# Physician Barriers in Recommending Flu Vaccine to Healthy Pregnant Women

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# THESIS

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# II. List of Abbreviations

- ACIP Advisory Committee of Immunization Practices
- ACOG American College of Obstetricians and Gynecologists
- CDC Centers for Disease Control and Prevention
- FDA US Food and Drug Administration
- FM Family Medicine
- GBS Guillain-Barre syndrome
- ILI Influenza-like illnesses
- IOM Institute of Medicine
- LAIV Live Attenuated Influenza Vaccine
- NK Natural killer cells
- OB/GYN Obstetrics and Gynecology
- OHA Oregon Health Authority
- OHSU Oregon Health & Science University
- **PSU Primary Sampling Unit**
- Th1 T-helper type I response. Cell-mediated immunity
- Th2 T-helper type II response. Humoral immunity
- TIV Trivalent Inactive Vacccine
- VAERS Vaccine Adverse Event Reporting System
- VSCEP California Vaccine Storage Capacity Expansion Program
- VFC Vaccine for Children

# III. Abstract

*Background*: Pregnancy is an immunosuppressed state which develops so that a woman may tolerate a genetically different fetus. This suppressed state poses an increased risk of infections such as influenza among pregnant women. In fact, several established organizations including the Centers for Disease Control and Prevention (CDC), the American College of Obstetricians and Gynecologists (ACOG), and the Advisory Committee of Immunization Practices (ACIP) have proposed that all women who are pregnant during the influenza season should be vaccinated <sup>1-5</sup>. Despite federal and state recommendations, only 51% of surveyed pregnant women in the US were estimated to have received the influenza vaccine during the 2009-2010 influenza season <sup>6</sup>.

*Objective*: The main purpose of this study is to determine if a physician's specialty background and practice location affect routine recommendation (i.e. 91-100% of the time) of flu vaccine to healthy pregnant women. In addition, this study aims to identify physician barriers to offering flu vaccine to pregnant patients. These barriers include beliefs, lack of proper storage facilities, cost, and whether or not offering flu vaccine to pregnant patients is part of routine patient-care activities.

*Study Design*: A cross-sectional survey of Obstetrics and Gynecology (OB/GYN) and Family Medicine (FM) physicians who have active licenses with Oregon's Board of Medical Examiners (BME) and have provided prenatal care within the last 12 months.

*Methods*: This study uses a mixed-mode design. A self-administered, paper survey was initially sent out to 1,114 physicians with an attached cover letter and a pre-paid return envelope. These physicians were given an option to return the questionnaire through regular mail, on-line internet form, fax, or email. Two weeks after the initial mail-out, reminder postcards were sent out to non-responders. Final reminders were done by telephone communication and occurred four weeks after the initial mail-out.

*Analysis*: Responses to each question were compared by specialties (OB/GYN vs. FM) and location (rural vs. urban) using Yates Corrected  $\chi^2$  or Fishers Exact Test when more than 25% of the cells had expected counts less than 5. All p-values were compared to an alpha significance level of .05. All statistical analysis, tables and figures were done using SAS v9.3 and Stata/IC 11.2.

*Results*: Of the 1,114 providers surveyed, 496 (44.5%) completed the survey. Twentynine subjects were either unreachable or inactive and were dropped from the study producing an adjusted response rate of 45.7%. Among the 496 completed surveys, 187 (37.7%) provided prenatal care within the past 12 months and were kept for further analysis. Similar proportions of OB/GYNs and FMs were found to routinely (i.e. 91-100% of the time) recommend flu vaccine to their healthy pregnant patients (89.2% vs. 87.6%; p-value = .5638). This did not vary between rural and urban locations.

Although ACIP currently recommends flu vaccine at any time during gestation, fewer than 50% of OB/GYNs and FMs indicated they would recommend flu vaccine at 'any time.' Among the remaining 50%, more OB/GYNs than FMs indicated they would

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only recommend flu vaccine at first encounter with their pregnant patient (44.5% vs 27.0%; p-value < .0001), and more FMs than OB/GYNs indicated they would only recommend flu vaccine during  $2^{nd}$  or  $3^{rd}$  trimester (15.4% vs 2.5%; p-value < .0001).

Among those that did not routinely recommend flu vaccine, a higher proportion of OB/GYNs than FMs reported the belief that benefits of the flu vaccine outweigh the risk in pregnant women (100.0% vs. 78.0%; p-value < .001). This did not vary between rural and urban locations. Similar proportions of OB/GYNs and FMs indicated they had sufficient storage units to store flu vaccines (89.4% vs. 100.0%; p-value = .056). However, after stratifying by location, few rural than urban OB/GYNs indicated they had the capacity to adequately store flu vaccines (54.5% vs. 100.0%; p-value < .001). A higher proportion of OB/GYNs than FMs reported inadequate reimbursement (19.1% vs 0.0%; p-value = .003) was a barrier to offering flu vaccine. After stratifying by location, more rural than urban OB/GYNs indicated that upfront cost (45.5% vs 0.0%; p-value < .001) and inadequate reimbursement (45.5% vs 11.1%; p-value = .023) were significant barriers. Furthermore, more rural than urban FMs indicated that offering flu vaccine was not part of their routine patient-care activities (22.5% vs 0.0%; p-value = .023).

*Discussion*: Similar proportions of OB/GYNs and FMs, regardless of practice location, were found to routinely recommend flu vaccine to healthy pregnant women. Subsequently, neither a physician's specialty background nor practice location affects routine recommendation of flu vaccine. The high proportions of physicians who routinely recommend also suggest that routinely recommending flu vaccine is not a significant factor to low vaccine coverage among healthy pregnant women. fewer than half of OB/GYN and FMs who provide prenatal care indicated they would recommend flu vaccine any time during pregnancy. Our data suggests that conversations reminding pregnant patients about the benefits and safety of the flu vaccine may be very minimal. While continuous outreaching to OB/GYNs and FMs who provide prenatal care would help to sustain the high proportion of physicians that routinely recommend flu vaccine to pregnant patients, guidelines should recommend that prenatal care providers have reminder conversations with their non-vaccinated pregnant patients at least once every trimester. These conversations should focus on the benefits, safety, and efficacy of the seasonal flu vaccine. These conversations will not only help improve vaccine coverage but will also help reduce the fear of vaccines in general.

Among the 11.6% of physicians who did not routinely recommend flu vaccine, the reported barriers varied by specialty. Cost-related and structural–related barriers were more prevalent among OB/GYNs. This includes inadequate reimbursement and upfront cost which was also more prevalent among rural than urban OB/GYNs. Furthermore, more rural than urban OB/GYNs lacked proper vaccine storage units. In contrast, belief and administrative-related barriers were more prevalent among FMs. In fact, 22% of FMs believed there was not enough evidence to assess the benefits and risk of flu vaccine in healthy pregnant women. This belief did not vary by practice location. More rural than urban FM's reported that offering flu vaccine was not part of their routine patientcare activities. This may be due to the fact that offering flu vaccine increases an already heavy workload, impedes the workflow, and is exacerbated by the delay in arrival of new vaccine after running out of existing supplies.

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Interventions that address these barriers may improve seasonal flu vaccine coverage among pregnant women. For example, reducing ordering cost and improving financial reimbursement would provide OB/GYNs a better incentive to offer flu vaccines from their practice site. Attempts should also be made to reduce the cost to storing seasonal flu vaccines. This can be achieved through a government subsidized program that reimburses physicians if they purchase a vaccine-quality storage refrigerator. This in turn would increase flu vaccine availability among OB/GYNs, especially in rural areas.

An education outreach to prenatal care providers is needed to impart information and awareness regarding the safety, efficacy and benefits of flu vaccine in pregnant women. This can be achieved by providing on-line courses for CME credits and should be made mandatory among FMs that provide prenatal care. Efforts should also focus on improving administrative procedures involved in ordering and administering flu vaccine. For example, improving flu vaccine inventory and patient reminder notification systems may decrease the burden of workload and disruption of workflow associated with offering flu vaccines among FMs. Although interventions targeting OB/GYNs and FMs have been suggested, concomitant intervention strategies targeting pregnant patients is also needed to improve seasonal flu vaccine coverage and to achieve an 80% seasonal flu vaccine coverage among pregnant women, an objective set by Healthy People 2020<sup>7</sup>.

#### IV. Introduction & Background

*Pregnancy Increases Risk to Flu and Flu-Like Illnesses.* Pregnancy is a risk factor for developing complications to seasonal flu infection <sup>8,9</sup>. These complications affect both the mother and fetus and are evident from the increased rate of hospitalizations and mortality. While the maternal changes that occurs during a healthy pregnancy is critical to bringing the fetus to full term, these physiological and immunological changes may also contribute to the increased risk of flu and flu-like illnesses <sup>10, 11, 12</sup>.

The mortality associated with influenza in pregnant women has been documented as early as 1918. During the 1918 flu season, 23% of pregnant women who had influenza-like illness died <sup>11</sup>. During the 1957 influenza epidemic, 22 pregnant women in New York City and 11 pregnant women in Minnesota died with "death attributed to respiratory dysfunction secondary to pulmonary edema and pneumonia" <sup>13</sup>.

The effect of influenza on healthy pregnant women is also made evident by the increased hospitalization rates during the flu season. In a retrospective study of a Tennessee Medicaid population that looked at flu seasons from 1974 to 1993, healthy pregnant women in the first, second and third trimesters were reported to have influenza-attributable, excess hospital admission rates of 3.06, 6.32 and 10.48 per 10,000 woman-months, respectively; in contrast, the excess hospital admission rate for non-pregnant women of child-bearing age was 1.91 per 10,000 woman-months<sup>14</sup>. In another retrospective study in Nova Scotia, Dodds et al observed a similar pattern of increasing hospitalization rates with increasing length of pregnancy: 2.4 in the first trimester, 3.0 in

the second trimester and 7.4 in the third trimester per 10, 000 woman-months<sup>15</sup>. In New York during the 2009 H1N1 epidemic, the severe case hospitalization rate was 4.3 times higher for pregnant than non-pregnant women of reproductive-age<sup>16</sup>.

Hospitalizations rates are even higher among pregnant women with comorbidities (including asthma, chronic heart disease, lung disease, renal disease, human immunodeficiency virus infection, diabetes mellitus, and cancer) <sup>17</sup>. For example, during eight influenza seasons (1985-1993), Hartert et al observed that pregnant women with a history of asthma had the highest rate of respiratory hospital admission (597 per 10,000) compared with healthy pregnant women (26 per 10,000) <sup>17</sup>. In a study that used the Healthcare Cost and Utilization Project National Inpatient Sample (NIS) of four flu seasons (1998-2002), Cox et al observed that respiratory illness was 3.2 times more likely to be present among hospitalized pregnant women with a high-risk condition than among healthy pregnant women <sup>18</sup>. These studies indicate pregnant women are prone to increased hospitalization during the flu season, and the risk in morbidity increases as the length of pregnancy increases <sup>19, 20</sup>.

Complications to influenza infection have also been shown to affect the fetus and neonate. For example, some studies have observed an association between influenza and limb reduction, neural tube defects, and cleft lip <sup>21, 22, 23</sup>. Furthermore, pneumonia is known to be associated with low weight babies and preterm birth <sup>24</sup>. While complications of flu infection may affect a healthy pregnancy, transplacental transmission of influenza infection is rare and believed to present low viral risk to the fetus <sup>25</sup>. Nonetheless, there have been documented cases of in-utero infection that have

been confirmed by viral culture in amniotic fluid and fetal tissue. As early as 1970, Yawn et al identified the influenza virus in maternal tissues and amniotic fluid of a 19 year old pregnant woman who died in her third trimester after being admitted for an influenza-like syndrome and who otherwise had an uncomplicated pregnancy; the same viral isolate was also identified in the fetal heart <sup>26</sup>. In 2007, Gu et al isolated the same influenza A (H1NA) isolate from the placenta and fetal lung in two Chinese pregnant women <sup>27</sup>. More recently, Lieberman et al reported a case in 2008 where the same viral isolate, seasonal influenza A virus (H1N1), was found in both the maternal and fetal tissue; although this pregnant woman had an extremely healthy medical history, she lost her baby at the 20th week of gestation <sup>28</sup>. These few documented cases of transplacental passage of influenza virus are suggestive of biological plausibility and lends to causal association between maternal influenza infection and adverse fetal outcome.

*Seasonal Flu Vaccine:* The seasonal flu vaccine is a three component vaccine that is selected to protect against the three main groups of influenza virus in the human population from the previous year and determined by the US Food and Drug Administration (FDA). The three components of the 2010-2011 seasonal flu vaccine was made to protect against A/California/7/2009 (H1N1)–like virus, A/Perth/16/2009 (H3N2)–like virus, and a B/Brisbane/60/2008–like virus <sup>29</sup>. Subsequently, the 2010-2011 flu vaccine distributed in the US was made to protect against the 2009 H1N1 virus, and two other influenza viruses (H3N2 and an influenza B virus).

There are two main types of influenza vaccines. The first is an inactivated vaccine which is administered by injection and cannot cause the flu. This vaccine has been

manufactured with and without a preservative called thimerosal and is recommended for pregnant women <sup>30</sup>. The second type is a live attenuated influenza vaccine (LAIV) and is administered as a nasal spray. This vaccine contains a weakened form of the influenza virus and is not recommended for pregnant women <sup>31</sup>.

Safety and Effectiveness of Seasonal Flu Vaccine. The trivalent inactive seasonal flu vaccine (TIV) is safe for healthy pregnant women. In a retrospective study that looked at five influenza seasons (July 1998 to June 2003) in a large Texas clinic, Munoz et al compared 225 healthy pregnant women vaccinated with the flu vaccine to 826 matched, healthy non-vaccinated pregnant women (control group)<sup>32</sup>. This study showed no increase in the rate of hospitalization of vaccinated pregnant mothers, and the most common causes of hospitalization among the vaccinated group (including cesarean delivery, labor threatened prematurely, labor threatened at term, and spontaneous rupture of the membrane) did not differ from that found in the control group. Furthermore, there was no increase in the frequency of fever, preeclampsia, eclampsia, or problems of the fetus as compared to non-vaccinated pregnant women. In a 2005 randomized control study in Bangladesh, Zaman et al. assigned 340 pregnant mothers to receive either the influenza vaccine or the pneumococcal polysaccharide vaccine (control group)<sup>33</sup>. This study also showed no significant difference in the frequency of adverse events between influenza vaccinated pregnant mothers and the control group. Finally, a review of the adverse events from 1990-2009 reported to the Vaccine Adverse Event reporting System (VAERS), a national surveillance system, revealed no unusual patterns of adverse events among pregnant women that received TIV <sup>34</sup>. The VAERS data reported spontaneous abortion as the most commonly reported adverse event among vaccinated pregnant

women which occurred at a rate of 2 cases per million vaccinated pregnant women <sup>34</sup>. The lack of any unusual patterns of adverse events supports the existing evidence on the safety of flu vaccine in healthy pregnant women <sup>35, 36, 37, 38</sup>.

