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Recommended Citation

Specker, Bonny; Wey, Betty; Fuller, Jill; Sandoval, Marie-Noel; Durkin, Maureen; Dole, Nancy; and Walter, Emmanuel B., "2009 H1N1 and Seasonal Influenza Immunization Among Pregnant Women: a Comparison of Different Sources of Immunization Information" (2014). *Ethel Austin Martin Program Publications*. 65.

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Published in final edited form as:

Matern Child Health J. 2014 April ; 18(3): 681–687. doi:10.1007/s10995-013-1293-y.

2009 H1N1 and Seasonal Influenza Immunization Among Pregnant Women: A Comparison of Different Sources of Immunization Information

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Abstract

Validity of prenatal immunization data from different sources has not been assessed. We evaluated prenatal 2009 H1N1 and seasonal influenza (FLU) data obtained from state immunization information systems (IIS), medical record abstraction (MRA), and participant recall using medical care logs (NCS–MCL). 2009 H1N1 and FLU data were obtained from IIS and MRA for 325 pregnant women participating in the National Children’s Study at three locations (SD/MN, NC, WI). Women recalled immunizations at first pregnancy visit and at 16–17 and 36 weeks’ gestation (NCS–MCL). The proportion of women with vaccine information obtainable from each data source was determined, and proportions immunized as determined using different data sources were compared. IIS data were available for 82 %, MRA for 97 %, and NCS–MCL for 93 % of women. No mention of either vaccine occurred in 29 % (range 4–48 %) of IIS, 40 % of MRA (25–59 %), and 59 % (43–82 %) in NCS–MCL. Best agreement between sources was 2009 H1N1 vaccine in MRA versus IIS [κ (95 % CI) of 0.44 (0.32–0.55)], with poorest agreement for FLU in IIS versus NCS–MCL [0.11 (–0.03 to 0.25)]. IIS was the most sensitive method for identifying women receiving 2009 H1N1 vaccine (92 %); MRA was most sensitive for FLU vaccine (81 %). IIS provided the most complete and sensitive data for 2009 H1N1 immunizations and MRA the most complete and sensitive data for FLU; IIS data were available for a smaller

percent of population than MRA. NCS–MCL was the least sensitive method for identifying vaccinated women.

Keywords

Data linkage; Immunizations; Perinatal; Pregnancy; Influenza; Immunization information system

Introduction

Safety and effectiveness of immunizations is of public health concern, and reliable and valid immunization data are important to obtain in prospective health studies. The National Children’s Study (NCS), a prospective cohort study of children in the US, will assess the effect of children’s environment on their health, growth, and development [1]. As such, the NCS offers a unique opportunity to prospectively evaluate vaccine safety, duration of immunity, and effectiveness in a large pediatric population.

The first phase of the NCS Vanguard Study was launched at seven locations in 2009. Participant data collection visits began during preconception or prenatal periods, occurring throughout pregnancy and at birthing hospitals. During pregnancy, women were asked to record on medical care logs (NCS–MCL) any immunizations they received. NCS–MCL were to be completed with help from health care providers, and the women could provide information recorded on the NCS–MCL to study center staff during subsequent in-person or telephone interviews. However, relying on patient-held vaccination records and ability to recall immunization information accurately has been shown to have considerable limitations [2, 3].

Medical record abstraction (MRA) is another method that is often used to obtain immunization information; however, MRA is time-intensive. Linking electronic databases, such as immunization information systems (IIS), to obtain immunization data should theoretically be more cost-effective. We previously reviewed the features, relationships, data availability, and architecture of IIS in 37 states and municipalities participating in the NCS [4]. Although the CDC uses IIS data for the New Vaccine Surveillance Network (<http://www.cdc.gov/vaccines/statssurv/nvsn/default.htm>), the use of state IIS data to document vaccine exposure has not been attempted in large cohort studies, and the availability of data from the IIS varies significantly among states participating in the NCS [4].

