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1 **FAILURE OF THE VACCINATION CAMPAIGN AGAINST A(H1N1) INFLUENZA IN**  
2 **PREGNANT WOMEN IN FRANCE**

3 **Results from a national survey**

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19

20 ABSTRACT

21 Background and objective: Pregnant women were a priority group for vaccination during the 2009  
22 A(H1N1) influenza pandemic. In France, vaccination was organized in ad hoc centers. Women  
23 received vouchers by mail and were given a non-adjuvanted vaccine. Our objective was to assess the  
24 national vaccination rate among pregnant women and to determine the association of vaccination with  
25 maternal characteristics, prenatal care, and pregnancy-related health behaviors.

26 Method: Data came from a national representative sample of women who gave birth in March 2010  
27 (N=13 453) and were interviewed in the hospital before discharge; they were in the second trimester of  
28 pregnancy during the vaccination campaign. Associations between vaccination and socio-  
29 demographic and medical characteristics, region of residence, care providers, and preventive  
30 behaviors were assessed with bivariable analyses and logistic regression models.

31 Results: Vaccine coverage was 29.3% (95% CI: 28.6-30.1). The main reason for not being vaccinated  
32 was that women did not want this immunization (91%). In adjusted analyses, vaccination was more  
33 frequent in women who were older, employed, born in France, with a parity of 1 or 2 and specific  
34 favourable health behaviors. The adjusted odds ratio for women with a postgraduate educational level  
35 was 4.1 (95% CI: 3.5-4.8) compared to those who did not complete high school. Women with  
36 additional risk factors for complications from A(H1N1) infection had a vaccination rate similar to that of  
37 other women.

38 Conclusion: The vaccination campaign resulted in poor vaccination coverage, strong social  
39 inequalities, and no special protection for pregnant women at the highest risk of complications. These  
40 findings provide essential information for the organization of future vaccination campaigns.

41

42 **Keywords:** A(H1N1) influenza; vaccination; pregnant women; maternal characteristics; health  
43 behavior; health services

44

## 45 INTRODUCTION

46 The consequences of pandemic and seasonal influenza during pregnancy are well known [1].

47 Particularly serious effects of A(H1N1) influenza on pregnant women and newborns were reported at  
48 the very beginning of the pandemic in July 2009 [2] and were subsequently confirmed [3-4].

49 International organizations [5-6] advised that all pregnant women be vaccinated against the 2009  
50 A(H1N1) flu, regardless of the type of vaccine or the trimester of pregnancy. In France, vaccination  
51 was recommended for the entire population and priority vaccination for some groups at high risk,  
52 including pregnant women in the second and third trimesters of pregnancy [7]. A non-adjuvanted  
53 vaccine (Panenza®) was recommended for this group, based on doubts about potential risks for  
54 fetuses, in contrast with most European countries which used adjuvanted vaccines [8]. The non-  
55 adjuvanted vaccine did not become available until November 20, 2009, ie, one month after the  
56 beginning of the epidemic [9] and the beginning of the vaccination campaign for the general population  
57 [10]. Vaccination was free and was performed most often in special ad hoc vaccination sites, such as  
58 local gymnasiums. During the 10 days before the non-adjuvanted vaccine became available, all  
59 pregnant women received invitations with vouchers by mail, with a list of vaccination centers close to  
60 their home.

61 The French vaccination campaign took place in a generally unfavorable climate, with heated debates  
62 about the utility and risks of vaccination. This resulted in low acceptability of the vaccine [11] and only  
63 7.9% of the general population was vaccinated [12].

64 Our objectives were to estimate the national rate of vaccination against A(H1N1) influenza in pregnant  
65 women and to assess whether vaccination uptake was associated with maternal socio-demographic  
66 and medical characteristics, prenatal care, and other maternal health-related behaviors. We used the  
67 National Perinatal Survey, carried out in March 2010, to study these questions.

68

## 69 METHODS

70 The National Perinatal Surveys are conducted routinely to monitor perinatal health. They include all  
71 births in one week in all maternity units [13]. Women are interviewed between delivery and discharge

72 about their socio-demographic characteristics, prenatal care and health behavior. Data on health and  
73 obstetric care are collected from medical records. In the 2010 survey, women were asked whether  
74 they had been vaccinated against A(H1N1) influenza and, if not, why not. The sample included 14,355  
75 women in mainland France and vaccination uptake was known for 13,453 women.