Maternal immunization of seasonal flu vaccine has also been shown to be safe to the fetus. In the 2005 Texas clinic study, Munoz et al followed children up to 6 months of age and found no increase in the rate of premature birth and infant medical conditions in infants born to vaccinated mothers <sup>32</sup>. These results are consistent with those found in a longitudinal study that followed children for 7 years and found no increase in stillbirths, congenital malformations, malignancies, or neurocognitive disabilities among those born to vaccinated mothers as compared to children born to non-vaccinated mothers <sup>39</sup>. Maternal influenza vaccine has been shown to be effective in reducing the amount of hospitalization and influenza-like illnesses (ILI) in both mother and infant. In the 2005 Bangladesh randomized control study, fewer cases of laboratory-confirmed influenza were observed among infants born to maternal influenza vaccinated mothers (6 cases) as opposed to those born to non-vaccinated mothers (16 cases); in this same study, Zaman et al reported a reduced rate of influenza-like illness (including respiratory illnesses with fever) by 36% in mothers and 29% in their infants up to 6 months of age <sup>33</sup>. In another study, Eick et al showed that infants born to influenza vaccinated mothers were 41% less likely to have laboratory-confirmed influenza virus infection as compared to infants born to non-vaccinated mothers <sup>40</sup>. Similar results were found in a separate retrospective study of seven influenza seasons (2002-2009) that observed a 44-48% reduction in influenza hospitalization of infants born to vaccinated mothers <sup>41</sup>. The studies described above

underscore the importance that maternal influenza vaccination can have in protecting their newborn <sup>42, 43, 44</sup>.

Despite the cumulative evidence supporting the safety and efficacy of the seasonal flu vaccine, some public concern has arisen from rare reports of adverse effects and deserves some discussion. For example, Guillain-Barre syndrome (GBS), an autoimmune disease of the nervous system, was found to be linked to influenza vaccine during the 1976-1977 swine flu pandemic <sup>45</sup>. This suspected link was due to the finding that 1 additional case per 100,000 people who received the swine flu vaccination was at greater risk of GBS <sup>46</sup>. This risk was not observed in the 2009 H1N1 pandemic and has not been observed since 1976<sup>47,48</sup>. In fact, 120-300 cases per 10 million people in the US are estimated to develop GBS regardless if they received the influenza vaccine or not  $^{49}$ . To date, there exists no evidence to support a causal association between the seasonal flu vaccine and GBS <sup>50, 51</sup>; moreover, no GBS cases had been observed in any of the studies cited above. Another concern of the flu vaccine stems from a mercury-containing compound, called thimerosal, which is used to prolong vaccine storage by reducing microbial growth. This fear grew out of a fraudulent study that suggested an association between MMR vaccine and autism and was later retracted from a popular journal <sup>52</sup>. Several studies have rejected any causality between thimerosal and autism <sup>53, 54, 55</sup>, and there is no scientific evidence that suggests thimerosal-containing vaccines cause adverse events in infants born to mothers who received the influenza vaccine during pregnancy <sup>56, 57</sup>. Nonetheless, in an effort to reduce public fear of vaccines, thimerosal-free versions of TIV have been made available 58.

*National Guidelines*. Several federal and local agencies recommend administering flu vaccine to healthy pregnant women. These agencies comprise of experts in various medical and scientific fields who extensively review existing studies to guide safe and best immunization practices.

The Advisory Committee on Immunization Practices (ACIP) is a federal entity consisting of 15 experts in immunization as well as 8 active members who represent other federal agencies <sup>59</sup>. Selected by the Secretary of the US Department of Health and Human Services, ACIP reviews existing evidence and develop written recommendations for the routine administration of vaccines which are commonly accepted by most states.

ACIP acknowledges pregnant women as a high-risk subpopulation and recommends that all pregnant women who are or will be pregnant during the influenza season receive the flu shot unless contraindications are present <sup>61</sup>. Furthermore, ACIP recommends that pregnant women be given the trivalent inactivated vaccine (TIV) and not the live attenuated vaccine <sup>1</sup>. Contraindications to TIV include anaphylactic hypersensitivity to eggs or components of the influenza vaccine. These current recommendations for seasonal flu vaccine have been the same over the past eight years. Prior to 2003, ACIP recommended administering seasonal flu vaccine to pregnant women only during their second or third trimester <sup>2</sup>. However, as of 2004, ACIP recommends administration of seasonal flu vaccine at any time during pregnancy and remains the current standard recommendation <sup>1, 3, 4</sup>.

The American Congress of Obstetricians and Gynecologists (ACOG) and the National Vaccine Advisory Committee (NVAC) also support the current recommendations made by ACIP <sup>5, 60</sup>. ACOG further states that "annual immunization is the most effective strategy for preventing influenza during pregnancy" <sup>5</sup>. NVAC further recommends outreaching to health-care providers who do not usually supply vaccination services which includes obstetricians/gynecologists and internists <sup>60</sup>.

Finally, in a joint letter addressed to the Department of Health and Human Services, the American Academy of Family Physicians (AAFP), American Academy of Pediatrics (AAP), American College of Nurse-Midwives (ACNM), American College of Obstetricians and Gynecologists (The College), American Medical Association (AMA), American Nurses Association (ANA), American Pharmacists Association (APhA), Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN), March of Dimes, and Centers for Disease Control and Prevention (CDC) support ACIP's recommendations on administering seasonal flu vaccine to pregnant women in any trimester <sup>61</sup>. This joint letter further supports the safety of seasonal TIV among pregnant women and stresses the important role that healthcare providers have in urging their pregnant patients to be vaccinated against seasonal influenza.

*Vaccine Coverage among Healthy Pregnant Women.* Despite the existing evidence and the several recommendations made by federal and international agencies, seasonal flu vaccine coverage among pregnant women has been traditionally low.

The 2006-2007 seasonal vaccine coverage among pregnant women was 13.4% and represents a minor increase from the preceding 2005-2006 flu season which saw only

12.3% of pregnant women vaccinated <sup>62 63</sup>. These two coverage rates were based on information gathered by the National Health Interview Survey (NHIS). A significant increase, however, was observed during the 2007-2008 flu season with a seasonal flu vaccine coverage rate of 24.2% <sup>62</sup>. However, this estimate has been criticized for having a small sample size based on NHIS data and may not reflect the actual vaccine coverage rates in each state or city <sup>62, 64</sup>. For example, Ahluwalia et al used data from the Pregnancy Risk Assessment Monitoring System (PRAMS) to report a vaccine coverage rate of 18.4% in Georgia and 31.9% in Rhode Island, both of which combines the 2006 and 2007 flu season <sup>65</sup>. PRAMS is a population-based surveillance system that continuously collects information on maternal and child health using a standardized core questionnaire from 37 participating states and territories <sup>6</sup>. Based on NHIS data, the vaccine coverage rate of the 2008-2009 flu season dropped back down to 13.4% <sup>66</sup>.

A record high was achieved during the 2009-2010 flu season. Using PRAMS data from 10 states, Ahluwalia et al reported a 50.7% vaccine coverage rate for pregnant women in the US <sup>6</sup>. These 10 states were the only ones that met the inclusion criteria of having a survey response rate over 65%. This coverage rate was similar to the 47.1% median reported by the CDC which used PRAMS data from 29 states and NY City <sup>67</sup>. The doubling of the vaccine coverage rate from the previous flu season was an achievement and may have been motivated by the 2009 H1N1 pandemic. This coverage rate has been sustained during the more recent 2010-2011 flu season which the CDC reported to be 49% based on an internet panel survey <sup>66</sup>. Although, the past two flu seasons have a record high in vaccine coverage among pregnant women in the US, it is still below the

Healthy People 2020 objective of 80%<sup>7</sup>. Much work is still needed to improve seasonal flu vaccine coverage among pregnant women.

# Survey Design:

Several methods and strategies have been developed to increase response rates <sup>68, 69, 70</sup>. For example, Dillman's Tailored Design Method (TDM) aims to maximize survey participation by reducing the encumbrance associated with survey participation <sup>71</sup>. The core of this method is based upon the Social Exchange theory, a social psychological theory, which proposes social behavior (i.e. survey participation) can be enticed through a process of mutual exchange <sup>72</sup>. Van Geest has reviewed several strategies to improve response rates among physicians and has categorized them into two main categories <sup>68</sup>: 1) incentive-based interventions (monetary and non-monetary), and 2) design based approaches (personalized mailings, design-friendly questionnaires, sponsorship).

*Monetary vs. non-monetary*: Studies have shown that upfront, monetary incentives often yield high response rates <sup>70, 73, 74</sup>. In a review of several studies, VanGeest et al (2007) determined the odds of obtaining an increased response rate when using a monetary incentive was 2.13 (95% CI: 1.7-2.6) times that when incentives are not used <sup>68</sup>. Monetary incentives of higher value have shown mixed results <sup>68, 74</sup>. For example, VanGeest et al (2001) observed a decrease in response rate when using a \$20 incentive (65.2%) as compared to when using a \$10 incentive (68.0%) <sup>75</sup>. It is possible that larger payments may be construed as payments, rather than a gesture of appreciation, and may affect physicians' willingness to participate in the survey.

Non-monetary incentives (i.e. candy, prize draws, and pens) do not increase response rates in physician surveys <sup>76, 77</sup>. For example, in a study among obstetricians and gynecologists, Moses et al found no difference in response rate between those that were offered a prize draw for a new PDA and those that were not offered the prize draw <sup>78</sup>. In fact, the overall odds of an increased response rate when using upfront, nonmonetary incentives has been determined to be 0.97 (95% CI: 0.82-1.14) times that of not using any incentive at all <sup>68</sup>.

Incentives conditioned on completing the survey also have not been shown to increase response rates <sup>79, 80</sup>. Among Canadian medical residents, Gubins et al used a monetary lottery incentive (\$1000 cash draw) and was unsuccessful in increasing the response rate in the 2007 Canadian National Physician Survey (27.9%) as compared to the response rate (35.6%) obtained in 2004, which did not use any incentives <sup>69</sup>. In contrast, Frederick et al obtained a response rate of 59% when using a paper survey and a \$1.00 donation to disaster relief efforts in South Asia for every survey completed; however, a response rate of only 26% was obtained when using an email survey and the same \$1.00 donation incentive <sup>81</sup>.

#### Design-Based Approaches:

*Length of Questionnaire*: If lack of time is a common reason that physicians do not participate in surveys, it seems reasonable that short questionnaires favor higher response rates. In fact, Hing et al determined the odds of a high response rate when using a shorter questionnaire was 1.78 (95% CI: 1.01-3.12) times that of using a long questionnaire <sup>82</sup>. Jespon et al also determined that the odds or a high response rate when using 1000 words

on the questionnaire was 2.3 (95% CI: 1.20-4.61) times that of using questionnaire with more than 1000 words  $^{83}$ .

*Single vs. double-sided*: Brehaut et al showed that a single-sided questionnaire yielded a 7% increase in response rate than using a double-sided questionnaire <sup>84</sup>. Also, it is possible that some participants may forget to look on the other side of a double-sided questionnaire resulting in a partially completed questionnaire. This partially completed questionnaire may have to be excluded due to incompleteness and subsequently any existing data will have been wasted. Therefore, single-sided questionnaire may reduce the likeliness of incomplete questionnaires.

*Cover letters*: Personalized cover letters provide a means to convey the importance of the study and helps to increase response rates. For example, Leece et al observed a 17% point increase in response rate if a personalized cover letter was used <sup>85</sup>. The odds of an increased response rate when using a personalized cover letter has been determined to be 1.51 (95% CI: 1.1-2.2) times that when a personalized cover letter is not used <sup>68</sup>. Personalized cover letters that are endorsed by agencies can also have a large impact on response. Asch et al observed a 20% point increase in response rate when using a Veterans Affair endorsement rather than a regular university endorsement on the envelopes <sup>86</sup>. However, Bhandari et al observed that response rates will not be increased if the endorsement comes from an agency which is not perceived as favorable by the study participants <sup>87</sup>.

*Delivery mode*: Several studies have shown that paper surveys are more superior than using web-based methods when surveying physicians <sup>68, 88, 89</sup>. In a meta-analysis of 39 published studies, Shih et al found a 23% decrease in response rate when using webbased surveys as opposed to using paper surveys among professional (i.e. physicians) <sup>90</sup>. According to Ackl et al, postal mail produced a better response rate among internal medicine residents and faculty than using electronic surveys <sup>88</sup>. Furthermore, Hocking et al observed that postal surveys with three reminders had a better response rate than a telephone interview among physicians <sup>91</sup>.

Several studies suggest that high response rates can be achieved using several different modes for a particular survey <sup>92-96</sup>. This mixed-mode design is often successful because it accommodates physicians' preferences to completing and returning questionnaires <sup>94</sup>. For example, Beebe et al observed that a methodology "using an initial mailing of a self-administered form followed by a web survey to nonrespondents provides slightly higher response rates" than using a single mode of delivery among physicians <sup>97</sup>. Dillman et al also suggests that a different technique than the original attempt should be used in order "to improve their effectiveness in obtaining maximum response" <sup>71</sup>.

# V. Materials & Methods

This study received approval from the Oregon Health & Sciences University Institutional Review Board (IRB).

#### **Study Design**

A cross-sectional, self-administered survey was distributed to a random sample of Oregon physicians whose specialty was either Obstetrics and Gynecology (OB/GYNs) or Family Medicine (FM) and had at least a two-year active license with Oregon's Board of Medical Examiners (BME). The primary sampling unit (PSU) used in this study was specialty type. The study began on September 1st, 2011 and ended December 15th, 2011 and questions the 2010-2011 flu season.

A 'master list' consisting of only OB/GYN and FM physicians currently licensed with BME was provided by Dr. Anne Thomas of the Oregon Department of Human Services and was used for projects prior to this study. This list consisted of 2,827 physicians. Subjects with 'Locum Tenens,' 'Military/Public Health,' or 'one-year active' licenses as well as those with 'temporary limited practice' license limitations were dropped from the study. Subjects with no practice address, subjects whose practice location was not Oregon, and any duplicate entries were also dropped from the study. This resulted in a new list comprising of 2,253 physicians and from here on will be referred to as the Target Population (N=2,253). This Target Population consisted of 1,711 FMs (538 rural and 1,173 urban) and 542 OB/GYNs (86 rural and 456 urban). Rural and urban locations were classified by zip code using the Rural Urban Commuting Areas (RUCA) version 2 code <sup>98</sup>. After stratifying by rural/urban locations and gender, the PSU's were randomly sampled in proportions similar to the Target Population. More specifically, 834 FMs (262 rural and 572 urban) and 280 OB/GYNs (45 rural and 235 urban) were randomly selected and is here on referred to as the Frame Population (n=1,114). The proportion of each gender in the Target Population was also factored into the sample selection. For example, among rural physicians, 33% were female and 67% were male in the Frame Population (Target Population: 32% female and 68% male); among urban physicians, 47% were female and 53% were male in the Frame Population (Target Population: 47% female and 53% male).