In prospective cohort studies like the NCS, it is desirable to maximize completeness of data, minimize burden to study participants, and find efficient and cost effective means for obtaining immunization information. The purpose of this study was to determine which data source (IIS, MRA, NCS–MCL) yields the most complete, reliable, and valid maternal immunization data in a cost effective manner. Data on 2009 H1N1 and seasonal flu immunizations obtained during the 2009 H1N1 influenza outbreak were used to compare the validity of different sources of prenatal immunization data. Accurate capture of maternal immunization data for the NCS and other prospective prenatal studies will ultimately help answer questions about vaccine safety, effectiveness, durability of vaccine immunity and protection, and the effect of maternal immunization on birth outcomes.

Methods

We identified NCS participants at three of the original Vanguard locations (Brookings County, South Dakota and Yellow Medicine, Pipestone and Lincoln Counties in Minnesota; Duplin County, North Carolina; and Waukesha County, Wisconsin) who were pregnant at

any time between September 1, 2009 and February 28, 2010. This window captured the typical influenza vaccination period and the period when MCL (NCS–MCL) were being distributed to participants in the NCS Vanguard Study. All women included in the current analyses had signed a NCS informed consent and a HIPAA medical record release. The NCS protocol was approved by the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the current project was approved by the participating institutions' Institutional Review Boards.

Immunization data (2009 H1N1 influenza vaccine and seasonal influenza vaccine) were obtained from the four respective state IIS and abstracted from medical records. Immunization information was reported by participants to study staff, sometimes using the NCS–MCL as a tool. Women recalled immunization information at the first pregnancy visit and NCS–MCL were used at 16–17 and 36 weeks' gestation, in response to questions about immunizations at medical visits: "Were you given any vaccinations at this visit?" and "What type of vaccination did you receive?" The interview included a probe for flu/influenza vaccines as well as others, but did not specifically include a probe for 2009 H1N1 influenza vaccine.

Statistical Analysis

The proportion of women whose vaccine information was obtainable from each data source was determined. We further determined the proportion of women who received either the 2009 H1N1 or seasonal influenza vaccine according to each data source. The proportion immunized, as determined by the different data sources, were compared and inter-record reliabilities were calculated using the kappa-coefficient [5]. Logistic regression analysis was used to determine which demographic variables (e.g., age, race, ethnicity, parity, maternal education, study center) were associated with the availability of IIS data. We particularly wanted to determine whether there were subpopulations not captured by the IIS.

To estimate costs associated with obtaining and abstracting medical records and obtaining IIS information, each site collected data on the amount of time spent accessing, reviewing, abstracting, and entering information.

Results

Between September 1, 2009 and February 28, 2010, 325 pregnant women were enrolled at the three study locations participating in this research. Of these women, 79 % were still enrolled at the time of birth (Table 1). Reasons for change with respect to enrollment status include pregnancy loss (4.0 %), moving out of a study-eligible household prior to birth (5.8 %), and withdrawal/no responses (11.1 %). Demographic characteristics differed among centers (Table 1). Women enrolled in Brookings County (SD) and Yellow Medicine, Pipestone, and Lincoln counties (MN) (BYPL) and Waukesha County (WI) were older and more likely to be white, non-Hispanic, married, and enrolled during the first trimester compared to women from Duplin County (NC). Educational attainment also differed, with a higher percent of BYPL women having a college degree compared to Waukesha and Duplin women.

MRA data were available for 97 %, IIS for 82 %, and NCS–MCL for 93 % of the women enrolled at the time of birth. Almost all immunization information reported at study interviews (NCS–MCL) was from the first pregnancy visit, with 16–17 and 36 weeks' gestation phone interviews yielding immunization data for only three additional participants.

