged pregnant women to get the vaccine.

The Question:

Under our current policy/medical directives pregnant women are not immunized in Peel Public Health immunization clinics. We would like to understand if there are safety risks in the clinic environment that should be considered prior to making a decision about whether to vaccinate pregnant women. As such our question is, “Do pregnant women, for whom vaccine is approved/recommended, experience more or different adverse events following immunization than non-pregnant women?” This question is not intended to address whether an individual vaccine, e.g. influenza, should be approved for administration to pregnant women. This is done either at the time of licensure or via our professional practice bodies such as National Advisory Committee on Immunization (NACI).

PICO:

P = pregnant women

I = immunizations recommended for pregnant women

C = non-pregnant women

O = adverse reaction to vaccine

Search Strategy

Our search criteria focused on risks or adverse events experienced by the pregnant woman immediately following vaccination. We were primarily interested in adverse events that may be different or occur more frequently in pregnant women than non-pregnant women. This is of particular relevance in a Public Health immunization clinic setting where all adverse events must be managed by clinic staff.

A systematic search of the Medline and Cochrane databases as well as clinical practice guideline websites including: National Guidelines Clearinghouse (NGC), National Institute for Health and Clinical Excellence Public Health Guidance, Registered Nurses Association of Ontario (RNAO), Trip Database, Canadian Medical Association, Alberta Medical Association, and the CDC Guide to Community Preventative Services were searched resulting in 30 articles and 2 clinical practice guidelines.

Medline and Cochrane Database Search Criteria:

- 1 Pregnant Women/ (4359)
- 2 exp Pregnancy/ (630208)
- 3 1 or 2 (630615)
- 4 exp Vaccination/ (46168)
- 5 immunization/ or immunization schedule/ or immunization, secondary/ (49277)
- 6 (vaccinat* or immuniz).tw. (73974)
- 7 4 or 5 or 6 (133193)
- 8 risk*.tw. (859659)
- 9 ae.fs. (1104138)
- 10 exp Drug Toxicity/ (24896)
- 11 or/8-10 (1815041)
- 12 7 and 11 (24189)
- 13 3 and 12 (1466)
- 14 meta-analysis.mp,pt. (38812)
- 15 (search or systematic review or medline).tw. (128726)
- 16 cochrane database of systematic reviews.jn. (6308)
- 17 or/14-16 (153310)
- 18 13 and 17 (32)

19 from 18 keep 1-32 (32)

Of the 32 articles/guidelines identified, 29 of the articles were assessed as not relevant based on the title and abstract. Of the four remaining articles that were reviewed, 2 were determined to be “not relevant” based on the inclusion/exclusion criteria and the remaining 2 clinical practice guidelines were critically appraised (Appendix B).

Inclusion Criteria:

- summaries
- evidence based clinical practice guidelines
- immunization/vaccination of pregnant women
- risk/adverse effects of vaccine that occur in pregnant women

Exclusion Criteria:

- single studies
- literature reviews that were not critically appraised
- medications other than vaccine
- studies focused only on disease risk and the ability of immunization to decrease disease risk
- studies focused only on the risk/benefit of vaccine for the developing fetus
- studies focused only on the efficacy of vaccine used in pregnant women

Critical Appraisal & Synthesis of Findings:

The systematic search for literature related to adverse effects of vaccine in pregnant women, which may differ from non-pregnant women, resulted in no articles. A subsequent search for clinical practice guidelines revealed two. These guidelines, which were critically appraised and rated as moderate or better, did not identify any increased or different immediate adverse events for pregnant women. Based on the absence of evidence it can be concluded that pregnant women do not have increased or different reactions to vaccine than non-pregnant women. This finding is consistent with the experience at physician-run clinics for pregnant women during H1N1 where an estimated 600 women were immunized and no adverse events were reported.

The benefit of immunizing against infectious diseases is well documented. However, pregnant women are considered a special population and the practice of immunizing pregnant women is not clear cut. Due to ethical considerations, pregnant women are not usually intentionally included in clinical trials testing vaccine safety. As a result, there are a very few studies that address the risks of immunizing pregnant women. Most of the literature on this subject discusses the safety of specific vaccine for the developing fetus and the efficacy of specific vaccine when given during pregnancy. None of the literature that we reviewed discussed any immediate adverse effects of vaccine in pregnant women that may occur in an immunization clinic setting.