#### **Inclusion Criteria**

There were three criteria for eligibility to participate in the study: 1) specialty was either OB/GYN or Family Medicine, 2) active licenses of two or more consecutive years with the Board of Medical Examiners (BME), and 3) provided prenatal care within the last 12 months upon receipt of the survey.

#### **Exclusion Criteria**

Subjects with 'locum tenens' or 'military/public health' licenses, subjects with restricted one-year active licenses, subjects with no practice address in Oregon, and subjects that did not provide prenatal care within the last year were excluded from the study.

Of the 1,114 physicians surveyed, 29 physicians were classified as either 'unreachable' or 'inactive' during the study period and dropped from the study. 'Unreachable' was

defined if the subject could not be contacted and no forwarding address could be found (n=22). 'Inactive' during the study period was defined if subject confirmed he/she had moved to a different state or retired at least one year prior to the beginning of the study (n=7). The adjusted frame population consisted of 1085 physicians.

# **Survey Design**

*Survey Instrument.* A self-administered, paper questionnaire was specifically designed for this study with the help of my committee. The survey was also posted on-line through use of SurveyMonkey. The survey consisted of 12 questions: 8 single-answer questions, 3 multiple-answers questions, and 1 open-ended question. The questionnaire was printed onto two, single-sided pages and consists of approximately 500 words.

*Survey Content.* The survey consists of a 2-page personalized cover letter (see Appendix A) and a 2-page questionnaire (see Appendix B). The personalized cover letter served two purposes: 1) to convey the importance of the study, and 2) to acknowledge participants' informed consent upon completing and returning the questionnaire. The cover letter used simple language and contained OHA endorsement. The cover letter also provided a URL link where the survey could be completed online as well as a fax number and email address in order to facilitate each physicians preference to completing and returning the questionnaire. The questionnaire. The complete.

# **Survey Delivery**

A three tier methodology was used to deliver the survey. The first wave of the survey was mailed out to 1,114 physicians using first class mail. Each package consisted of the questionnaire (2 pages), a personalized cover letter (2 pages), and a postage-paid return envelope.

The second wave involved sending out reminder postcards to physicians who had not returned their questionnaires. These reminder postcards were sent two weeks after the initial mailing. Replacement questionnaires were not used. However, a URL link, fax number, email address and contact information was provided on the postcard.

The third wave served as a final reminder and involved telephone communication. If the physician could not be reached, messages were left with the physician's assistant, voicemail, or the administrative staff.

# **Data Collection**

Data were collected and initially entered into an Excel spreadsheet. This spreadsheet was then entered into SAS v9.2 for further data cleaning.

No names or addresses were recorded on the questionnaires. Only numbers that were randomly assigned to each physician were recorded on the questionnaire. Subsequently, there was no identifiable information in the survey itself, and the completed questionnaires were identified by these numeric codes. A master list linking physician with code was kept on a secure, password protected OHSU workstation and was used to

link the subjects with their zip code in order to analyze patterns in rural versus urban practices. The master list was destroyed upon completion of the study.

#### **Statistical Analysis**

All p-values were calculated using Yates Corrected  $\chi^2$ , unless indicated. Exact binomial test was used to compare the respondents to the target population. Fishers Exact Test was used for tables where more than 25% of the cells have expected counts less than 5. Statistical significance was determined at an alpha level of .05. Stata/IC 11.2 was used to randomly sample PSU's from target population. All statistical analysis, graphs, and figures were produced using SAS v9.3 and Stata/IC 11.2.

*Power and Sample Size*: From a discussion with the committee, it was anticipated that only 30% of OB/GYNs routinely recommended flu vaccine to healthy pregnant women and 70% had not. This conservative estimate was based on the finding that approximately 40% of surveyed pregnant women did not have conversations with their physicians regarding seasonal flu vaccine <sup>65</sup>. Therefore, based on a one-sided test of binomial proportions at an  $\alpha$  level of .05, a total sample size of 334 physicians would provide 80% power to detect at least a 10% difference in the proportion of family physicians that routinely recommended flu vaccine among pregnant women. Since the true population of family practitioners is 3 times the amount of OB/GYNs, the sample population would consist of 250 family practitioners and 84 OB/GYNs. Furthermore, based on a conservative 30% response rate, it is suggested that 280 OB/GYNs and 834 family practitioners should be surveyed (n=1114).

*Weights*: Base weights were calculated as the inverse of the probability of selection of each PSU and stratified by rural and urban location. The non-response adjustment factor was calculated using the weight class adjustment (WCA) approach. In this approach, the responders and non-responders were classified into groups by age and gender. The final weight was obtained by multiplying the base weight by the non-response adjustment factor. All formulas and calculations were carried out as described by Levy et al <sup>99</sup>.

# VI. Results

## **Response Rate**

Of the 1,114 surveys sent out, 496 were returned yielding a response rate of 44.5%. However, 29 subjects were unreachable or inactive as described in 'Material & Methods.' This resulted in an adjusted response rate of 45.7%. Of the 496 surveys returned, 187 reported they provided prenatal care within the last 12 months and were kept for further analysis.

# Distribution of OB/GYNs and FMs who Provide Prenatal Care

During the 2010 flu season, approximately 71.5% OB/GYN and 21.9% Family Medicine (FM) physicians provided prenatal care in Oregon (see table 1). Among OB/GYNs, 20.5% provide prenatal care in rural areas and 79.5% provided prenatal care in urban areas; among FMs, 40.0% provide prenatal care in rural areas, and 60.0% provide prenatal care in urban areas (see table 1). In rural areas, there are approximately 1.6 times more FMs than OB/GYNs who provide prenatal care; whereas in urban areas, there are approximately 1.6 times more OB/GYNs than FMs (see figure 1).

| Distribution of Physicians that Do & Do Not Provide Prenatal Care, by Location |                          |                           |                 |                           |                           |                  |  |  |
|--|--------------------------|---------------------------|-----------------|---------------------------|---------------------------|------------------|--|--|
| Provides<br>Prenatal Care  |                          | OB/GYN                    |                 | FM                        |                           |                  |  |  |
| FrequencyImage: Col PctImage: Col PctRow PctRuralUrbanTotal                    |                          |                           | Rural           | Urban                     | Total                     |                  |  |  |
| Yes  | 89.125<br>83.41<br>20.51 | 345.395<br>69.00<br>79.49 | 434.52<br>71.53 | 141.306<br>25.84<br>40.03 | 211.735<br>19.85<br>59.97 | 353.041<br>21.88 |  |  |
| Total  | 106.847                  | 500.603                   | 607.45          | 546.917                   | 1066.461                  | 1613.378         |  |  |

Table 1: OB/GYNs and FMs who Provide Prenatal Care, Stratified by Specialty & Location

All values represent weighted results





# Bias

After stratifying by location (urban vs rural) and gender, there did not appear any bias between responders and non-responders (see table 2). However, there was slight evidence to suggest urban OB/GYNs and FMs were over-sampled (see table 3). Furthermore, no clustering patterns were evident when comparing zip codes between the responders and non-responders (see figure 2).

|                 |        | RESPONDERS |                | NON-<br>RESPONDERS |                |     |        |         |
|-----------------|--------|------------|----------------|--------------------|----------------|-----|--------|---------|
| Location Gender |        | FMs        | <b>OB/GYNs</b> | FMs                | <b>OB/GYNs</b> | n   | χ2     | p-value |
|                 |        | 120        | 44             | 204                | 47             |     |        |         |
| Unhan           | Male   | 0.7317     | 0.2683         | 0.8127             | 0.1873         | 415 | 3.3467 | 0.0673  |
| Urban           |        | 118        | 74             | 117                | 64             |     |        |         |
|                 | Female | 0.6146     | 0.3854         | 0.6464             | 0.3536         | 373 | 0.2798 | 0.5978  |
|                 |        | 82         | 12             | 97                 | 11             |     |        |         |
| Dunal           | Male   | 0.8723     | 0.1277         | 0.8981             | 0.1019         | 202 | 0.1253 | 0.7234  |
| Kural           |        | 35         | 11             | 42                 | 7              |     |        |         |
|                 | Female | 0.7609     | 0.2391         | 0.8571             | 0.1429         | 95  | 0.8737 | 0.3499  |

Table 2: Confirming Absence of Non-Response Bias

 Table 3: Representativeness of Sample

| n   | Observed                      | Expected  | True  | Observed   | P-value**   |
|-----|-------------------------------|---|---|--|---|
|     | k                             | K   | р   | Р  | (two-sided)   |
| 496 | 117                           | 118.64  | .2392   | .2359  | .916173   |
| 496 | 23                            | 18.30   | .0369   | .0464  | .281437   |
| 496 | 238                           | 258.71  | .5216   | .4798  | .065359   |
| 496 | 118                           | 100.34  | .2023   | .2379  | .050468   |
|     | <b>n</b><br>496<br>496<br>496 | n         Observed           496         117           496         23           496         238           496         118 | n         Observed         Expected           k         K           496         117         118.64           496         23         18.30           496         238         258.71           496         118         100.34 | n         Observed         Expected         True           k         K         p           496         117         118.64         .2392           496         23         18.30         .0369           496         238         258.71         .5216           496         118         100.34         .2023 | n         Observed         Expected         True         Observed           k         K         p         P           496         117         118.64         .2392         .2359           496         23         18.30         .0369         .0464           496         238         258.71         .5216         .4798           496         118         100.34         .2023         .2379 |

\*\* Used Two-Sided Exact Binomial Test

| <b>T</b> ' 0 | ~ ·                                   | $C_1$ $\cdot$ $\cdot$ $1$ $T_2$ |                 | D 1   | IN D I           |
|--------------|---------------------------------------|---------------------------------|-----------------|---|------------------|
| Figure 2:    | Comparing                             | Clustering by Zi                | b Codes Between | Responders an   | d Non-Responders |
| 0            | · · · · · · · · · · · · · · · · · · · |                                 |                 | The second se |                  |



# **PRIMARY & SECONDARY OBJECTIVES:**

# **Frequency of Recommending Flu Vaccine**

*Almost always/Routinely (91-100%)*: The proportion of OB/GYNs (89.2%) as compared to FMs (87.6%) that 'routinely' recommend flu vaccine to pregnant women was found to be statistically similar (p-value = .5638) (see table 4 and figure 3).

*Less than Routinely* ( $\leq$  90%): When considering OB/GYNs and FMs combined, 11.6% of physicians did not routinely recommend flu vaccine to healthy pregnant patients and are described below. Furthermore, only 5.0% of FMs and no OB/GYNs reported to recommend flu vaccine either occasionally or rarely (see table 4 and figure 3).

| Frequency of Flu Vaccine Recommend |                                   |         |        |  |  |  |
|------------------------------------|-----------------------------------|---------|--------|--|--|--|
| Flu vaccine recommended            | Flu vaccine recommended Specialty |         |        |  |  |  |
| Frequency<br>Col Pct               | OB/GYN FM p-valu                  |         |        |  |  |  |
| Almost Always/Routinely            | 387.395                           | 309.179 | .5638  |  |  |  |
| (91-100%)                          | 89.15                             | 87.57   |        |  |  |  |
| Most of the time                   | 47.125                            | 26.0292 | .1221  |  |  |  |
| (76-90%)                           | 10.85                             | 7.37    |        |  |  |  |
| Occasionally                       | 0                                 | 13.895  | <.0001 |  |  |  |
| (25-50%)                           | 0.00                              | 3.94    |        |  |  |  |
| Rarely                             | 0                                 | 3.9375  | .040*  |  |  |  |
| (11-24%)                           | 0.00                              | 1.12    |        |  |  |  |

Table 4: Frequency of Recommending Flu Vaccine

\* Used Fishers Exact Test

All values represent weighted results





## Effect of Location on the Frequency of Recommending Flu Vaccine

*Almost always/Routinely (91-100%)*: The proportion of OB/GYNs who 'routinely' recommend flu vaccine did not vary between rural and urban areas (87.7% vs. 89.5%; p-value = .7500) (see table 5). Similarly, the proportion of FMs who 'routinely' recommend flu vaccine also did not vary between rural and urban areas (87.6% vs. 87.6%; p-value = 1.000) (see table 5).
| Frequency of Recommending Flu Vaccine By Location |                 |                 |         |                  |                  |         |  |
|---|-----------------|-----------------|---------|------------------|------------------|---------|--|
| How often flu<br>vaccine is<br>recommended        |                 | OB/GYN          | ſ       |                  | FM               |         |  |
| Frequency<br>Col Pct                              | Rural           | Urban           | p-value | Rural            | Urban            | p-value |  |
| Almost<br>Always/Routinely<br>(91-100%)           | 78.125<br>87.66 | 309.27<br>89.54 | .7500   | 123.765<br>87.59 | 185.415<br>87.57 | 1.00    |  |
| Most of the time<br>(76-90%)                      | 11<br>12.34     | 36.125<br>10.46 | .7500   | 10.6292<br>7.52  | 15.4<br>7.27     | 1.00    |  |
| Occasionally<br>(25-50%)                          | 0<br>0.00       | 0<br>0.00       | -       | 2.975<br>2.11    | 10.92<br>5.16    | .2438   |  |
| Rarely<br>(11-24%)                                | 0<br>0.00       | 00.00           | -       | 3.9375<br>2.79   | 0<br>0.00        | .025*   |  |

Table 5: Recommending Flu Vaccine, Stratified by Specialty & Location

All values represent weighted results

## **TERTIARY OBJECTIVES**

### Beliefs among those that Did Not Routinely Recommend Flu Vaccine

Among the 11.6% of physicians who did not routinely recommend flu vaccine, more OB/GYNs than FMs reported the belief that 'benefits of flu vaccine outweigh the risk' in healthy pregnant women (100.0 vs. 78.0; p-value < .001, Fishers Exact Test) (see table 8 and figure 4). The remaining FMs (22%) reported there was 'not enough evidence' in assessing the benefits/risk of flu vaccine. These two beliefs were the only ones reported, and they did not vary between rural and urban locations for both OB/GYNs and FMs (see table 7). A similar pattern was also observed among physicians who routinely recommended flu vaccine whereby more OB/GYNs than FMs reported the belief that 'benefits of flu vaccine outweigh the risk' (see table 6).