Overall, 40 % of the women had no record of either the 2009 H1N1 or seasonal influenza vaccine in the MRA with a range of 25–59 % across the three centers (Table 2). A relatively

high percent of women (61.5 %, range 37–93 %) received 2009 H1N1 vaccine as reported in the state IIS (2009 H1N1 Only plus Both Vaccines), and only 28.6 % (range 4–48 %) who had state IIS information had no mention of receiving either vaccine. Immunization data collected from the NCS–MCL at the time of interviews had the highest percent of women with no mention of receiving either vaccine (59 %, range 43 to 82 %).

The degree of agreement (kappa coefficients) between different data sources are shown in Fig. 1 for 2009 H1N1 (solid circles) and seasonal influenza (open circles). The best agreement was between MRA and IIS for 2009 H1N1 vaccine data. The poorest agreement was between IIS and NCS–MCL for seasonal influenza vaccine data. Although agreement between MRA and NCS–MCL was fair to moderate for H1N1, no mention of 2009 H1N1 vaccine in either record occurred in 47 % of the women.

To calculate sensitivity and specificity of the data sources for identifying participants who received either vaccine, a gold standard—or definition of ‘truth’, was needed. We used state IIS information as the gold standard for the 2009 H1N1 vaccine and MRA information as the gold standard for seasonal influenza vaccine due to the high reporting rates for these vaccines from these data sources. Another definition used the mention of the vaccine in either the IIS or the MRA as evidence that the vaccine was administered, and if the vaccine was not mentioned in either data source, but records were available, we assumed the woman had not received the vaccine (Table 3). Overall, the IIS was the most sensitive source for identifying receipt of the H1N1 vaccine, while MRA was the most sensitive source for identifying receipt of the seasonal influenza vaccine.

χ^2 tests were conducted to determine which demographic variables (e.g., age, race, ethnicity, marital status, maternal education, study center) were associated with IIS availability (Table 4). We wanted to determine whether there were subpopulations that were not represented in the IIS and whether this varied by study center (tested using logistic regression with demographic variable-by-center interactions). Maternal age, ethnicity, marital status, and education were not associated with availability of IIS information. Because no black participants with IIS information available were enrolled in the South Dakota/Minnesota or Wisconsin sites, we were unable to determine a race-by-center interaction. In North Carolina, 92 % of black participants and 63 % of white participants had vaccine information available in the IIS ($p = 0.02$).

The average medical record required 26 ± 19 (\pm SD) min to access, review, and abstract, and the average registry record required 14 ± 5 min. Time spent traveling to and from the data abstraction sites and entering data were not included in these estimates. MRA abstraction typically occurred at the birth hospital, while access to the IIS varied by study location and access to the IIS system.

Discussion

The purpose of this study was to determine which immunization data collection source yields the most complete prenatal immunization data. Unfortunately, in the United States there is no national immunization registry and the use and availability of data from state registries is variable, especially with respect to adult immunizations [6]. The NCS Vanguard Study began recruiting pregnant women in their first trimester in early 2009, and data collection occurred during the 2009 H1N1 outbreak. State health departments, which support and maintain the IISs, were actively involved in distribution of the 2009 H1N1 vaccines. Therefore, it is not surprising that the IIS was the best method for identifying women who had received the 2009 H1N1 vaccine. However, information on seasonal influenza vaccines was best identified through medical records abstraction, indicating the

high variability among states and low inclusion of routine adult immunizations in state IIS. A national immunization registry, or more complete coverage of state immunization registries, should result in the IIS being a reliable source of information on adult immunizations.

Overall, 71 % of the women had at least one vaccine mentioned in their state registry, compared to only 60 % that were mentioned in the medical records. However, registry information was only available on 83 % of the participants, while medical records were available on 97 % of them. Based on these percentages, 59 % (0.71×0.83) and 58 % (0.60×0.97) of the women had one or more vaccines according to registry and medical record information, respectively. In comparison, only 38 % (0.41×0.93) of the women had one or more vaccines mentioned during NCS interviews.