76 We studied several categories of determinants of vaccination uptake: maternal socio-demographic  
77 characteristics, medical characteristics, prenatal care and health behaviors. The medical  
78 characteristics included conditions associated with complications during influenza infection (e.g.,  
79 diabetes mellitus, asthma, respiratory or renal failure, chronic hepatitis B and C infections, and BMI  
80  $\geq 30$ ) [14-15]. In addition, we identified women belonging to priority groups for vaccination,  
81 independently of pregnancy [7]: those in contact with children (e.g., teachers and daycare personnel)  
82 and those in the health-care sector (e.g., doctors, nurses, and nurses' aides).

83 The prenatal care characteristics were the number of prenatal visits (classified with respect to the  
84 minimum number of visits recommended in France according to the duration of pregnancy), the care  
85 provider at the beginning of pregnancy (obstetrician/gynecologist, general practitioner, or midwife),  
86 and the use of public or private care. We considered that care was mainly in the private sector if the  
87 woman delivered in a private maternity unit, because most of those women receive prenatal care from  
88 a private obstetrician/gynecologist associated with the unit.

89 We studied the following health behaviors: consumption of folic acid in periconceptional period, not  
90 smoking during the third trimester of pregnancy, and participating in antenatal classes.

91 We first assessed the vaccination rate and then studied the factors associated with vaccination  
92 uptake. Variables were studied using a bivariate and then a logistic regression analysis. The final  
93 model included all the variables which were associated with vaccination at the previous step (p value  
94  $< 0.10$ ). Risk factors for complications from flu infection and high-risk occupations were kept in the  
95 model, regardless of the association at the previous stage of analysis. SAS 9.2 software was used for  
96 the statistical analyses.

97

98 RESULTS

99 Almost all women (99%) were in the second trimester of pregnancy when the non-adjuvanted vaccine  
100 became available. The vaccination rate was 29.3% (95% CI: 28.6-30.1). The main reasons that  
101 women reported that they were not vaccinated were: not wanting the vaccine (91.2%), not offered a  
102 vaccination (5.3%), already had flu symptoms (1.0%), practical reasons (1.6%), and other reasons  
103 (0.9%).

104 The vaccination rate was higher in older women, in those with parity less than 3, and in those without  
105 any risk factor for complications from flu infection (Table 1). Married women, those with a higher  
106 educational level, born in France, employed during pregnancy, or at high risk of flu exposure or  
107 transmission because of their occupation were also vaccinated more frequently. Among healthcare  
108 workers, the vaccination rate was 84% among medical doctors, pharmacists, and dentists, 46%  
109 among nurses, midwives, and physical therapists, and 24% in women in less skilled occupations.  
110 Variations were also found between regions (results not shown).

111 The vaccination rate was very low for women who had fewer than the minimum number of visits  
112 required by French regulations; it was also lower in women who had care provided by GPs and who  
113 had prenatal care mainly in the public sector. Vaccination was less frequent among women who did  
114 not take folic acid in the periconception period, who smoked during pregnancy and who did not attend  
115 antenatal classes.

116 In the adjusted model, risk factors for complications and number of prenatal visits were not associated  
117 with vaccination. The odds ratio for women with a postgraduate educational level was 4.1 (3.5-4.8),  
118 compared to those who did not complete high school; the odds ratios were between 0.6 and 0.8 for  
119 women under 25 year old compared to older women, for single women compared to married women,  
120 and for women who were born abroad compared to native born women. There was lower vaccination  
121 coverage in several regions, including Paris and its metropolitan area (data available on request).

122

## 123 DISCUSSION

124 In 2009, the rate of vaccination against 2009 A(H1N1) influenza among pregnant women in France  
125 was quite low. It was higher among women with a high educational level and those with positive health

126 behavior during pregnancy. Having medical characteristics associated with the risk of severe influenza  
127 complications did not influence the vaccination rate.

128 The principal strength of our study is that it provides data about a representative national sample of  
129 women [13] in the second trimester of pregnancy during the vaccination campaign. Very few European  
130 countries were able to provide precise population-based estimates of vaccine coverage among  
131 pregnant women [8]. Nonetheless, given the number of topics covered by the national perinatal  
132 survey, few questions focused on flu prevention, and we did not evaluate women's views about  
133 vaccination and barriers to it in great detail. Women were interviewed after birth, about three months  
134 after the vaccination campaign. However memory errors were unlikely because going to a vaccination  
135 center was the women's decision and was not easily forgotten (travel to an unusual location, long wait  
136 times).