| Table 6: Self-Reported Bel | iefs |
|----------------------------|------|
|                            |      |

| Comparing Beliefs by Specialty |                  |                  |           |                         |                  |         |  |
|--------------------------------|------------------|------------------|-----------|-------------------------|------------------|---------|--|
| Beliefs                        | DID NOT          | Routinely        | Recommend | DID Routinely Recommend |                  |         |  |
| Frequency<br>Col Pct           | OB/GYN           | FM               | p-value   | OB/GYN                  | FM               | p-value |  |
| Not Enough<br>Evidence         | 0<br>0.00        | 9.66<br>22.02    | <.001*    | 0<br>0.00               | 4.725<br>1.53    | .017*   |  |
| Benefits > Risk                | 47.125<br>100.00 | 34.2017<br>77.98 | <.001*    | 387.395<br>100.00       | 304.454<br>98.47 | .017*   |  |
| Risk < Benefit                 | 0<br>0.00        | 0<br>0.00        | -         | 0<br>0.00               | 0<br>0.00        | -       |  |
| Other                          | 0<br>0.00        | 0<br>0.00        | -         | 0<br>0.00               | 0<br>0.00        | -       |  |

All values represent weighted results

# Fig. 4: Belief that Benefits Outweigh the Risk



| Comparing Beliefs by Location Among Those that DID NOT Routinely Recommend |              |                  |         |                  |                |         |  |
|--|--------------|------------------|---------|------------------|----------------|---------|--|
| Beliefs  |              | OB/GYN           |         |                  | FM             |         |  |
| Frequency<br>Col Dat   | Dunal        | Tubou            |         | Dunal            | Unber          |         |  |
| CorPet   | Kurai        | Urban            | p-value | Kurai            | Urban          | p-value |  |
| Not Enough<br>Evidence   | 0<br>0.00    | 0<br>0.00        | -       | 4.2<br>23.94     | 5.46<br>20.74  | 1.0*    |  |
| Benefits > Risk  | 11<br>100.00 | 36.125<br>100.00 | -       | 13.3417<br>76.06 | 20.86<br>79.26 | 1.0*    |  |
| Risk < Benefit   | 0<br>0.00    | 0<br>0.00        | -       | 0<br>0.00        | 0<br>0.00      | -       |  |
| Other  | 0<br>0.00    | 0<br>0.00        | -       | 0<br>0.00        | 0<br>0.00      | -       |  |

Table 7: Beliefs among Those DID NOT Routinely Recommend, Stratified by Specialty & Location

All values represent weighted results

#### **Barriers among the 11.6% of Physicians who Did Not Routinely Recommend**

Cost-related barriers were found to be more prevalent among OB/GYNs. When comparing between specialties, 'Inadequate reimbursement' was more of a significant barrier among OB/GYNs than FMs (19.1% vs. 0.0%; p-value = .003, fishers exact) (see table 8 and figure 7). After stratifying by practice location, more rural than urban OB/GYNs reported that 'inadequate reimbursement' (45.5% vs. 11.1%; p-value = .023, fishers exact) and 'upfront cost' (45.5% vs. 0.0%; p-value < .001, fishers exact) were significant barriers (see table 10 and figure 5). Fewer rural than urban OB/GYNs also had the capacity to store flu vaccines (54.5% vs 100.0%) (see table 9). Furthermore, a similar pattern was observed among physicians who routinely recommended flu vaccine, whereby more OB/GYNs than FMs reported 'inadequate reimbursement' (8.3% vs. 4.2%; p-value = .0426) and 'upfront cost' (9.2% vs. 4.2%; p-value = .0167) as significant barriers (see table 8). Administrative-related barriers were found to be more prevalent among FMs. When comparing between specialties, a significantly higher proportion of FMs than OB/GYNs reported there were 'other' barriers (37.5% vs. 8.5%; p-value = .0022) (see table 8 and figure 7). Among FMs who reported 'other' barriers, the following were supplemented with their responses: 'running out of vaccine/delay of arrival' (43%); 'patient refusal' (33%); and 'workload/workflow' (24%) (see table 11). After stratifying by practice location, more rural than urban FMs indicated that offering flu vaccine was 'not part of their usual patient-care activities' (22.5% vs. 0.0%; p-value = .023, fishers exact) (see table 10 and figure 6). Furthermore, a similar pattern was observed among physicians who routinely recommend flu vaccine whereby more FMs than OB/GYNs reported offering flu vaccine to pregnant women was not part of their routine patient-care activities (4.6% vs. .90%; p-value = .0048) (see table 8).

Similar proportions of OB/GYNs and FMs indicated there were no barriers to offering flu vaccine (64.7% vs. 55.8%) (see table 8). This did not vary between rural and urban locations for either OB/GYNs or FMs (see table 10). Similar proportions of OB/GYNs and FMs also reported 'low patient demand' (0.0% vs 6.8%) and did not vary by practice location. Finally, there were no OB/GYNs or FMs who reported they were 'not comfortable with administering vaccines.'

| Comparing Self-Reported Barriers by Specialty |               |              |          |               |                         |         |  |
|---|---------------|--------------|----------|---------------|-------------------------|---------|--|
| Barriers                                      | DID NOT       | Routinely Ro | ecommend | DID R         | DID Routinely Recommend |         |  |
| Frequency                                     |               |              |          |               |                         |         |  |
| Col Pct                                       | <b>OB/GYN</b> | FM           | p-value  | <b>OB/GYN</b> | FM                      | p-value |  |
| Upfront Cost is too                           | 5             | 0            | .056*    | 35.4821       | 13.055                  | 0.0167  |  |
| Expensive                                     | 10.61         | 0.00         |          | 9.16          | 4.22                    |         |  |
| Inadequate                                    | 9             | 0            | .003*    | 32.2          | 13.02                   | 0.0426  |  |
| Reimbursement                                 | 19.10         | 0.00         |          | 8.31          | 4.21                    |         |  |
| Not Part of Usual                             | 7.625         | 3.9375       | 0.4741   | 3.5           | 14.1225                 | 0.0048  |  |
| Patient-Care Activity                         | 16.18         | 8.98         |          | 0.90          | 4.57                    |         |  |
| Not Comfortable                               | 0             | 0            | -        | 0             | 0                       | -       |  |
|   | 0.00          | 0.00         |          | 0.00          | 0.00                    |         |  |
| Low Patient Demand                            | 0             | 2.975        | .109*    | 22.7667       | 13.5625                 | 0.4793  |  |
|   | 0.00          | 6.78         |          | 5.88          | 4.39                    |         |  |
| Lack of Storage                               | 5             | 0            | .056*    | 3.625         | 2.1                     | .698*   |  |
|   | 10.61         | 0.00         |          | 0.94          | 0.68                    |         |  |
| Other   | 4             | 16.4325      | 0.0022   | 97.3115       | 46.2438                 | 0.0014  |  |
|   | 8.49          | 37.46        |          | 25.12         | 14.96                   |         |  |
| None  | 30.5          | 24.4542      | 0.5096   | 233.126       | 239.599                 | <.0001  |  |
|   | 64.72         | 55.75        |          | 60.18         | 77.50                   |         |  |

| Table  | 8. | Self-Re | norted | <b>Barriers</b> | hy 9 | Specialty |
|--------|----|---------|--------|-----------------|------|-----------|
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All values represent weighted results

| Table 0. Loalt of Storega  | among those that | Did Mat Dautinal                        | Decommond Fly Vessine    |
|----------------------------|------------------|---|--------------------------|
| TADIE 9: LACK OF STORAGE   | among mose mar   | пла могкошнием                          | И Кесопппена вни масстве |
| Tueste > Eucli et Storiage | among mode ma    | 210100010000000000000000000000000000000 |                          |

| Lack of Storage vs. Adequate Storage Among those that Did Not Routinely Recommend |            |                  |         |                   |                 |         |
|---|------------|------------------|---------|-------------------|-----------------|---------|
| Barriers  | OB/GYN     |                  |         | FM                |                 |         |
| Frequency   |            |                  |         |                   |                 |         |
| Col Pct   | Rural      | Urban            | p-value | Rural             | Urban           | p-value |
| Lack of Storage   | 5<br>45.45 | 0<br>0.00        | < .001* | 0<br>0.00         | 0<br>0.00       | -       |
| Adequate Storage  | 6<br>54.55 | 36.125<br>100.00 | <.001*  | 17.5417<br>100.00 | 26.32<br>100.00 | -       |

\* Used Fishers Exact Test All values represent weighted results

| Effect of Location on Self-Reported Barriers Among Those that DID NOT Routinely<br>Recommend Flu Vaccine |            |                |         |                  |                 |         |  |
|--|------------|----------------|---------|------------------|-----------------|---------|--|
| Barriers   |            | <b>OB/GYN</b>  |         |                  | FM              |         |  |
| Frequency  |            |                |         |                  |                 |         |  |
| Col Pct  | Rural      | Urban          | p-value | Rural            | Urban           | p-value |  |
| Upfront Cost is too<br>Expensive   | 5<br>45.45 | 0<br>0.00      | <.001*  | 0<br>0.00        | 0<br>0.00       | -       |  |
| Inadequate<br>Reimbursement  | 5<br>45.45 | 4<br>11.07     | .023*   | 0<br>0.00        | 0<br>0.00       | -       |  |
| Not Part of Usual<br>Patient-Care Activity   | 0<br>0.00  | 7.625<br>21.11 | .170*   | 3.9375<br>22.45  | 0<br>0.00       | .023*   |  |
| Not Comfortable  | 0<br>0.00  | 0<br>0.00      | -       | 0<br>0.00        | 0<br>0.00       | _       |  |
| Low Patient Demand   | 0<br>0.00  | 0<br>0.00      | -       | 2.975<br>16.96   | 0<br>0.00       | .062*   |  |
| Lack of Storage  | 5<br>45.45 | 0<br>0.00      | <.001*  | 0<br>0.00        | 0<br>0.00       | -       |  |
| Other  | 0<br>0.00  | 4<br>11.07     | .560*   | 7.2975<br>41.60  | 9.135<br>34.71  | 0.8858  |  |
| None   | 6<br>54.55 | 24.5<br>67.82  | .486*   | 7.26923<br>41.44 | 17.185<br>65.29 | 0.2121  |  |

| Table 10: Barriers amon | g those that Did NOT R | outinely Recommend. | Stratified by St | pecialty & Location |
|-------------------------|------------------------|---------------------|------------------|---------------------|
|                         |                        |                     |                  |                     |

All values represent weighted results

# Table 11: 'Other' Reported Barriers

| <b>'Other' Reported Barriers By Each Specialty</b> |               |                             |  |  |  |
|--|---------------|-----------------------------|--|--|--|
| <b>'Other' Barriers</b>                            | DID NOT Routi | DID NOT Routinely Recommend |  |  |  |
| Frequency<br>Col Pct                               | OB/GYN        | FM                          |  |  |  |
| Workload/Workflow                                  | 0<br>0.00     | 3.9375<br>23.96             |  |  |  |
| Patient Refusal                                    | 0<br>0.00     | 5.46<br>33.23               |  |  |  |
| Ran out of Vaccine/Delay of<br>Arrival             | 4<br>100.00   | 7.035<br>42.81              |  |  |  |



Figure 5: OB/GYNs who Reported 'Upfront Cost,' "Inadequate Reimbursement,' and 'Lack of Storage.'

Fig. 6: FMs who Reported 'Not Part of Usual Patient-Care Activities'





Fig. 7: Comparing 'Inadequate Reimbursement' and 'Other' Between Specialties

### EXPLORATORY ANALYSIS:

### Vaccine Availability

More FMs than OB/GYNs reported that flu vaccine was available at their offices (98.1% vs. 91.8%; p-value = .0002) (see table 12 and figure 8). This did not vary between rural and urban locations (see table 13).





Our data revealed that smaller practice sizes did not have flu vaccine available at their offices. For example, 52.5% of OB/GYNs who worked in 1-2 provider settings reported they did not have vaccine available at their offices (see table 14). Among FMs who worked in 1-2 provider settings, 13.7% reported they did not have vaccine available at their offices (see table 14). In contrast, there was no report of unavailable vaccine made by OB/GYNs or FMs from the larger practices ( $\geq 11$  providers) (see table 14).

Table 12: Vaccine Available

| Vaccine Available    |                   |                  |        |  |  |  |
|----------------------|-------------------|------------------|--------|--|--|--|
| Available            |                   | Specialty        |        |  |  |  |
| Frequency<br>Col Pct | OB/GYN FM p-value |                  |        |  |  |  |
| Yes                  | 398.961<br>91.82  | 346.216<br>98.07 | 0.0002 |  |  |  |
| No                   | 35.5583<br>8.18   | 6.825<br>1.93    | 0.0002 |  |  |  |

All values represent weighted results

| Effect of Location on Vaccine Availability |                              |                  |        |                  |                 |         |
|--|------------------------------|------------------|--------|------------------|-----------------|---------|
| Beliefs                                    | OB/GYN   Rural Urban p-value |                  |        | FM               |                 |         |
| Frequency<br>Col Pct                       |                              |                  |        | Rural            | Urban           | p-value |
| Yes  | 77.7<br>87.18                | 321.261<br>93.01 | 0.1155 | 139.206<br>98.51 | 207.01<br>97.77 | .707*   |
| No   | 11.425<br>12.82              | 24.1333<br>6.99  | 0.1155 | 2.1<br>1.49      | 4.725<br>2.23   | .707*   |

\* Used Fishers Exact Test

All values represent weighted results

| Vaccine Availability by Practice Sizes |           |           |           |           |           |           |  |
|--|-----------|-----------|-----------|-----------|-----------|-----------|--|
| Available                              |           | OB/GYN    |           | FM        |           |           |  |
| Frequency                              | 1-2       | 3-10      | ≥ 11      | 1-2       | 3-10      | ≥ 11      |  |
| Col Pct                                | providers | providers | providers | providers | providers | providers |  |
| Yes                                    | 25.2333   | 218.509   | 155.219   | 29.8604   | 181.039   | 135.316   |  |
|  | 47.50     | 96.61     | 100.00    | 86.34     | 98.85     | 100.00    |  |
| No                                     | 27.8917   | 7.66667   | 0         | 4.725     | 2.1       | 0         |  |
|  | 52.50     | 3.39      | 0.00      | 13.66     | 1.15      | 0.00      |  |

Table 14: Vaccine Availability by Specialty & Practice Size

## Vaccine Coverage

A higher proportion of FMs than OB/GYNs reported that most if not all (i.e. 76-100%) of their pregnant patients received the flu shot (58.4% vs. 44.1%; p-value < .0001) (see table 15 and figure 9). Among FMs, this vaccine coverage was reported more among rural than urban areas (65.8% vs. 53.5%; p-value = .0292) (see table 16). In contrast, more urban than rural OB/GYNs reported this vaccine coverage (47.6% vs. 30.6%; p-value = .0056) (see table 16).