It is generally accepted that non-live vaccines are safe for use in pregnant women (3, 4). Influenza vaccine has been used in this population for many years with no

documented adverse effects (3, 4). Pregnant women who are otherwise healthy are known to experience greater morbidity when infected with the influenza virus than their healthy non-pregnant counterparts (3, 4). Although the reason for their increased vulnerability to the influenza virus is yet unknown, pregnant women are identified as a target group for seasonal influenza vaccination and were considered a vaccine priority group during the H1N1 pandemic due to their increased risk of morbidity and mortality.

The CDC Guidelines for Vaccinating Pregnant Women (2) (an excerpt of CDC General Recommendations on Immunization (ACIP) (3)) and the SOGC Clinical Practice Guideline: Immunization in Pregnancy (4) were reviewed using the Appraisal of Guidelines for Research and Evaluation (Agree) Instrument (9).

The recommendations presented in the CDC Guidelines for Vaccinating Pregnant Women (2) were rated based on a critical evaluation of the source document, CDC General Recommendations on Immunization (ACIP) (3). It rated highly in the domains named Scope & Purpose and Clarity & Presentation (76%-100%) and received a medium rating in the areas of Rigour & Development, Applicability, Stakeholder Involvement and Editorial Independence (46%-75%). The guideline was rated independently by two reviewers and they both felt that this was a strong guideline which resulted in an overall rating of "Strongly Recommended".

The recommendations in the CDC Guidelines for Vaccinating Pregnant Women that were extracted from the main document are clearly presented with key recommendations in bold lettering. Supplementary materials were retrieved to evaluate

the literature review process and to confirm that the recommendations were evidence based. However, the recommendations are not rated so the strength of the evidence reviewed is not transparent. Despite this apparent weakness, the contents of the guideline are well organized, comprehensive and consistent with the recommendations made in the SOGC Clinical Practice Guideline: Immunization in Pregnancy (4).

The SOGC guideline rated highly in the domains named Scope & Purpose and Clarity & Presentation (76%-100%), received a medium rating in the areas of Rigour & Development, Applicability and Editorial Independence (46%-75%), and received a low rating in the area of Stakeholder Involvement (0%-45%). This guideline was rated independently by four reviewers. Some of the reviewers felt that the guideline lacked strength due to the medium and low ratings in four of the six Agree Instrument domains. However, this guideline received an overall rating of “Recommended with Provisos or Alterations”.

The Rigour & Development section of this guideline scored low due to lack of information provided about the author’s search criteria and methods for reviewing the identified evidence. The recommendations are clearly presented and rated using an adapted model developed by the Canadian Task Force on Preventative Health Care. The contents of the guideline are well organized, comprehensive and consistent with the recommendations made in the CDC General Recommendations on Immunization.

The Canadian Immunization Guide (CIG) was considered for critical appraisal but was eventually rejected for inclusion in this literature review. The CIG was not identified as

part of the systematic search for evidence during this review and is referred to in other literature as a “handbook” (5) rather than as a guideline, recommendation or protocol (7). Although a supplementary document published by the Canada Communicable Disease Report (CCDR) asserts that National Advisory Committee on Immunization (NACI) recommendations have always been “...based on review of available evidence...” the link between NACI Statements and the CIG are not explicit (7). As such, the reviewers were not confident that this guide meets the established inclusion criteria.

However, NACI published a statement in January 2009 indicating that they will be adopting a more transparent, evidence based approach when developing their recommendations (7). Additionally, the format of the CIG is also expected to change to meet these new standards. Once these standards are implemented the CIG will likely meet the established inclusion criteria and may be appraised as part of future literature reviews. Finally, the CIG recommendations are consistent with the guidelines that were reviewed.