137 The vaccination rate in our study (29.3%) was higher than the estimate by the agency that monitored  
138 vaccination coverage (22.7%). The latter was obtained by comparing the number of invitations sent to  
139 to the number of women vaccinated in these centers [12]. It is known that some pregnant women who  
140 were vaccinated in a center were not recorded in the campaign's monitoring system [10]. Some others  
141 may have been vaccinated in the hospital where they had prenatal visits. Moreover, our sample  
142 included women in the 2<sup>nd</sup> trimester during the vaccination campaign, while vouchers were sent to  
143 pregnant women in their 2<sup>nd</sup> and 3<sup>rd</sup> trimesters; those in their 3<sup>rd</sup> trimester may have delivered before  
144 they were able to be vaccinated or were too tired to travel and stand in line for a vaccination.

145 Rates of vaccination among pregnant women were higher than 50% in Quebec and Norway, around  
146 50% in Finland and the USA, and around 25% in the UK, while they were much lower in some other  
147 countries [8,16-18]. In France the priority given to pregnant women had an effect, for their vaccination  
148 rates were clearly higher than those of the general population (7.9%) [12]. Nonetheless, this rate was  
149 lower than in many other countries and did not exceed 50% among women who had jobs at high risk  
150 of exposure to and transmission of influenza. The rates observed among health care workers were  
151 rather low and suggest that these professionals were not always aware of the utility of vaccination  
152 [11,19].

153 Countries made very different choices in implementing their campaign, and these could have had an  
154 effect on population adhesion. Pregnant women in Canada were directed mainly to vaccination

155 centers [17], in Australia to their GPs [20], and in the US to either a doctor's office, clinic or health  
156 center [21]. In France, vaccination was organized in ad hoc centers, mainly to avoid wasting vaccine  
157 doses and to deal with the lack of storage capacity in doctors' offices [22]. The health insurance fund  
158 sent all pregnant women a personal notification. This was possible because pregnant women must be  
159 registered to receive reimbursement of prenatal care expenses. In our study, very few women did not  
160 receive the invitation. This direct contact gave all women the opportunity to get similar information  
161 about the vaccination campaign. Nonetheless, the exclusion of personal health care providers from the  
162 vaccination campaign may have been a 'missed opportunity to increase vaccination uptake' [23]; for  
163 example French GPs play a key role in vaccination and management of seasonal influenza and had a  
164 positive attitude towards A(H1N1) vaccination. The involvement of obstetricians/gynecologists and  
165 midwives would have made vaccination easier, as pregnant women have prenatal visits at least once  
166 a month [13]. For instance, a program, which actively involved prenatal care providers and maternity  
167 units, resulted in a 77% vaccination rate in an American county [24]. The participation of care  
168 providers might also have resulted in wider vaccination coverage for the women with additional risk  
169 factors for complications, generally known to their doctor.

170 Preventive behavior, such as not smoking and attending antenatal classes, were strong predictors of  
171 vaccination because women take these actions mainly on their own initiative, in the same way as they  
172 went for this vaccination. We also found that high educational level was a major factor associated with  
173 vaccination among pregnant women [21,25-26]. Material and financial constraints do not appear to  
174 have played an important role, as very few women reported that practical reasons explained why they  
175 were not vaccinated. The importance of the sociocultural environment may reflect women's ability to  
176 analyze the discordant information put forward by the media and public agencies during that period.

177 The decision to accept A(H1N1) vaccination depended on many factors: the perception of the risk of  
178 being infected by this virus, the perception of the consequences of this flu, worries about vaccine  
179 safety, and distrust in the vaccine's effectiveness [11,21,26-29]. These perceptions and worries were  
180 reinforced among pregnant women because of the potential consequences for the fetus' development  
181 in utero. Knowing all of the reasons that women refused vaccination is essential for clarifying complex  
182 information, guiding the messages of information campaigns directed at pregnant women, and  
183 developing recommendations for healthcare providers. For instance quality websites with validated

184 and frequently updated information or telephone services specialized in counseling pregnant women  
185 [17,28] were especially useful tools for information diffusion in Canada during the pandemic.