More OB/GYNs than FMs reported '51-75%' of their pregnant patients received the flu vaccine (49.4% vs. 29.7%; p-value < .0001) (see table 15 and figure 9). Among OB/GYNs, this did not vary between rural and urban locations (see table 16). Among FMs, this vaccine coverage was reported more in urban than rural areas (37.9% vs. 17.5%; p-value < .0001) (see table 16).

| Vaccine Coverage   |                  |                  |         |  |  |  |
|--|------------------|------------------|---------|--|--|--|
| Estimated Percentage of<br>Pregnant Patients Receiving<br>Flu Shot |                  | Specialty        |         |  |  |  |
| Frequency<br>Col Pct   | OB/GYN           | FM               | p-value |  |  |  |
| ≤ 25%  | 8.8<br>2.03      | 19.5475<br>5.54  | 0.0147  |  |  |  |
| 26-50%   | 19.6<br>4.51     | 22.3542<br>6.33  | 0.3309  |  |  |  |
| 51-75%   | 214.519<br>49.37 | 104.859<br>29.70 | <.0001  |  |  |  |
| 76-100%  | 191.601<br>44.09 | 206.28<br>58.43  | <.0001  |  |  |  |

Table 15: Vaccine Coverage

| Effect of Location on Vaccine Availability |                     |                  |        |                  |                  |        |
|--|---------------------|------------------|--------|------------------|------------------|--------|
| Beliefs                                    | OB/GYN              |                  |        | FM               |                  |        |
| Frequency<br>Col Pct                       | Rural Urban p-value |                  | Rural  | Urban            | p-value          |        |
| ≤ 25%                                      | 8.8<br>9.87         | 0<br>0.00        | <.001* | 11.6375<br>8.24  | 7.91<br>3.74     | 0.1155 |
| 26-50%                                     | 9.6<br>10.77        | 10<br>2.90       | .003*  | 11.9942<br>8.49  | 10.36<br>4.89    | 0.2560 |
| 51-75%                                     | 43.4917<br>48.80    | 171.027<br>49.52 | 0.9984 | 24.7154<br>17.49 | 80.1439<br>37.85 | <.0001 |
| 76-100%                                    | 27.2333<br>30.56    | 164.368<br>47.59 | 0.0056 | 92.9593<br>65.79 | 113.321<br>53.52 | 0.0292 |

Table 16: Vaccine Coverage by Specialty & Location





### When Flu Vaccine is Recommended

 $1^{st}$  trimester: Similar proportions of OB/GYNs and FMs reported they would recommend flu vaccine to healthy pregnant women in their  $1^{st}$  trimester (49.2% vs. 53.8%) (see table 17 and figure 10). Among OB/GYNs, this did not vary between rural and urban locations (see table 18). In contrast, more urban than rural FMs would recommend during  $1^{st}$ trimester (59.5% VS. 45.2%; p-value = .0113) (see table 18).

 $2^{nd}$  trimester: A higher proportion of FMs than OB/GYNs reported they would recommend flu vaccine to healthy pregnant women in their  $2^{nd}$  trimester (68.2% vs. 50.3%; p-value < .0001) (see table 17 and figure 10). This did not vary between rural and urban locations for either OB/GYNs or FMs (see table 18).

 $3^{rd}$  trimester: A higher proportion of FMs than OB/GYNs also reported they would recommend flu vaccine to healthy pregnant women in their  $3^{rd}$  trimester (63.6% vs. 48.7%; p-value < .0001) (see table 17 and figure 10). This was reported more among urban than rural FMs (68.5% vs. 56.4%; p-value = .0277) (see table 18). Among OB/GYNs, recommending flu vaccine during  $3^{rd}$  trimester did not vary between rural and urban locations (see table 18).

*First encounter:* A higher proportion of OB/GYNs than FMs reported they would recommend flu vaccine to healthy pregnant women during first encounter with their patients (88.9% vs. 72.8%; p-value < .0001) (see table 17 and figure 10). This did not vary between rural and urban locations for either OB/GYNs or FMs (see table 18).

| Table of trim by spec |                  |                  |        |  |  |  |
|-----------------------|------------------|------------------|--------|--|--|--|
| Time                  | Specialty        |                  |        |  |  |  |
| Frequency             | OB/GYN FM p-valu |                  |        |  |  |  |
| 1st trimester         | 213.942<br>49.24 | 189.887<br>53.79 | 0.2306 |  |  |  |
| 2nd Trimester         | 218.707<br>50.33 | 240.865<br>68.23 | <.0001 |  |  |  |
| 3rd trimester         | 211.407<br>48.65 | 224.625<br>63.63 | <.0001 |  |  |  |
| 1st encounter         | 386.418<br>88.93 | 256.843<br>72.75 | <.0001 |  |  |  |

Table 17: When Flu Vaccine is Recommended, by Location

All values represent weighted results

Fig. 10: Times when Flu Vaccine is Recommended



| Time of Recommend |                  |                  |         |                  |                  |         |  |
|-------------------|------------------|------------------|---------|------------------|------------------|---------|--|
| Barriers          | OB/GYN           |                  |         | FM               |                  |         |  |
| Frequency         |                  |                  |         |                  |                  |         |  |
| Col Pct           | Rural            | Urban            | p-value | Rural            | Urban            | p-value |  |
| 1st trimester     | 44.9917<br>50.48 | 168.95<br>48.92  | 0.8848  | 63.8703<br>45.20 | 126.017<br>59.52 | 0.0113  |  |
| 2nd Trimester     | 49.325<br>55.34  | 169.382<br>49.04 | 0.3460  | 88.0203<br>62.29 | 152.844<br>72.19 | 0.0658  |  |
| 3rd trimester     | 49.325<br>55.34  | 162.082<br>46.93 | 0.1941  | 79.6553<br>56.37 | 144.969<br>68.47 | 0.0277  |  |
| 1st encounter     | 84.7917<br>95.14 | 301.626<br>87.33 | 0.0567  | 109.981<br>77.83 | 146.862<br>69.36 | 0.1032  |  |

Table 18: Times when Flu Vaccine is Recommended, Stratified by Specialty & Location

All values represent weighted results

*Combination of responses:* Since this survey question was open-ended, multiple answers were possible. A response that included all possible answers (i.e.  $1^{st}$  trimester,  $2^{nd}$  trimester,  $3^{rd}$  trimester, and first encounter) was interpreted as recommending flu vaccine 'any time.' Among OB/GYNs, the most commonly reported combination of answers were first encounter only (44.5%), 'any time' (42.1%), and  $1^{st}$  trimester only (3.9%); among FMs, the most commonly reported combination of answers were 'any time' (43.3%), first encounter (27.0%),  $2^{nd}/3^{rd}$  trimester (15.4%),  $1^{st}/2^{nd}/3^{rd}$  trimester (4.1%), and  $2^{nd}$  trimester only (3.1%) (see table 19 and figure 11).

'*Any time*': Only 42.1% of OB/GYNs and 43.3% of FMs would recommend flu vaccine at 'any time.' This was not significantly different (p-value = .7939) (see table 19 and figure 11). Furthermore, the proportion of OB/GYNs and FMs who would recommend flu vaccine did not vary between rural and urban locations for either OB/GYNs or FMs (see table 20).

*First encounter only:* A higher proportion of OB/GYNs than FMs reported they would recommend flu vaccine at first encounter only (44.5% vs. 27.0%; p-value < .0001) (see table 19 and figure 11). Among OB/GYNs this did not vary between rural and urban locations; however, a higher proportion of rural than urban FMs reported they would recommend flu vaccine at first encounter only (35.6% vs. 21.2%; p-value = .0041) (see table 20).

 $1^{st}$  trimester only: Similar proportions of OB/GYNs and FMs indicated  $1^{st}$  trimester only (3.9% vs. 2.7%) (see table 19 and figure 11). More urban than rural OB/GYNs reported they would recommend in  $1^{st}$  trimester only (4.9%% vs. 0.0%; p-value = .030, fishers exact) (see table 23). Similarly, more urban than rural FMs reported they would recommend at  $1^{st}$  trimester only (4.5% vs. 0.0%; p-value = .013, fishers exact) (see table 20).

 $2^{nd}$  trimester only: Similar proportion of OB/GYNs and FMs indicated  $2^{nd}$  trimester only (3.9% vs. 2.7%; p-value = .4715) (see table 19 and figure 11). This did not vary between rural and urban locations for either OB/GYNs or FMs (see table 20).

 $2^{nd}/3^{rd}$  trimester: A higher proportion of FMs than OB/GYNs reported they would recommend flu vaccine only in  $2^{nd}/3^{rd}$  trimester (15.4% vs. 2.5%; p-value < .0001) (see table 19 and figure 11). This did not vary between rural and urban locations for either OB/GYNs or FMs (see table 20).  $1^{st}/2^{nd}/3^{rd}$  trimester: Similar proportion of OB/GYNs and FMs indicated they would recommend flu vaccine only in  $1^{st}/2^{nd}/3^{rd}$  trimester (4.1% vs. 2.5%) (see table 19 and figure 11). Among OB/GYNs, this did not vary between rural and urban locations (see table 20). However, more urban than rural FMs reported they would only recommend in  $1^{st}/2^{nd}/3^{rd}$  trimester (6.9% vs. 0.0%; p-value = .0037) (see table 20).



Fig. 11: Combination of Responses as to when Flu Vaccine is Recommended

| Table of trim by spec                          |                  |                  |         |  |  |  |  |
|--|------------------|------------------|---------|--|--|--|--|
| trim(Trimester recommendation)                 |                  | Spec             |         |  |  |  |  |
| Frequency<br>Col Pct                           | OB/GYN           | FM               | p-value |  |  |  |  |
| 1st trimester                                  | 16.7684<br>3.86  | 9.45<br>2.68     | 0.4715  |  |  |  |  |
| 2nd Trimester                                  | 9.8<br>2.26      | 10.815<br>3.06   | 0.6298  |  |  |  |  |
| 3rd trimester                                  | 0<br>0.00        | 2.975<br>0.84    | .089*   |  |  |  |  |
| 1st encounter                                  | 193.211<br>44.47 | 95.1313<br>26.95 | <.0001  |  |  |  |  |
| 1st,2nd,3rd trim & 1st encounter<br>(any time) | 183.04<br>42.12  | 152.892<br>43.31 | 0.7939  |  |  |  |  |
| 1st & 2nd trimester                            | 0<br>0.00        | 4.2<br>1.19      | .040*   |  |  |  |  |
| 1st trimester & 1st encounter                  | 3.33333<br>0.77  | 4.62<br>1.31     | .478*   |  |  |  |  |
| 2nd & 3rd trimester                            | 10.7333<br>2.47  | 54.2325<br>15.36 | <.0001  |  |  |  |  |
| 3rd trimesters & 1st encounter                 | 2.5<br>0.58      | 0<br>0.00        | .257*   |  |  |  |  |
| 1st,2nd,3rd trimester                          | 10.8<br>2.49     | 14.525<br>4.11   | 0.2777  |  |  |  |  |
| 1st,2nd trimester & 1st encounter              | 0<br>0.00        | 4.2<br>1.19      | .040*   |  |  |  |  |
| 2nd,3rd trimester & 1st encounter              | 4.33333<br>1.00  | 0<br>0.00        | .132*   |  |  |  |  |
| Total  | 434.52           | 353.041          |         |  |  |  |  |

Table 19: Combination of Responses - When Flu Vaccine is Recommended

\* Used Fishers Exact Test All values represent weighted results

|   | Time of Recommend |                  |         |                  |                  |         |  |  |
|---|-------------------|------------------|---------|------------------|------------------|---------|--|--|
| Barriers  |                   | OB/GYN           |         |                  | FM               |         |  |  |
| Frequency   |                   |                  |         |                  |                  |         |  |  |
| Col Pct   | Rural             | Urban            | p-value | Rural            | Urban            | p-value |  |  |
| 1st trimester                                     | 0<br>0.00         | 16.7684<br>4.85  | .030*   | 0<br>0.00        | 9.45<br>4.46     | .013*   |  |  |
| 2nd Trimester                                     | 0<br>0.00         | 9.8<br>2.84      | .225*   | 7.14<br>5.05     | 3.675<br>1.74    | .124*   |  |  |
| 3rd trimester                                     | 0<br>0.00         | 0<br>0.00        | -       | 2.975<br>2.11    | 0<br>0.00        | .063*   |  |  |
| 1st encounter                                     | 39.8<br>44.66     | 153.411<br>44.42 | 1.0000  | 50.3112<br>35.60 | 44.8202<br>21.17 | 0.0041  |  |  |
| 1st,2nd,3rd trim & 1st<br>encounter<br>(any time) | 44.9917<br>50.48  | 138.049<br>39.97 | 0.0946  | 59.6703<br>42.23 | 93.2218<br>44.03 | 0.8221  |  |  |
| 1st & 2nd trimester                               | 0<br>0.00         | 0<br>0.00        | -       | 4.2<br>2.97      | 0<br>0.00        | .025*   |  |  |
| 1st trimester & 1st<br>encounter                  | 0<br>0.00         | 3.33333<br>0.97  | 1.00*   | 0<br>0.00        | 4.62<br>2.18     | .162*   |  |  |
| 2nd & 3rd trimester                               | 4.33333<br>4.86   | 6.4<br>1.85      | .128*   | 17.01<br>12.04   | 37.2225<br>17.58 | 0.2061  |  |  |
| 3rd trimesters & 1st<br>encounter                 | 0<br>0.00         | 2.5<br>0.72      | 1.00*   | 0<br>0.00        | 0<br>0.00        | -       |  |  |
| 1st,2nd,3 <sup>rd</sup> trimester                 | 0<br>0.00         | 10.8<br>3.13     | .131*   | 0<br>0.00        | 14.525<br>6.86   | 0.0037  |  |  |
| 1st,2nd trimester &<br>1st encounter              | 0<br>0.00         | 0<br>0.00        | -       | 0<br>0.00        | 4.2<br>1.98      | .153*   |  |  |
| 2nd,3rd trimester &<br>1st encounter              | 0<br>0.00         | 4.33333<br>1.25  | .586*   | 0<br>0.00        | 0<br>0.00        | -       |  |  |

Table 20: Combination of Responses - When Flu Vaccine is Recommended, by Specialty & Location

## **ACIP Familiarity**

Significantly more OB/GYNs than FMs reported they were familiar with the 2010 ACIP recommendations for recommending flu vaccine to healthy pregnant women (95.9% vs. 90.7%; p-value = .0047) (see table 21 and figure 12). Among OB/GYNs, a higher proportion was reported in rural than urban areas (100.0% vs. 94.8%; p-value = .031, fishers exact) (see table 22). Among FMS, in contrast, a higher proportion was reported among urban than rural areas (94.8% vs. 84.5%; p-value = .0021) (see table 22).