Neither guideline received a high rating in the area of editorial independence but the reviewers did not feel that this was a significant barrier to implementation. The SOCG has published statements of their goal to engage a broad spectrum of qualified health care professionals in the development of their guidelines and have explicit conflict of interest policies and procedures for its application. ACIP has published a current committee membership roster that provides details about their committee members.

However, this list reflects current membership which has changed since the guideline was published. Additionally, CDC documents state that ACIP members must have no conflicts of interest in order to be a participating member.

In summary, two guidelines which rated as strong or moderate evidence were reviewed, the recommendations are clearly presented, the content are consistent between the two guidelines and the recommendations are highly applicable to our setting. Additionally, the recommendations made in both guidelines are highly generalizable to our population, and reflect current practice in most other Health Units in Ontario.

In light of this evidence, our recommendation is to provide immunization services, in the immunization clinic setting, to pregnant women for those vaccines which are recommended for use in pregnant women. The literature does not reveal any evidence that pregnant women experience more or different adverse events following immunization. As such, risk to the organization and professional staff administering vaccine is low and does not support the exclusion of pregnant women from our services; especially when the risk of disease for this population has been clearly identified.

Adaptation & Transferability:

The outcomes of the research evidence in combination with our local community health needs, community and political preferences, our resources and expertise, all strongly support the final recommendation to immunize pregnant women in Peel Public Health (PPH) immunization clinics. PPH is currently one of only a few health units in Ontario

that do not immunize pregnant women in public health clinics. Lack of evidence to support our current practice and strong evidence to support a change of practice facilitate adopting a change in policy and practice.

Political acceptability and social acceptability are expected to be strong in support of this change. Councillors in the region of Peel have advocated on behalf of their constituents during the H1N1 pandemic, for a change in policy which would allow PPH to immunize pregnant women in our clinics. Additionally, pregnant women seeking immunization are expected to welcome the option of attending a public health immunization clinic in Peel if they find it difficult to access a physician offering immunization.

The impact of this change on the workload of clinic staff is expected to be small (a generous estimate of an additional 160 clients in a flu season). Ideally, providing access to public health clinics will result in greater uptake of flu vaccine in this population and consequently result in the prevention of some cases of the disease. Pregnant women who get influenza are more likely to become seriously ill and require medical attention and hospitalization. In addition to preventing the burden of illness on both mother and baby, vaccination reduces the burden on the health care system. Public Health measures which result in reduced pressure on the health care system are generally welcome and influenza immunization clinics achieve this goal.

Any anticipated negative reaction from the public as a result of this change is likely to occur in the relatively small segment of the population which is anti-vaccine. It is felt

that the proposed policy change is not likely to warrant wide media coverage and those pregnant women presenting at public health clinics will be pro-vaccine.

The Immunization Clinics team, which will be the primary group impacted by this policy change, are anticipated to welcome the proposed change in practice. The impact on workload for immunizing nurses in the clinic setting is expected to be minimal. No new clinical expertise is needed to administer vaccine to pregnant women. However, program staff will need to develop new resources and adapt existing screening criteria and medical directives to ensure that immunizing staff are able to practice and answer common questions that pregnant women may ask prior to consenting to immunization, e.g. FAQs.

In understanding the context of this decision it was clear that missing or ambiguous information could be perceived as potential risk and could result in a decision not to immunize when in fact it is safe to do so. As such there may be opportunities to benefit the program as a whole by ensuring that information clearly addresses all the areas of risk and includes disease risk as well as vaccine risk/benefits. In addition clearer background related to the reason for immunization assessment questions may result in improved consistency of administration of vaccine by decreasing the frequency of encountering 'unusual or unknown' scenarios that may cause the nurse to not vaccinate when it is safe to proceed.

Although this review has been primarily focused on influenza vaccine, as this is the vaccine routinely offered in public health immunization clinics, the proposed change in

policy could have impacts on other routine vaccine delivery clinics. For example, vaccinating grade seven girls against Hepatitis B who are, or suspect that they are, pregnant may be considered as well. Additionally, whether to vaccinate pregnant women in infectious disease outbreak scenarios may need to be considered based on emerging information specific to the outbreak.