186

## 187 CONCLUSION

188 The campaign to vaccinate pregnant women against pandemic flu did not meet its objective in France.

189 The initiative for vaccinations was left mainly to women and led to low vaccination coverage, strong  
190 social differences in uptake and no special protection for women at the highest risk of complications.

191 Confronted with a novel and urgent situation, health authorities had difficulties developing policies  
192 quickly based on limited evidence. The evaluation of these policies is thus essential to help plan for  
193 future pandemics [22,30-31]. Lessons learned can also be applied to other vaccination policies, such  
194 as for the seasonal flu vaccine, which is expected to be recommended for use during pregnancy in  
195 France.

196

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201

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**Table I. Vaccination rates and Odds Ratios adjusted for all variables in the table**

	n	Rate %	p	Adjusted OR (1)	95% CI	p
<b>Age (years)</b>			<0.0001			<0.0001
<24	2229	13.0		0.72	0.61-0.84	
25-29	4441	26.7		1		
30-34	4124	36.7		1.29	1.16-1.43	
35 +	2529	36.5		1.50	1.32-1.70	
<b>Parity</b>			<0.0001			<0.0001
0	5916	28.7		1		
1-2	6425	31.4		1.26	1.13-1.40	
3+	995	19.1		1.07	0.86-1.33	
<b>Risk factors for complications</b>			<0.0001			0.4291
No	11866	30.1		1		
Yes	1587	23.3		0.94	0.82-1.08	
<b>Family situation</b>			<0.0001			0.0001
Married & cohabiting with partner	6232	33.1		1		
Cohabiting	6196	28.3		0.88	0.80-0.96	
Not cohabiting	958	12.6		0.64	0.50-0.80	
<b>Educational level</b>			<0.0001			<0.0001
Middle school or less	3720	14.7		1		
High school	2681	19.0		1.06	0.91-1.23	
Some college	2875	30.7		1.56	1.36-1.80	
College	2368	42.2		2.33	2.00-2.70	
Postgraduate	1750	57.0		4.08	3.46-4.81	
<b>Maternal country of birth</b>			<0.0001			<0.0001
France	11.043	31.8		1		
Outside of France	2397	18.0		0.61	0.53-0.70	
<b>Employment during pregnancy</b>			<0.0001			0.0319
No	3885	17.3		0.88	0.78-0.99	
Yes	9448	34.4		1		
<b>Occupation characteristics</b>			<0.0001			0.003
Contact with children	774	51.0		1.26	1.06-1.49	
Healthcare worker	818	39.5		1.23	1.04-1.45	
Other (2)	11861	27.2		1		
<b>Number of visits</b>			<0.0001			0.2712
<Minimum(3)	466	14.8		0.73	0.52-1.01	
Minimum or +1	2288	27.8		1		
Minimum +2 or +3	4450	30.9		0.98	0.86-1.12	
Minimum +4 or more	6037	30.3		0.96	0.85-1.09	
<b>Place of care</b>			<0.0001			0.0015
Mainly public	9696	27.3		1		
Mainly private	3757	34.5		1.17	1.06-1.28	
<b>Main healthcare provider</b>			<0.0001			<0.0001
Ob-gyn	9574	32.4		1		
General practitioner	2904	21.4		0.78	0.69-0.88	
Other	697	21.4		0.82	0.66-1.02	

296  
297

**Table I (continued). Odds Ratios for vaccination adjusted for all variables in the table**

	n	Rate %	p	Adjusted OR (1)	95% CI	p
<b>Folic acid consumption</b>			<0.0001			<0.0001
No	9246	25.6		0.70	0.63-0.77	
Yes	3286	41.8		1		
<b>Smoking during pregnancy</b>			<0.0001			0.0476
No	11042	31.3		1		
Yes	2387	19.9		0.88	0.77-1.00	
<b>Prenatal classes</b>			<0.0001			<0.0001
No	6941	21.4		0.68	0.62-0.76	
Yes	6473	37.9		1		

298

299 (1) adjusted for all variables in the table and region ( $p < 0.001$ ),  $N = 11,685$

300 (2) other occupation or no occupation during pregnancy

301 (3) 7 visits for a full term pregnancy according to French regulation

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