Table 21: ACIP Familiarity

| ACIP Familiarity     |                   |                  |        |  |  |  |  |
|----------------------|-------------------|------------------|--------|--|--|--|--|
| Familiar             | Specialty         |                  |        |  |  |  |  |
| Frequency<br>Col Pct | OB/GYN FM p-value |                  |        |  |  |  |  |
| Yes                  | 416.714<br>95.90  | 320.116<br>90.67 | 0.0047 |  |  |  |  |
| No                   | 17.8056<br>4.10   | 32.925<br>9.33   | 0.0047 |  |  |  |  |

Fig. 12: ACIP Familiarity



| ACIP Familiarity     |                     |                  |       |                  |                 |         |
|----------------------|---------------------|------------------|-------|------------------|-----------------|---------|
| Familiar             | OB/GYN              |                  |       | FM               |                 |         |
| Frequency<br>Col Pct | Rural Urban p-value |                  |       | Rural            | Urban           | p-value |
| Yes                  | 89.125<br>100.00    | 327.589<br>94.84 | .031* | 119.406<br>84.50 | 200.71<br>94.79 | 0.0021  |
| No                   | 0<br>0.00           | 17.8056<br>5.16  | .031* | 21.9<br>15.50    | 11.025<br>5.21  |         |

Table 22: ACIP Familiarity by Specialty & Location

\* Used Fishers Exact Test

All values represent weighted results

## Year Began Providing Prenatal Care

As a group, the mean (median) year when rural OB/GYNs began providing prenatal care

(excluding residency) was found to be 1994 (1994); and for urban OB/GYNs, it was 1995

(1996) (see figure 13). The mean (median) year when rural FMs began providing

prenatal care (excluding residency) was found to be 1999 (2002); and for urban FMs, it

was 2000 (2001) (see figure 13).

Fig 13: Year Began Providing Prenatal Care



### Places Where Pregnant Women get their Flu Shot

Significantly more FMs than OB/GYNs indicated their pregnant patients get their flu shots at their provider's location (98.1% vs. 93.4%; p-value = .0029) and 'other' locations not mentioned on the questionnaire (10.7% vs. 1.9%; p-value < .0001) (see table 23 and figure 14). Among FMs who selected 'other,' Public Health Departments (68%), hospital (24%), and visiting RN/community centers (8%) were supplemented as their written response (see table 25). Furthermore, more rural than urban FMs indicated their pregnant patients get their flu shots at 'other' places not mentioned on the questionnaire (17.3% vs 6.3%; p-value = .0019) (see table 24).

Significantly more OB/GYNs than FMs indicated their pregnant patients get their flu shots at 'another health-care provider' (46.2% vs. 11.1%; p-value < .0001), 'pharmacy/supermarket' (49.2% vs. 24.4%; p-value < .0001), and at the patient's 'place of employment' (52.1% vs. 18.7%; p-value < .0001) (see table 23 and figure 14). Furthermore, more rural than urban OB/GYNs indicated their pregnant patients get their flu shots at 'another health-care provider' (65.9% vs. 41.4%; p-value < .0001) (see table 24).

Similar proportions of OB/GYNs (6.0%) and FMs (3.1%) indicated they did not know where their pregnant patients got their flu shots (see table 23 and figure 14).

| Places Pregnant Women Get their Flu Shot |                  |                  |         |  |  |  |
|--|------------------|------------------|---------|--|--|--|
| Places                                   |                  | Specialty        |         |  |  |  |
| Frequency                                | OB/GYN           | FM               | p-value |  |  |  |
| Your Practice Location                   | 405.761<br>93.38 | 346.216<br>98.07 | 0.0029  |  |  |  |
| Another Health-Care provider             | 200.783<br>46.21 | 39.0062<br>11.05 | <.0001  |  |  |  |
| Pharmacy or Supermarket                  | 213.979<br>49.24 | 86.1862<br>24.41 | <.0001  |  |  |  |
| Place of Employment                      | 226.345<br>52.09 | 66.1679<br>18.74 | <.0001  |  |  |  |
| Other                                    | 8.33333<br>1.92  | 37.7318<br>10.69 | <.0001  |  |  |  |
| Unknown                                  | 25.75<br>6.01    | 10.92<br>3.09    | 0.0804  |  |  |  |

Table 23: Places where Pregnant Women Get their Flu Shots



Fig. 14: Places where Physicians Reported their Pregnant Patients get their Flu Shots.

| Places Where Pregnant Patients Get their Flu Shot |                  |                  |         |                  |                  |         |  |  |
|---|------------------|------------------|---------|------------------|------------------|---------|--|--|
| Familiar  | OB/GYN           |                  | FM      |                  |                  |         |  |  |
| Frequency   |                  |                  | _       |                  |                  |         |  |  |
| Col Pct   | Rural            | Urban            | p-value | Rural            | Urban            | p-value |  |  |
| Your Practice<br>Location                         | 80.5<br>90.32    | 325.261<br>94.17 | 0.2873  | 139.206<br>98.51 | 207.01<br>97.77  | .707*   |  |  |
| Another Health-<br>Care provider                  | 58.6917<br>65.85 | 142.091<br>41.14 | <.0001  | 16.1942<br>11.46 | 22.8119<br>10.77 | 0.9774  |  |  |
| Pharmacy or<br>Supermarket                        | 45.1583<br>50.67 | 168.821<br>48.88 | 0.8550  | 36.6167<br>25.91 | 49.5694<br>23.41 | 0.6820  |  |  |
| Place of<br>Employment                            | 44.525<br>49.96  | 181.82<br>52.64  | 0.7390  | 17.7926<br>12.59 | 48.3754<br>22.85 | 0.0226  |  |  |
| Other   | 4.66667<br>5.24  | 3.66667<br>1.06  | .020*   | 24.4318<br>17.29 | 13.3<br>6.28     | 0.0019  |  |  |
| Unknown   | 0<br>0.00        | 25.75<br>7.59    | .004*   | 0<br>0.00        | 10.92<br>5.16    | .004*   |  |  |

Table 24: Places Where Pregnant Women Get their Flu Shot, by Specialty & Location

All values represent weighted results

| <b>'Other' Places Specified by Provider</b> |                   |                  |  |  |  |  |
|---|-------------------|------------------|--|--|--|--|
| Other places                                | Specialty         |                  |  |  |  |  |
| Frequency<br>Col Pct                        | OB/GYN            | FM               |  |  |  |  |
| Public Health Dpt                           | 8.33333<br>100.00 | 25.5042<br>67.59 |  |  |  |  |
| Visiting RN/Community Cntr                  | 0<br>0.00         | 9.15833<br>24.27 |  |  |  |  |
| Hospital                                    | 0<br>0.00         | 3.06923<br>8.13  |  |  |  |  |

## VII. Conclusion

#### Primary & Secondary Objectives

A high proportion of OB/GYNs (89%) and FMs (88%) routinely recommend flu vaccine to their healthy pregnant patients, where 'routinely' is interpreted as 91-100% of the time. Neither physician specialty (OB/GYN vs. FM) nor location (rural vs. urban) were significant factors in affecting the proportion of OB/GYNs and FMs who routinely recommend flu vaccine. These high proportions also suggest that routinely recommending flu vaccine may be a weak contributing factor to the low seasonal flu vaccine coverage of pregnant women. However, a higher proportion of FMs than OB/GYNs recommended flu vaccine less than routinely (i.e.  $\leq$  90% of the time). This suggests there are some barriers to recommending flu vaccine which vary by physician specialty.

#### **Tertiary Objectives**

Among the 11.6% of physicians that did not routinely recommend flu vaccine, barriers were found to be unique among each specialty.

Among FMs who did not routinely recommend flu vaccine, belief and administrativerelated barriers were more prevalent. For example, 22% of FMs reported there was not enough evidence to assess the benefits and risks of flu vaccine in healthy pregnant women; whereas, all OB/GYNs reported the belief that benefits of the flu vaccine outweigh the risks. More FMs indicated there were barriers other than those provided on the questionnaire (p-value = .0022). The most frequent supplemented response by FMs who did not routinely recommend flu vaccine was that they ran out of vaccine and there

was a delay in arrival of new supplies (43%). A higher proportion of rural than urban FMs reported that offering flu vaccine to pregnant women was not part of their routine patient-care activities (p-value = .023). Furthermore, a significant proportion of FMs who routinely recommended flu vaccine also reported offering flu vaccine to pregnant women was not part of their routine patient-care activities (p-value = .0048).

Among OB/GYNs who did not routinely recommend flu vaccine, cost and structurerelated barriers were more prevalent. For example, 11% of OB/GYNs reported 'inadequate reimbursement' as a barrier; whereas, no FMs reported this barrier (p-value =.003). Inadequate reimbursement and upfront cost were also reported as barriers among rural than urban OB/GYNs (p-value = .023 and <.001, respectively). There was also more rural than urban OB/GYNs who lacked proper refrigeration units to store seasonal flu vaccines (p-value < .001). Furthermore, a significantly higher proportion of OB/GYNs who routinely recommended flu vaccine also reported 'inadequate reimbursement' (p-value = .0426) and 'upfront cost' (p-value = .0167) as significant barriers.

### **Exploratory Analysis**

*Vaccine availability*: Fewer OB/GYNs than FMs had flu vaccine available at their offices (p-value .0002). Within each specialty, the proportion that had available flu vaccine did not vary between rural and urban locations. As mentioned above, cost-associated barriers and patient refusal may have deterred some OB/GYNs from storing flu vaccine in their offices.

Moreover, smaller OB/GYN practices (1-2 provider practices) tended not to have flu vaccine available in their offices. Among these smaller (1-2 provider) practices, 41% of rural OB/GYNs and 66% of urban OB/GYNs reported they did not have flu vaccine available.

*Vaccine coverage*: More FMs than OB/GYNs reported that most if not all of their pregnant patients (i.e. 76-100%) received the flu shot within the past 12 months (58% vs. 44%; p-value < .0001). In contrast, more OB/GYNs tended to report a more conservative vaccine coverage rate (i.e. 51-75%) among their healthy pregnant patients (p-value < .0001). This may be due to the fact that fewer OB/GYNs than FMs had flu vaccines available in their offices.

*When flu vaccine is recommended*: A trend pertaining to when physicians would recommend flu vaccine to their healthy pregnant patients was apparent when comparing between OB/GYNs and FMs. OB/GYNs tend to recommend flu vaccine during first encounter with their patient (p-value < .0001), whereas FMs tend to recommend flu vaccine during  $2^{nd}$  trimester (p-value < .001) as well as the  $3^{rd}$  trimester (p-value < .0001).

After analyzing the various combinations of responses, fewer than half of the physicians (42% of OB/GYNs and 43% of FMs) selected all possible responses indicating they

would recommend flu vaccine at any time of pregnancy (see figure 23). This did not vary between rural and urban locations for either OB/GYNs or FMs. Of the remaining half of physicians, 44% of OB/GYNs (vs. 27% of FMs) indicated they would recommend flu vaccine only during first encounter with their patient (p-value = .0041), and 15% of FMs (vs. 3% of OB/GYNs) indicated they would recommend flu vaccine only during  $2^{nd}$  and  $3^{rd}$  trimester (p-value < .0001). This supports the earlier observation that OB/GYNs tend to recommend flu vaccine only during first encounter with patient, and FMs tend to recommend flu vaccine only during  $2^{nd}$  and/or  $3^{rd}$  trimester. Furthermore, these patterns of flu recommend reflect weak adherence to the current 2010 ACIP guidelines of administering flu vaccine to healthy pregnant women at any time.

The weak adherence to ACIP guidelines cannot be attributed to lack of familiarity of the current 2010 ACIP guidelines. That is, high proportions of OB/GYNs (96%) and FMs (91%) reported they were familiar with the current 2010 ACIP guidelines to recommending flu vaccine to pregnant women. This may suggest that physicians disagree with ACIP guidelines as to the most effective time to recommend flu vaccine in healthy pregnant women.

*Places where patients get their flu shots*: More OB/GYN pregnant patients, as compared to FM pregnant patients, got their flu shots from places other than their provider (p-value = .0029). This may be due to the finding that fewer OB/GYNs than FMs have flu vaccines available in their offices. As a result, more OB/GYNs reported that their

pregnant patients got their seasonal flu vaccines from other places including another provider, pharmacy/supermarket, or place of employment.

In short, routinely recommending flu vaccine does not appear to be a barrier to flu vaccine coverage among pregnant women, in either rural or urban areas; however, barriers were identified among physicians that did not routinely recommend flu vaccine and varied between physician specialties and practice locations. Our study shows that cost-related barriers, including upfront cost and inadequate reimbursement, were associated with OB/GYNs. Despite these barriers, a high proportion of OB/GYNs still routinely recommend flu vaccine to their healthy pregnant patients. These cost-related barriers may help to explain why a lower proportion of OB/GYNs than FMs had flu vaccines available at their offices. Since fewer OB/GYNs had vaccine available at their offices, it is understandable why more OB/GYNs than FMs reported their pregnant patients got their flu shots from places other than their provider's location. Cost-related barriers may also prevent OB/GYNs from having proper vaccine storage refrigerator units. This was found to be true among rural OB/GYNs but not among FMs. In contrast, administrative-related barriers were more associated with FMs. These barriers include not offering flu vaccine as part of their routine patient-care activities as well as running out of vaccine followed by a delay in the arrival of a new shipment.

Furthermore, fewer than half of OB/GYNs and FMs were found to recommend flu vaccine at any time during pregnancy. This suggests that repeated conversations pertaining to flu vaccine with each pregnant patient are very low. This may be a significant barrier to increasing vaccine coverage especially if pregnant patients require

constant reminding or convincing in getting a flu shot. The low proportion of physicians that would recommend flu vaccine at any time during pregnancy conflicted with the current ACIP guidelines. However, this could not be attributed to unawareness since over 90% of OB/GYNs and FMs reported they were familiar with current 2010 ACIP guidelines to recommending flu vaccine to pregnant women. The low proportion of physicians that would recommend at any time during pregnancy also could not be attributed to safety concerns since over 95% of OB/GYNs and FMs reported they believe the benefits outweigh the risk. Instead, out data may suggest that OB/GYNs and FMs disagree with ACIP as to the time during which flu vaccine is most safe and effective to administer to pregnant women.