Recommendations:

It is our recommendation that Peel Public Health offer immunization services for pregnant women for those vaccines that are recommended for them. If the recommendation is approved it is further recommended that implementation be scheduled for Fall 2010. This timeline would allow vaccination of pregnant women for the upcoming influenza season.

The staff that participated in the Applicability and Transferability discussions identified the following steps needed for implementation:

1. Presentation of the literature review to all immunization clinic staff. For casual staff this would have to happen during the annual orientation.
2. Review and update medical directives, policy and procedures and the standard assessment questions for all vaccines which are recommended for use in pregnant women that are offered in PPH immunization clinics. It should be determined if any changes to the standard assessment tools could be made that

would increase the clarity about risk and when to proceed with vaccinating an individual client and the rare circumstances when they should delay.

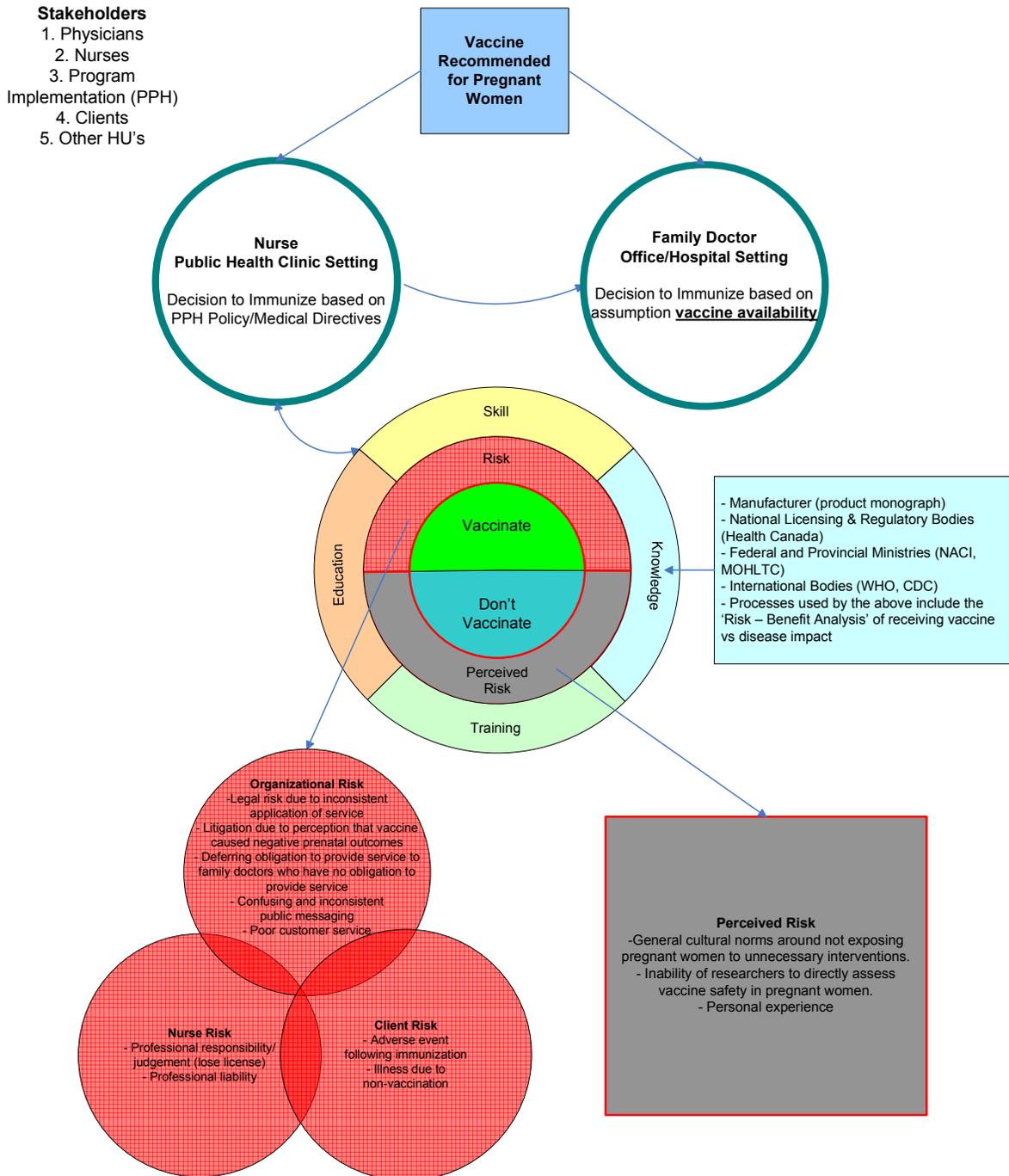
3. Development of frequently asked questions (FAQ) for immunization clinic staff to assist with answering questions that may be posed by pregnant women prior to consenting to immunization is required.
4. Development of internal and external communication strategies. An internal strategy to update public health staff, the majority of whom were engaged in offering H1N1 clinics and will be interested in this new direction. In addition, staff will need updated information about clinic eligibility that can be shared with their clients who enquire. An external communication strategy would be needed to update Peel physicians and other stakeholders that may refer clients to PPH immunization clinics. Health promotion materials will need to be updated to ensure that the public is aware that pregnant women can now attend Peel public health immunization clinics.
5. Finally, data collection and evaluation measures will be needed to track program impacts and service outcomes.