The percent of women who were registered in their state IIS as having received the 2009 H1N1 vaccine ranged from 6 to 78 % among the three states, which was higher than the percent identified through MRA (1–23 %). MRA, however, was the most sensitive method for identifying women who received the seasonal influenza vaccine, perhaps indicating that seasonal influenza vaccine was more likely to have been administered in the physician's office when compared to the 2009 H1N1 vaccine, as found by others [7].

Most studies on the validation of methods to collect immunization data involve pediatric populations and parental recall. Participant report of immunization information was not found to be sensitive in identifying women who were vaccinated, and agreements were fair between participant-reported and registry data for 2009 H1N1 vaccine, and participant-reported and medical record data for both 2009 H1N1 and seasonal influenza. Only slight agreement was observed between participant-reported data and registry information for seasonal influenza vaccine, a finding that is consistent with pediatric studies [2, 3, 8]. Bolton et al. [2], however, found that vaccination cards and parent interview overestimated pediatric vaccine coverage, while others found parental interview and home-held records underestimated coverage compared to medical records [3, 8, 9]. We found that participant-reported information underestimated maternal 2009 H1N1 and seasonal influenza vaccine coverage based on both registry data and MRA.

A strength of this study was our ability to compare prospective information from three diverse study locations. In addition, we have immunization data for pregnant women, a subpopulation for whom immunization data are under-analyzed and for whom immunization patterns are underreported. Immunization rates were found to vary significantly by study location and, due to the heterogeneity between locations and homogeneity within some, it was not possible to determine whether specific population characteristics were associated with availability of registry data. We would not expect to find that availability of IIS information is associated with any specific demographic characteristics in our populations, based on our statistical tests. However, because of the racially homogeneous samples in BYPL and Waukesha counties, the lack of a race difference in registry coverage should be interpreted with caution.

Limitations

A limitation of this study is the assumption that if a vaccine administration was not mentioned in either the registry or the medical record, it was not received. With the options now available for obtaining influenza immunizations (e.g., at places of employment, pharmacies, health fairs), it is possible that dependence on either the registry or medical record would result in underestimating vaccination rate and misclassifying whether someone received a particular vaccine. Another limitation was the incompleteness of data from phone interviews conducted later in pregnancy. Most data obtained from participants were

collected at the initial study visit, but it is possible that some received vaccines after that visit and did not complete a subsequent phone interview, which would result in underreporting of immunizations to the NCS. Future studies could more rigorously estimate the cost effectiveness of the different data sources. Time associated with data entry and travel to collect and abstract medical records were not included in the current estimates, and direct assessment of total costs per record were not calculated.

Conclusions

In summary, in our study of pregnant women from three NCS study centers, we found that medical records provided the most complete and sensitive data for seasonal influenza immunizations. State immunization registries provided the most complete and sensitive data for 2009 H1N1 immunizations, but those data are available for a smaller percentage compared to medical records. NCS data, as reported to field staff during interviews—sometimes facilitated by MCL—were the least sensitive for identifying vaccinations in pregnant women.

Acknowledgments

We would like to thank the South Dakota, Minnesota, North Carolina, and Wisconsin Health Departments for their assistance in accessing the IIS registries. The views expressed in this paper are the responsibility of the authors and do not necessarily represent the position of the NCS, the National Institutes of Health, or the Department of Health and Human Services. This project was conducted as formative research for the National Children's Study, supported by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, and funded, through its appropriation, by the Office of the Director of the National Institutes of Health via contracts HHSN27520063416C and HHSN275201100004C (South Dakota State University Study Center), HHSN275200503413C and HHSN275201100005C (North Carolina Study Center), and HHSN275200503396C and HHSN275201100014C (University of Wisconsin Madison Study Center). It also was supported in part by the Ethel Austin Martin Endowment at South Dakota State University and R24 HD050924 awarded to the Carolina Population Center at The University of North Carolina at Chapel Hill.