Our data indicates that OB/GYNs and FMs are presented with different barriers. Addressing these cost, structural, and administrative related barriers may help to increase the vaccine coverage among pregnant women. Our study also suggests that repeated flu vaccine conversations with each patient are very low, and this may be an important barrier to increasing vaccine coverage especially among those patients that are still undecided about getting the flu shot.

#### **Response Rates and Methods for Surveys of Physicians**

The response rate obtained in this study (46%) was similar to other mail-survey studies that sampled OB/GYNs and FMs and did not use any incentives. For example, the 2009 Oregon Physician Workforce Survey yielded an OB/GYN response rate of 40% and a FM response rate of 45% <sup>111</sup>. In a mailed survey sent to OB/GYN members of the

Collaborative Ambulatory Research Network (CARN), Power et al (2009) achieved a response rate of 51.2% <sup>102</sup>. However, this sample may be biased since CARN members consist of volunteers whose job is to participate in surveys. Among a sample of non-CARN members, Schrag et al obtained a response rate of 44% <sup>105</sup>. In a mailed survey analyzing FM barriers to administering flu vaccine to infants throughout Connecticut, Shanley et al achieved a response rate of 40.5% among FMs <sup>112</sup>.

Physician surveys tend to yield lower response rates than that of the general public. However, several methods exist that may be used to increase these response rates.

Self-administered paper surveys generate higher response rates among physicians than to web-based surveys. Among the 496 participants who completed and returned their questionnaire in our study, 75% completed the questionnaire by paper form, 16% had completed the survey on paper form and faxed it back, and 9% (n=46) completed the survey online using Survey Monkey. Similarly, in a randomized study of 442 surgeons, a higher response rate was observed among participants that were administered a traditional mailed-survey as compared to an internet-based survey (58% vs 45%; p-value < .01) <sup>85</sup>. Frederick et al. also observed that a higher proportion of physicians had completed and returned their paper survey than did those physicians who were sent e-email surveys with an URL link (59% vs 26%; p-value = .0005) <sup>81</sup>. Other studies also indicated that paper surveys generate higher response rates as compared to on-line surveys or telephone surveys <sup>88, 89, 91, 93</sup>. Subsequently, it is recommended that a paper form be used as the primary mode although this may change in the future as physicians become more comfortable with online surveys.

Multiple survey mailings may not be as effective in yielding high response rates as opposed to multiple reminder follow-ups. For example, one study used three survey mailings, one postcard mailing, and one reminder phone call and achieved a response rate of only 29% among physicians <sup>74</sup>. Our study used one primary survey mailing, and two reminder notifications (one postcard reminder and one final reminder by telephone) to achieve a 46% response rate. Similarly, in a survey of General Practitioners, a 59.9% response rate was achieved using a postal survey with three reminders <sup>91</sup>. Thus, it is recommended that a primary mail-out using paper form followed by two to three reminders should serve as the basis for survey delivery and can be augmented by other methods to increase the response rate.

Other methods that could help increase response rates among physician surveys include using small monetary incentives (that accompany the first mailing of the survey) and prenotification letters. Although incentives were not used in our study, upfront monetary incentives are generally known to increase response rates  $^{68, 113}$ . For example, Delnevo et al observed a higher response among physicians given an upfront-incentive (\$25 gift card) as compared to those who were promised the same incentive upon completion and return of the survey (72% vs 56%; p-value < .01) <sup>80</sup>. Kasprzyk et al. also found that an incentive of \$15 produce a much higher response rate (67%) as compared to not using any incentives (29%) <sup>74</sup>. In fact, after reviewing over 21 articles, Van Geest determined the odds of a high response rate when using monetary incentives was 2.13 times (95% CI: 1.7-2.6) that when not using monetary incentives <sup>68</sup>. Even small dollar amounts (\$1) have been associated with high response rates. For example, Everett et al achieved a 64% response rate among FMs when using a \$1 incentive as compared to a response rate

of 45% when no incentive was included <sup>113</sup>. Although pre-notifications were not used in this study, several other studies suggest that pre-notification can help to increase the survey response rate. For example, Ward et al (1998) observed that advanced prompts by a medical peer resulted in a significantly greater response rate than when no advanced prompts were used <sup>114</sup>. In another study conducted by the Bureau of Labour Statistics, Chun et al reported a higher response rate when a pre-notification letter was used (52%) as compared to no pre-notification (42%) <sup>115</sup>. Furthermore, Marsden et al recommends that pre-notification letters "should be timed to arrive about a week before the first mailing of the survey itself" <sup>116</sup>.

In summary, a self-administered paper survey followed by two or three reminder postcards and a final telephone reminder should serve as the basis to conduct physician surveys in Oregon. The response rate can be further enhanced by the use of up-front monetary incentives as well as pre-notification letters. In order to facilitate any differences among physicians regarding their preferences in returning completed surveys, faxes could serve as a secondary alternative to regular mail.

#### VIII. Discussion

### **Routinely Recommending Flu Vaccine**

A high proportion of physicians (89% of OB/GYNS and 88% of FMs) that provide prenatal care were found to routinely recommend flu vaccine to healthy pregnant patients. These results were similar to the 86% of OB/GYNs who 'always' recommend flu vaccine in the 2010 study by Panda et al <sup>100</sup>. The proportion of FMs who routinely recommend flu vaccine in our study was slightly higher than the 74% of FMs in the study conducted by Silverman et al <sup>101</sup>. However, 10 years have passed since the Silverman study and the slight difference may reflect the increasing awareness of recommending flu vaccine to pregnant women. Nonetheless, continuous outreach to prenatal-care providers would help maintain the high rate of physicians that routinely recommend flu vaccine to pregnant women.

#### Beliefs

All OB/GYNs (100%) in our study believe the 'benefits of the flu vaccine outweigh the risk' in healthy pregnant women. A similar observation was found in the 2009 study by Power et al who reported 90% of OB/GYNs agreed the flu vaccine was safe to administer during pregnancy <sup>102</sup>.

In contrast, the proportion of FMs who believe the 'benefits of flu vaccine outweigh the risk' in healthy pregnant women varied between those that did and those that did not routinely recommend flu vaccine. Ninety-eight percent of FMs who routinely recommend flu vaccine reported that the 'benefits outweigh the risk.' However, only

78% of FMs who did not routinely recommend flu vaccine reported this same belief: the remaining 22% of FMs reported there was 'not enough evidence' to assess the benefits/risks. No other studies could be found that report the beliefs among FMs who did not routinely recommend flu vaccine.

Our study suggests there are a small proportion of FMs who are still unconvinced of the efficacy and safety of seasonal flu vaccine in healthy pregnant women. This may be due to an unawareness of current literature that supports the safety and efficacy of flu vaccines. Thus, it is suggested that a short, on-line course be developed which describes current studies, ACIP guidelines, safety, benefits, and efficacy of the seasonal flu vaccine in pregnant women. In exchange, completion of these courses would earn CME credits. Furthermore, this on-line course should be made mandatory among FMs that provide prenatal care.

### Barriers

Our study identified barriers to offering flu vaccine that varied between OB/GYNs and FMs. Cost-related and structural-related barriers were reported among OB/GYNs, and administrative-related barriers were reported among FMs. Identifying these barriers will help guide future policies and strategic interventions.

Cost-related barriers among OB/GYNs include 'upfront cost,' and 'inadequate reimbursement.' These barriers were reported by OB/GYNs (9.2% and 8.3%, respectively) who routinely recommended flu vaccine as well OB/GYNs (10.6% and

19.1%, respectively) who did not routinely recommend. This underscores the significance of cost-related barriers among OB/GYNs in offering flu vaccine to pregnant women. These cost-related barriers were also identified in other studies but were reported by much higher proportions <sup>109, 111</sup>. For example, in a separate study by Power et al, 56% of OB/GYNs reported 'upfront cost,' and 60% of OB/GYNs reported 'inadequate reimbursement' as significant barriers to recommending flu vaccine <sup>102</sup>. However, the study by Power et al involved 9 different vaccines (including seasonal flu vaccine) making it impossible to identify barriers associated only with the seasonal flu vaccine. In another study, Panda et al observed 25% of OB/GYNs in a single hospital had reported 'poor reimbursement' <sup>100</sup>. Whereas Panda et al surveyed a single hospital; our study surveyed all of Oregon. These cost-related barriers may also limit the capacity for OB/GYNs to afford appropriate storage facilities for vaccine supplies. For example, our study found that 'lack of storage' was more of a significant barrier among rural than urban OB/GYNs regardless of whether or not they routinely recommended flu vaccine. In order to address the 10% of rural OB/GYNs who reported lack of vaccine storage as a significant barrier, the Oregon Health Authority (OHA) could create a program similar to the California Vaccine Storage Capacity Expansion Program (VSCEP). This program reimbursed physicians \$250 for the purchase of vaccine-quality storage refrigerators that were in compliance with the California Vaccine for Children (VFC) guidelines and requirements <sup>103</sup>. Purchasable refrigerators ranged from low volume units (i.e. < 500 doses of vaccine) to very high volume units (i.e. > 10,000 doses of vaccine)<sup>104</sup>. Similarly, OHA could reimburse \$250 for each vaccine-quality refrigerator purchased by rural OB/GYNs. This would cost OHA at least \$2,025 if 90% of rural OB/GYNs purchased a refrigerator. Alternatively, since there are a relatively small number of rural
OB/GYNs who lack vaccine-quality refrigerator storage units, a government subsidized program would have to spend \$6,480-\$8,100 to provide free 11 cubic foot vaccinequality refrigerators to 90% of the rural OB/GYNs who requested one. Funding for this program could be made available through use of Public Health Emergency Response funds and emphasizes the importance of flu vaccination among pregnant women.

Administrative-related barriers to offering flu vaccine among FMs include 'not being part of their usual patient-care activities.' This was a significant barrier among FMs who routinely recommended flu vaccine (p-value =.0048) as well as rural FMs who did not routinely recommend flu vaccine (p-value = .023). No current literature could be found that reports the proportion of FMs who do/do not offer flu vaccines to pregnant women as part of their routine patient-care activities. Our data suggest FMs do not offer flu vaccine to pregnant women as part of their routine patient-care activities because it impedes workflow and adds to an already heavy workload. This is also encumbered by the delay in arrival of new shipment, as reported by several FMs.

The notion that offering flu vaccine to pregnant women is not part of routine patient-care activities may be due to ineffective administrative procedures. For example, Davis et al found that only one quarter of their surveyed physicians (US internists and FMs) used any form of reminder notification system to contact high-risk patients, including pregnant women <sup>106</sup>. Suh et al found that over 35% of primary care physicians worry about having supplies left over at the end of the season that they can't return <sup>107</sup>.

Fortunately, processes and procedures can often be optimized to improve performance. For example, Lean Six Sigma methodology aims to identify, quantify, and eliminate procedural 'waste' which includes the time it takes to correct mistakes, reducing inventory that is not being used, and optimizing patient reminder notification systems, to name a few 108. Another option is the development of a smart-phone application that automatically sends out vaccine reminders to pregnant women. Administrators at each physician's office would be able to enter information quickly into a database managed by OHA. This reminder system would serve as a surrogate to routinely recommending flu vaccine and lessen the workload/workflow among prenatal care providers. This application not only has the potential to include other vaccine information, but it would also allow OHA to better approximate the proportion of pregnant women that have not received flu vaccines as well as the frequency of reminders. These two interventions would most likely be adopted in stages as described by the theory of 'Diffusion of Innovation' starting with the early adopter stage <sup>109</sup>. It is recommended that more imaginative settings, such as OHSU, pilot these innovations in order to develop a costbenefit analysis.

A high proportion of physicians indicated there were 'other' barriers that were not provided on the questionnaire. Physicians who reported this barrier also provided their own written response. This included 'patient refusal,' 'running out of vaccine/delay of arrival,' and 'heavy workload/workflow.' Unfortunately, our study was not powered enough to compare the written responses between specialties and location. These supplemented responses may be important barriers and should be further investigated. For example, in the study by Panda et al, 43% of OB/GYNs reported 'pregnant women

do not want to be vaccinated' <sup>100</sup>; and in the study by Shrag et al, 26% of OB/GYNs reported 'patient refusal' as significant barriers <sup>105</sup>.

Although our study has identified some physician barriers to offering flu vaccine to pregnant women, efforts should continue to educate pregnant women about the benefits and safety of receiving the seasonal flu vaccine. For example, having posters in physician offices that promote the safety and efficacy of the flu vaccine would help reduce patient refusal.

#### Vaccine availability

More FMs (98%) than OB/GYNs (92%) had flu vaccine available at their office. These proportions were much higher than that found in other studies. For example, during the 2007/2008 flu season, Panda et al found only 50% of physicians had flu vaccine in their offices <sup>100</sup>. However, Panda's study involved physicians that provided prenatal care at a single hospital and may not fully represent the vaccine available at other healthcare facilities. A similar limitation was also present in the study by Power et al that found 67% of OB/GYNs at a single hospital stored the seasonal flu vaccine <sup>102</sup>. Our results are more similar to a study done in a suburban community where more FMs (90.5%) than OB/GYNs (68.4%) were also found to carry the flu vaccine (p-value=.027) <sup>110</sup>.

Although our study found that a high proportion of physician offices carried the seasonal flu vaccine, it was unknown what proportion of these vaccines were thimerosal-free. This may be a barrier among pregnant women and may increase patient refusal.

Physicians may also feel uncomfortable administering thimerosal-containing vaccines to pregnant women. Future studies should examine the proportion of stored seasonal flu vaccines that are thimerosal-free and whether or not this is a barrier to physicians offering flu vaccine to healthy pregnant women.

### The Time when Physicians Recommend Flu Vaccine

A very surprising result in our study was that OB/GYNs and FMs vary greatly in regards to when they recommend flu vaccine to healthy pregnant women. Significantly more FMs than OB/GYNs reported they would recommend flu vaccine during 2<sup>nd</sup> trimester (68% vs. 50%) and 3<sup>rd</sup> trimester (64% vs. 49%). In contrast, there were more OB/GYNs (89%) than FMs (73%) that reported they would recommend on first encounter with their patients. Similar proportions of OB/GYNs and FMs reported they would recommend flu vaccine during first trimester.

After analyzing the various combinations of responses to this multiple-answer question, fewer than half of OB/GYNs and FMs (42% and 43%, respectively) checked all responses indicating they would recommend flu vaccine to healthy pregnant women at any time. Of the remaining physicians, 45% of OB/GYNs and 27% of FMs reported they would recommend flu vaccine only at first encounter with their patient, and 15% of FMs indicated they would recommend flu vaccine only in 2<sup>nd</sup> or 3<sup>rd</sup> trimester. This supports our earlier finding that OB/GYNs tend to recommend flu vaccine only during first encounter with the patient, and FMs tend to recommend flu vaccine only during 2<sup>nd</sup> and/or 3<sup>rd</sup> trimester.