References

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- (3) Centres for Disease Control and Prevention. General Recommendations on Immunization (ACIP). Morbidity and Mortality Weekly Report December 1, 2006;55(RR-15):June 1, 2010.
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- (7) National Advisory Committee on Immunization. Canada Communicable Disease Report January 2009;35(ACS-1):July 15, 2010.
- (8) Smith JC. The structure, role, and procedures of the U.S. Advisory Committee on Immunization Practices (ACIP). Vaccine 2010 4/19;28(Supplement 1):A68-A75.
- (9) The AGREE Collaboration. Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument. 2001; Available at: www.agreecollaboration.org. Accessed June 1, 2010.

Appendices A: Concept Model

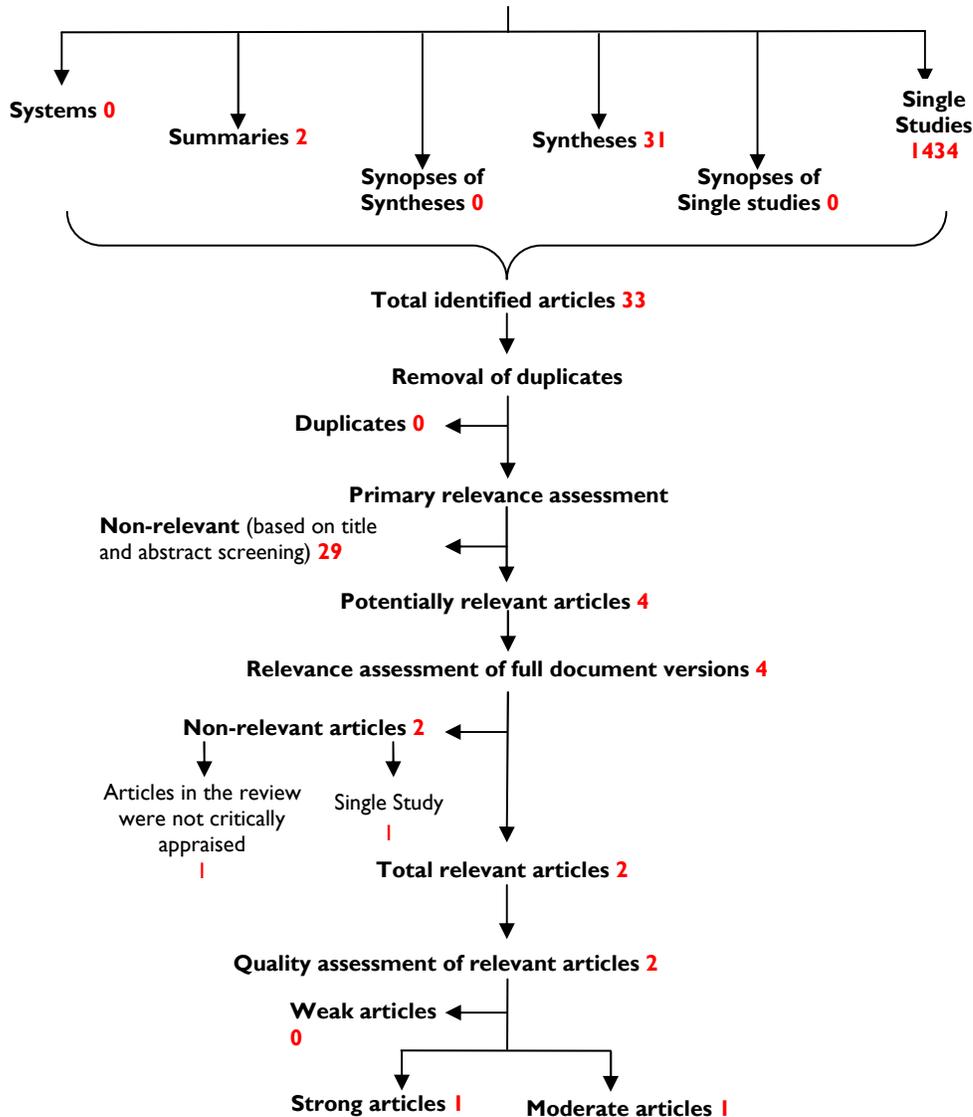
Immunization Clinics Influences of Decision Making Related to Vaccination of Pregnant Women at Peel Public Health