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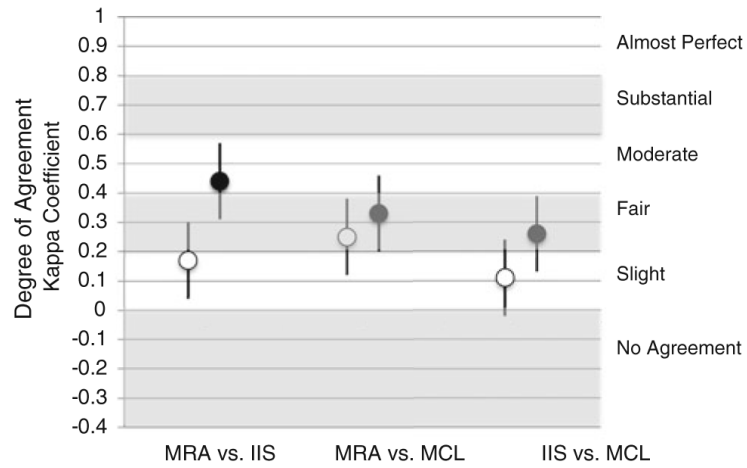


Fig. 1. Kappa coefficients for agreement between different data sources for 2009 H1N1 (*solid circles*) and seasonal influenza (*open circles*) immunizations. Coefficient < 0 indicate no agreement, 0–0.20 slight agreement, 0.21–0.40 fair agreement, 0.41–0.60 moderate agreement, 0.61–0.80 substantial agreement, and 0.81–1 almost perfect agreement [5]

Table 1

Population characteristics of enrolled women by study location

	BYPL	Duplin	Waukesha	Total
# Participants enrolled and pregnant at any time between 9/1/09 and 2/28/10	122	135	68	325
% Participants still enrolled at the time of their delivery	77	70	100	79
Reasons for non-participation (%)				
Pregnancy loss (%)	4.1	5.9	0	4.0
Moved from eligible household prior to delivery (%)	6.6	8.1	0	5.8
Withdrawal/no response (%)	11.5	16.3	0	11.1
Characteristics of women still enrolled at the time of delivery				
Availability of immunization data (%)				
Medical records abstracted (MRA) (%)	98.9	97.9	94.1	97.3
Immunization information systems (IIS) (%)	87.2	77.7	80.9	82.0
Medical care logs (MCL) (%)	98.9	83.0	100	93.3
Trimester of enrollment (%)				
1st (%)	43.6	22.3	54.4	38.7
2nd (%)	50.0	43.6	41.2	45.3
3rd (%)	6.4	34.0	4.4	16.0
Maternal age at enrollment (%) ^a				
<26 years (%)	30.9	54.3	8.8	33.5
26–35 years (%)	58.5	36.2	72.1	53.9
>35 years (%)	10.6	9.6	19.1	12.5
Race and ethnicity (%) ^{a,b}				
White, non-Hispanic (%)	91.5	26.6	36.8	53.1
White, Hispanic (%)	3.2	7.5	1.5	4.3
White, unknown ethnicity (%)	0	0	33.8	9.0
Black, non-Hispanic (%)	0	25.5	0	9.4
Multi- or other-race, non-Hispanic (%)	5.3	4.3	1.5	3.9
Multi- or other-race, Hispanic (%)	0	36.2	0	13.3
Multi- or other-race, unknown ethnicity (%)	0	0	5.9	1.6
Unknown race, non-Hispanic (%)	0	0	5.9	1.6
Unknown race, unknown ethnicity (%)	0	0	14.7	3.9
Marital status (%) ^a				
Married (%)	84.0	34.0	92.7	68.0
Unmarried (%)	16.0	58.5	7.4	29.3
Unknown/not stated (%)	0	7.5	0	2.7
Maternal education (%) ^a				
<High school (%)	13.8	60.6	23.5	33.6
High school + some college (%)	29.8	23.4	54.4	34.0
College + (%)	56.4	4.3	19.1	27.3
Unknown/not stated (%)	0	11.7	2.9	5.1