The combinations of responses varied uniquely between specialties, and it reflected weak adherence to ACIP guidelines in recommending flu vaccine to healthy pregnant women at any time. This is an odd finding considering 96% of OB/GYNs and 91% of FMs reported they were familiar with the 2010 ACIP recommendations in recommending flu vaccine to healthy pregnant women, and 100% of OB/GYNs and 96% of all FMs reported they believe the benefits of the flu vaccine outweigh the risks. This seems to suggest there is still confusion among physicians as to when it is safe and effective to administer flu vaccine during pregnancy. Future studies should examine whether this is the case.

The low proportion of physicians that would recommend flu vaccine to healthy pregnant women at any time may also indicate that the conversations between pregnant patients and physicians pertaining to seasonal flu shots are very minimal. For example, upon first encounter with the physician, the pregnant patient may elect to go home to think about whether or not she wants to get the flu shot. The results of our study suggests that further conversations or reminders about getting the flu shot may not occur during subsequent visits. This may help to explain the lower number of pregnant patients (as compared to the higher number of providers) that are able to recall having discussions about flu vaccinations. That is, pregnant patients may not be able to recall one or two specific conversations they had with their providers especially when they are encumbered by a period of physiological stress. In light of the public fear regarding vaccines in general that arose from the mistaken MMR-autism debate <sup>52</sup>, repeated conversations and

reminders is essential to winning back patients' confidence in vaccines and increasing vaccine coverage.

In summary, policies and programs are needed to address the unique barriers that challenge OB/GYNs and FMs in offering flu vaccines to pregnant women. Government subsidized programs are needed to reduce the burden of cost associated with storing and administering flu vaccines to pregnant women. Policies should also aim to provide better flu vaccine reimbursement as well as reduce up-front costs. This is especially needed by smaller practices (i.e. 1-2 provider practices) that provide prenatal care and are financially unable to store vaccines in their offices. Efforts are also needed to determine the actual administrative barriers among FM offices. That is, interventions are needed to identify factors that impede optimal performance of patient-reminder notification and vaccine inventory systems. This in turn may help to improve quality, reduce cost and subsequently increase flu vaccine coverage among pregnant women.

## **Disconnect Between Physicians and Pregnant Patients Regarding Recommending** Seasonal Flu Vaccine

Our study indicates that more than 90% of physicians (OB/GYN and FM combined) recommend flu vaccine to at least 76% of their pregnant patients. These proportions conflict with values reported from other studies that report a lower proportion of pregnant women indicated their provider recommended the seasonal flu vaccine to them. In one study, only 55% of pregnant women indicated their physicians recommended flu vaccine to them <sup>118</sup>. In another study, Ahluwalia (2010) reported only 57% of pregnant patients indicated they discussed the seasonal flu vaccine with their physicians <sup>6</sup>.

One possible reason for the discord between the number of physicians and pregnant patients that report having recommended the seasonal flu vaccine may lie in the intensity of these discussions. For example, a conversation between physician and pregnant patient may involve explaining the benefits of the seasonal flu vaccine; however, if these conversations do not use the word 'recommend,' the patient may not report that their provider 'recommended' the seasonal flu vaccine. Also, if physicians did not elaborate their recommendation with a deep explanation of the benefits, safety, and efficacy of the flu vaccine, the context of the discussion and subsequently the recommendation may not resonate as being important by the pregnant patient. Subsequently, the pregnant patient may not be inclined to remember their physician's recommendation. Clearly, these conversations are dependent on perspectives between the physician and the pregnant patient, and, subsequently, physicians should avoid simply recommending flu vaccine in a single statement. Rather, physicians should engage in deep conversations with their pregnant patients that elaborates on the protective benefits and the risk that pregnancy poses to complications to the seasonal flu infection.

Further studies should investigate the conversations that occur between physicians and their pregnant patients regarding the seasonal flu vaccine. This would impart better detail regarding what information is being communicated and how information is being conveyed. A short script of these conversations would also help to identify the concerns among pregnant women regarding seasonal flu vaccines. Another option would be to supplement PRAMS questionnaires with additional questions that would help to clear the

ambiguity regarding physicians that discuss the flu vaccine, recommend the flu vaccine, and offer the flu vaccine. For example, the following questions may be included:

- 1) Did your physician discuss the seasonal flu vaccine with you?
  - a. If yes, did your physician recommend you get the seasonal flu vaccine.
  - b. If yes to (a) how strong would you consider this recommendation.
- 2) Did you get the seasonal flu vaccine?
  - a. If yes to (2), how long after the physician recommend the seasonal flu vaccine did you get your seasonal flu shot?

#### Low Vaccine Coverage Among Pregnant Women

Low vaccine coverage among pregnant women may arise from the different perspectives that physicians and pregnant patients have regarding the seasonal flu vaccine. Although physicians may regard vaccines as perhaps one of the greatest medical breakthroughs in history, pregnant women may perceive foreign agents, including vaccines, as unnatural.

Another reason why vaccine coverage among pregnant women may be low may be due to the fact that it is unclear which physician specialty should take on the role of offering flu vaccine as part of their routine patient-care activities. For example, there has been much debate about OB/GYNs taking on primary care roles. In one study, 34% of OB/GYNs agreed to the statement "Routine screening for vaccine-preventable diseases falls outside of the routine practice of an ob/gyn" <sup>102</sup>. In contrast, several FMs in our study indicated offering flu vaccine to pregnant women was not part of their routine-patient care

activities. Subsequently, there exists some debate as to whose role it is to offer flu vaccine to pregnant women.

While this debate needs to be settled, educations campaigns for prenatal care providers are needed. Providing physicians with the needed information and background is essential in order for them to engage conversations with pregnant patients regarding the safety, benefits, and efficacy of the seasonal flu vaccines. These campaigns may include having infectious disease specialists talking to prenatal care providers, or else having these discussions as part of Grand Rounds. On-line courses should also be developed that includes topics about the risk pregnancy poses to complications to seasonal flu infection and the importance of the seasonal flu vaccine. As an incentive, CME credits could be offered upon completion of the course.

Education campaigns for pregnant women are also needed. This is important in conveying the importance of vaccines and to tackle the public fear of vaccines in general. These campaigns can occur through television ads as well as hanging posters at places of employment including physicians' offices. These posters should warn against seasonal flu infection and the safety of the seasonal flu vaccine among pregnant women.

While these suggested interventions may not have an immediate effect, it is suspected that these changes will occur cumulatively and in turn provide a better protected community of pregnant mothers to seasonal flu complications

#### **Study Limitations**

Sample surveys are a relatively fast and inexpensive way of obtaining information and estimating characteristics of a population <sup>99</sup>. These surveys, often referred to as cross-sectional studies, capture a snapshot of the characteristics of a population at a single point in time. The wealth of information obtained from these surveys are useful for policy-decision makers, Public Health Departments, government agencies, and other stake-holders responsible for implementing health and social services. However, cross-sectional studies may be prone to selection and information bias.

In our study, there was suggestive evidence of a small amount of selection bias among urban OB/GYNs. The observed proportion of urban OB/GYNs was only 3.6 percentage points more than expected and was marginally significant (p-value = .050). Although this bias was small, it may affect how well the sample represents the target population. This selection bias was due to a conservative response rate of 30% that was initially factored into the initial design. It is recommended that a higher response (i.e. 40-50%) be anticipated in future studies involving urban OB/GYNs who provide prenatal care. Although over-representation of urban OB/GYNs is suggestive, it is not overly excessive and thus not believed to invalidate the results of this study.

Information bias may also be present in our study. First, all surveys were filled out retrospectively and so there is potential for errors due to recall. Second, the responses to each survey could not be checked for accuracy against medical charts or receipts. For example, the vaccine coverage rates and places where pregnant patients received their flu shots were reported by physicians and not the pregnant patients themselves.

This study could not adequately determine preferential places where pregnant patients got their flu shots. The reason for this was that the question allowed for multiple answers. Future studies that ask physicians where their pregnant patients get their flu shots should instruct the physician to either rate each response or else allow only single responses. This would allow for a better determination of where pregnant patients get their flu shots.

The quality of patient-physician discussion of flu vaccine was not addressed in this study. This may be important in determining how well vaccine safety and efficacy is being conveyed to pregnant patients. Some important topics in this patient-physician conversation should include vaccine content, passive immunity, vaccine efficacy, and vaccine safety. A short script of these discussions would provide deeper insight as to how flu vaccine is being recommended. This would also reveal what vaccine topics are important to pregnant patients.

As mentioned earlier, our study was not powered enough to test written responses that were not listed as barriers on the questionnaire. This includes patient refusal, running out of vaccine/delay of arrival, and disruption to workload/workflow and should be examined further in future studies. The proportion of stored flu vaccines that are thimerosal-free and thimerosal-containing should also be explored in future studies as the content of seasonal flu vaccines may be a barrier among physicians and pregnant women.

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X. Appendices

Appendix A: Cover Letter

September 1, 2011

# PARTICIPANT ID NUMBER: <u>«id»</u>

Dr. «firstn» «midn» «lastn» «mailstr1» «mailstr2» «mailcity», «mailstate» «mailzip»

Dear Dr. «lastn»:

Oregon Health & Science University (OHSU), in partnership with the Oregon Public Health Division, is conducting a study to identify barriers among Oregon physicians in recommending influenza vaccination to pregnant women. During the 2010-2011 influenza season, the Centers for Disease Control and Prevention (CDC) reported that fewer than 50% of surveyed pregnant women in the United States had received the influenza vaccine. **We invite you to participate in this study** to learn about your experiences and ideas.

If you are willing to participate, please complete the questionnaire by September 19<sup>th</sup> and either mail it back using the supplied return envelope, or fax it to 503-418-0125 (Attention: Dr. Shannon McWeeney / Rob Arao). If you would prefer, you can complete the questionnaire online at <u>https://www.surveymonkey.com/s/G5CG79G</u>. (Please **do not forget to include the Participant ID number** provided on this letter and the questionnaire).

Your participation in this study is voluntary and the completion of the questionnaire constitutes your consent to participate in the study. To protect your privacy, we will not record your name or address on the questionnaire, but assign a unique, random number to each participant. The key linking site and code will be kept on a secure, password-protected OHSU workstation. Questionnaires and personal information will not be shared with any person(s) outside the study and will be destroyed upon completion

of the study. Although we have made every effort to protect your identity, there is a minimal risk of loss of confidentiality. Although you will not benefit directly from participating in this study, the results of your participation will help the Oregon Public Health Division understand issues related to vaccinating pregnant women against influenza.

If you have questions about this study, contact *Robert Arao* at (801) 707-5227 or Principal Investigator *Dr. Shannon McWeeney* (503) 494-8347.

Thank you in advance for your participation in this study!

Sincerely,

Katrina Hedberg, MD, MPH State Epidemiologist & Administrator, Office of Disease Prevention and Epidemiology Oregon Public Health Division 800 NE Oregon St., Suite 730 Portland, OR 97232

Robert F. Arao, MPH Candidate Oregon Health & Science University Dept of Public Health and Preventive Medicine Mail code: CB 669 3181 SW Sam Jackson Park Rd. Portland, OR 97239-3098 Tel: 801-707-5227 Fax: 503-494-4551 eIRB # 7200 **Appendix B: Survey Instrument** 

Participant ID Number: \_\_\_\_\_

# **Questionnaire: Physician Barriers in Recommending Flu** Vaccine to Healthy Pregnant Women

1. Did you provide prenatal care within the past 12 months?

 $\Box$  Yes

- $\square$  No  $\longrightarrow$  End Survey. Please go to directions at the end of this survey.
- 2. Not including residency, what year did you begin providing prenatal care?

## 3. Which of the following best describes your primary practice setting?

- □ Solo or two provider practice
- $\Box$  3 to 10 provider practice
- $\square \ge 11$  provider practice

\_\_\_\_\_•

- 4. How many pregnant patients do you see in a typical week?
  - $\Box$  0-5
  - □ 6 to 10
  - □ 11 to 20
  - $\Box$  21 or more
- 5. Among healthy pregnant women, how often do you recommend the flu vaccine?
  - $\Box$  Almost always (91-100%)
  - $\Box$  Most of the time (76-90%)
  - $\Box$  Some of the time (51-75%)
  - $\Box$  Occasionally (25-50%)
  - □ Rarely (11-24%)
  - $\Box$  Almost never (0-10%)

- 6. During the flu season, when would you recommend flu vaccine to a **healthy** pregnant patient? (Please select all that apply)
  - □ First Trimester
  - □ Second Trimester
  - □ Third Trimester
  - □ First encounter with patient
- 7. During the flu season, are flu vaccines available at your practice?
  - $\Box$  Yes
  - 🗆 No
- 8. During the flu season, which of the following makes it difficult to offer flu vaccines at your primary practice location? (Please select all that apply)
  - Up-front costs of ordering vaccines are too expensive
  - □ Inadequate reimbursement
  - □ Not part of usual patient-care activities
  - $\Box$  Not comfortable with administering vaccines
  - $\Box$  Low patient demand
  - □ Lack of proper vaccine storage facilities
  - □ None
  - □ Other\_\_\_\_\_
- 9. Which best describes your beliefs about flu vaccines and **healthy** pregnant women?
  - $\Box$  Benefits of the flu vaccine outweigh the risk
  - □ Risk of flu vaccine side-effects outweigh the benefits
  - □ There is not enough scientific evidence to properly make a risk-benefit assessment
  - □ Other:\_\_\_\_\_
- 10. What proportion of your **healthy** pregnant patients has received the flu vaccine in the past 12 months?
  - $\Box$  25% or less
  - □ 26 to 50%
  - □ 51 to 75%
  - □ 76 to 100%

- 11. Where do your pregnant patients receive flu vaccines? (Please select all that apply)
  - $\Box$  Your practice location
  - $\Box$  From another health care practice
  - □ Pharmacy or supermarket
  - $\Box$  At their place of employment
  - □ Unknown
  - □ Other:\_\_\_\_\_
- 12. Are you familiar with the 2010 Advisory Committee on Immunization Practices (ACIP) recommendations for flu vaccinations for pregnant women?
  - $\Box$  Yes
  - 🗆 No

**-End of Survey:** Thank you for your time and participation. Please return this survey in the envelope provided and mail; or else please fax your completed questionnaire to 503-418-0125 (Attention: Dr. Shannon McWeeney / Rob Arao).