Appendices B: Literature Search Flowchart

Overview of Search Process March 5, 2010

Do pregnant women, for whom vaccine is recommended, experience more or different adverse reactions following immunization than non-pregnant women?



Appendices C: Data Extraction Table

General Info/Quality Rating for Review	Details of Each Review	Details of Interventions in Review	Outcome Measurements in Review	Results of Review
<p>SOGC Clinical Practice Guideline Immunization in Pregnancy</p> <p>Canada</p> <p>Population: Pregnant Women</p> <p>Intended Audience: Obstetrical Care Providers</p> <p>Rated using the Agree Instrument</p> <p>Domain Name & Overall Reviewers Score (4 reviewers): Scope and Purpose = 92% Stakeholder Involvement = 44% Rigour of Development = 55% Clarity and Presentation = 81% Applicability = 58% Editorial Independence = 46%</p> <p>Final Rating: "Recommended with Provisos or Alterations"</p>	<p>Reviewed 27 articles</p> <p>Searched Medline and Cochrane databases for articles up to June 2008 on the topic of immunization in pregnancy.</p> <p>The guideline was updated in November 2009 to include a section on H1N1 vaccine.</p> <p>No inclusion/exclusion criteria provided for the selection of their evidence.</p>	<p>The guideline discusses the effectiveness of immunizing pregnant women and disease prevention and the risks of administering vaccines that are contraindicated during pregnancy.</p>	<p>The evidence used to support each recommendation was rated according to adapted guidelines developed by the Canadian Task Force on Preventive Health Care.</p>	<p>9 clear, concise recommendations are made for vaccinating pregnant women.</p> <p>The recommendations that are of specific interest to us received a high rating (II-1A) with the rating tool the reviewers used. This means that the evidence came from well designed control trials and there is good evidence to recommend the clinical practice.</p>