BYPL Brookings (SD) and Yellow Medicine, Pipestone and Lincoln (MN) counties

^a $\chi^2, p < 0.001$

^b Race and ethnic categories not listed did not have any participants

Table 2

Summary of Immunization data for those women who were enrolled at birth (n = 256) by data source

	MRA	IIS	MCL
% of Women with any records available	97 (94–99)	83 (79–87)	93 (83–100)
% Immunized for ^a			
2009 H1N1 influenza only			
BYPL (%)	12.9	78.1	18.3
Duplin (%)	1.1	5.5	0
Waukesha (%)	23.4	16.4	13.2
Total (%)	11.2	36.7	10.9
Seasonal influenza only			
BYPL (%)	17.2	3.7	15.1
Duplin (%)	26.1	15.1	9.0
Waukesha (%)	7.8	12.7	4.4
Total (%)	18.1	10.0	10.0
Both vaccines			
BYPL (%)	45.2	14.6	23.7
Duplin (%)	14.1	31.5	9.0
Waukesha (%)	32.8	30.9	27.9
Total (%)	30.5	24.8	20.1
Neither vaccine recorded			
BYPL (%)	24.7	3.7	43.0
Duplin (%)	58.7	48.0	82.1
Waukesha (%)	35.9	40.0	54.4
Total (%)	40.2	28.6	59.0
Total % with one or more vaccines noted (%)	60	71	41

Data are overall percent (range among the three centers)

Distribution of immunizations varied significantly by study center for all data sources (all, χ^2 , $p < 0.001$)

BYPL Brookings (SD) and Yellow Medicine, Pipestone and Lincoln (MN) counties

^aDenominator is the number of women who had records available

Table 3

Sensitivity and specificity of different data sources for identifying women receiving 2009 H1N1 or seasonal influenza vaccines

	Gold standard #1: women considered to have received vaccine if it is mentioned in either MRA or IIS^a		Gold standard #2: women considered to have received H1N1 vaccine if mentioned in IIS and seasonal influenza vaccine if mentioned in MRA^b	
	Sensitivity	Specificity	Sensitivity	Specificity
2009 H1N1 influenza				
MRA (%)	68	100	63	85
IIS (%)	92	100	–	–
MCL (%)	46	92	45	85
Seasonal influenza				
MRA (%)	81	100	–	–
IIS (%)	56	100	44	73
MCL (%)	43	89	43	82

MRA medical record abstraction, *IIS* immunization information system, *MCL* medical care logs

^aBased on the definition for this gold standard, specificity of both MRA and IIS will be 100 %

^bBased on the definition for this gold standard, specificity and sensitive could not be calculated for 2009 H1N1 vaccine for the IIS and for the seasonal influenza vaccine for MRA

Table 4

Percent of women with IIS data available by demographic characteristics and study location

	<u>% of Women with IIS data available</u>			
	<u>BYPL</u>	<u>Duplin</u>	<u>Waukesha</u>	<u>Total</u>
# Participants	94	94	68	256
Maternal age at enrollment				
<26 years (%)	86	86	83	86.1
26–35 years (%)	89	68	78	79.7
>35 years (%)	80	67	92	81.3
Race				
White (%)	88	63 ^a	84	81.8
Black (%)	–	92	–	91.7
Multi or other (%)	80	82	40	77.1
Unknown/not stated (%)	–	–	86	85.7
Ethnicity				
Hispanic (%)	100	83	100	84.4
Non-Hispanic (%)	87	74	80	81.6
Unknown/not stated (%)	–	–	81	81.1
Marital status				
Married (%)	85	72	79	80.5
Unmarried (%)	100	84	100	88.0
Unknown/not stated (%)	–	57	–	57.1
Maternal education				
<High school (%)	77	81	88	81.4
High school + some college (%)	86	68	78	78.2
College+ (%)	91	100	77	88.6
Unknown/not stated (%)	–	73	100	76.9

^a Race was associated with availability of IIS data among Duplin County women, with a higher percent of black women (92 %) having IIS data available compared to white women (63 %) (χ^2 , $p < 0.05$)