General Info/Quality Rating for Review	Details of Each Review	Details of Interventions in Review	Outcome Measurements in Review	Results of Review
<p>CDC Clinical Practice Guideline: Immunizing Pregnant Women, ACIP, an excerpt of: CDC General Recommendations on Immunization USA</p> <p>Population: Pregnant Women</p> <p>Intended Audience: Any person or Institution that provides vaccination services.</p> <p>Rated using the <u>Agree Instrument</u></p> <p>Domain Name & Overall Reviewers Score (2 reviewers): Scope and Purpose = 94% Stakeholder Involvement = 63% Rigour of Development = 69% Clarity and Presentation = 79% Applicability = 61% Editorial Independence = 50%</p> <p>Final Rating: “Strongly Recommended”</p>	<p>Reviewed 21 articles</p> <p>This guideline is an excerpt of the CDC General Recommendations on Immunization, which reviewed 202 articles.</p> <p>The Guideline was updated on December 1, 2006.</p> <p>No search criteria are provided.</p> <p>No inclusion/exclusion criteria provided for the selection of their evidence.</p>	<p>The guideline provides recommendations for routine and other vaccine usage in pregnant women. Contraindications and precautions for specific vaccines are provided.</p>	<p>The evidence used to develop the guideline is not rated. However, in supplementary documents the process for establishing evidence for the development of ACIP recommendations appears rigorous.</p>	<p>Recommendations are vaccine specific and organized in table format.</p> <p>Inactivated Influenza vaccine is recommended for pregnant women.</p> <p>The guideline does not include H1N1 vaccine.</p>

Appendices D: Applicability & Transferability Worksheet

Factors	Questions	Notes
Applicability (feasibility)		
Political acceptability or leverage <p style="text-align: center;">STRONG</p>	<ul style="list-style-type: none"> • Will the intervention be allowed or supported in current political climate? • What will the public relations impact be for local government? • Will this program enhance the stature of the organization? <ul style="list-style-type: none"> ○ <i>For example, are there reasons to do the program that relate to increasing the profile and/or create a positive image of public health?</i> • Will the public and target groups accept and support the intervention in its current format? 	<ul style="list-style-type: none"> • Expect strong political support as there was a lot of concern expressed to local politicians when H1N1 vaccine was not available in the regular PH clinics. • Public relations impact is likely minimal as it is unlikely to be picked up, i.e. there won't be a media release, or report to council. If so would likely be positive with some risk of negative press if anti-vaccine groups aware.
Social acceptability <p style="text-align: center;">MODERATE - STRONG</p>	<ul style="list-style-type: none"> • Will the target population find the intervention socially acceptable? Is it ethical? <ul style="list-style-type: none"> ○ <i>Consider how the program would be perceived by the population.</i> ○ <i>Consider the language and tone of the key messages.</i> ○ <i>Consider any assumptions you might have made about the population. Are they supported by the literature?</i> ○ <i>Consider the impact of your program and key messages on non-target groups.</i> 	<ul style="list-style-type: none"> • There is a strong social cautionary principle regarding medical therapies for pregnant women. (i.e. thalidomide example still quoted) • Anti vaccine movement would not view as positive. • Risk of influenza for pregnant women is more known because of H1N1 publicity. • Those pregnant women who seek vaccine and health care professionals will find it acceptable. • There is positive messaging for decreasing risk of disease among those most vulnerable and around increase in available services.
Available essential resources (personnel and financial) <p style="text-align: center;">MINIMAL IMPACT</p>	<ul style="list-style-type: none"> • Who/what is available/essential for the local implementation? • Are they adequately trained? If not, is training available and affordable? • What is needed to tailor the intervention locally? • What are the full costs? <ul style="list-style-type: none"> ○ <i>Consider: in-kind staffing,</i> 	<ul style="list-style-type: none"> • Can be implemented using current clinic resources. • A generous estimate of the potential number of pregnant women in Peel that might seek immunization against flu is 160 (based on H1N1 uptake in Canada). Of these only a

Factors	Questions	Notes
	<p><i>supplies, systems, space requirements for staff, training, and technology/administrative supports.</i></p> <ul style="list-style-type: none"> • Are the incremental health benefits worth the costs of the intervention? <ul style="list-style-type: none"> ○ <i>Consider any available cost-benefit analyses that could help gauge the health benefits of the intervention.</i> ○ <i>Consider the cost of the program relative to the number of people that benefit/receive the intervention.</i> 	<p>proportion would seek vaccine at community based clinics.</p> <ul style="list-style-type: none"> • Minor costs to administer vaccine would be outweighed exponentially by the savings to the system related to hospitalization of even one pregnant woman due to influenza.
<p>Organizational expertise and capacity</p> <p style="text-align: center;">STRONG</p>	<ul style="list-style-type: none"> • Is the intervention to be offered in line with Peel Public Health's 10-Year Strategic Plan (i.e., 2009-2019, 'Staying Ahead of the Curve')? • Does the intervention conform to existing legislation or regulations (either local or provincial)? • Does the intervention overlap with existing programs or is it symbiotic (i.e., both internally and externally)? • Does the intervention lend itself to cross-departmental/divisional collaboration? • Any organizational barriers/structural issues or approval processes to be addressed? • Is the organization motivated (learning organization)? • <i>Consider organizational capacity/readiness and internal supports for staff learning.</i> 	<ul style="list-style-type: none"> • Does conform to expectations of PH under Provincial Program Standards. • Consistent with other programs and allows for inclusion of pregnant women in other immunization services, e.g. vaccine recommended during pregnancy that are administered at Routine Immunization Clinics and schools. • No identified barriers. Medical Directives and assessment tools will have to be updated accordingly. • Messaging to other programs that interact with pregnant women will be required (e.g. family health prenatal instructors) • Staff are supportive of the change as long as they have the information they need to answer questions that clients have.
Transferability (generalizability)		
<p>Magnitude of health issue in local setting</p>	<ul style="list-style-type: none"> • What is the baseline prevalence of the health issue locally? • What is the difference in prevalence of the health issue (risk status) between study and local settings? <ul style="list-style-type: none"> • <i>Consider the Comprehensive</i> 	<ul style="list-style-type: none"> • The 2008 incidence rate of influenza in Peel was 35/100,000 which was comparable to the provincial rate. The number of pregnant women in Peel affected is

Factors	Questions	Notes
SMALL (similar to other jurisdictions)	<i>Health Status Report, and related epidemiological reports.</i>	<p>unknown but is likely to be small in total numbers. Despite that, each case of influenza illness in a pregnant woman has the potential for grave outcomes and considerable cost to the acute care system because hospitalization and death are more likely for pregnant women.</p> <ul style="list-style-type: none"> • It is estimated that 600 pregnant women were immunized at special PPH clinics during H1N1. Of those one AEFI was reported 2.5 days post vaccination that was subsequently determined by the physician to not be vaccine related (had symptoms consistent with a cold). No other incidents were reported. • Based on early numbers from H1N1 presented by PHAC at CPHA conference in June 2010, of the total doses of H1N1 vaccine given, .8% was to pregnant women. Peel administers approximately 13,000 doses annually if that were increased to 20,000 as a generous estimate, assuming a high uptake year; at .8% that would equal 160 pregnant clients.
Magnitude of the “reach” and cost effectiveness of the intervention above	<ul style="list-style-type: none"> • Will the intervention appropriately reach the priority population(s)? <ul style="list-style-type: none"> ○ What will be the coverage of the priority population(s)? 	<ul style="list-style-type: none"> • Yes. • Cost of one case of influenza
Target population characteristics	<ul style="list-style-type: none"> • Are they comparable to the study population? • Will any difference in characteristics (e.g., ethnicity, socio-demographic variables, number of persons affected) impact 	<ul style="list-style-type: none"> • The literature reviewed provided no explicit identification of race or ethnicity having an impact on safety to administer vaccine

Factors	Questions	Notes
	intervention effectiveness locally? <ul style="list-style-type: none"> ○ <i>Consider if there are any important differences between the studies and the population in Peel (i.e., consider demographic, behavioural and other contextual factors).</i> 	to pregnant women and there is no plausible connection. <ul style="list-style-type: none"> • Although total costs were not calculated the cost related to hospitalization of even one pregnant woman due to influenza would far outweigh the cost of including pregnant women in PPH clinics.
<p>Proposed Direction (after considering the above factors):</p> <p>That Peel Public Health include pregnant women in the inclusion criteria for vaccination with those antigens that are approved and recommended for them.</p>		

Form Completed by: Loretta Rowan

Worksheet adapted from: Buffet C., Ciliska D., and Thomas H. National Collaborating Centre for Methods and Tools. November 2007. *Can I Use this Evidence in my Program Decision? - Assessing Applicability and Transferability of Evidence.*