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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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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 ≥ 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 2nd trimester during the vaccination campaign, while vouchers were sent to
143 pregnant women in their 2nd and 3rd trimesters; those in their 3rd 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
Age (years)			<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	
Parity			<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	
Risk factors for complications			<0.0001			0.4291
No	11866	30.1		1		
Yes	1587	23.3		0.94	0.82-1.08	
Family situation			<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	
Educational level			<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	
Maternal country of birth			<0.0001			<0.0001
France	11.043	31.8		1		
Outside of France	2397	18.0		0.61	0.53-0.70	
Employment during pregnancy			<0.0001			0.0319
No	3885	17.3		0.88	0.78-0.99	
Yes	9448	34.4		1		
Occupation characteristics			<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		
Number of visits			<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	
Place of care			<0.0001			0.0015
Mainly public	9696	27.3		1		
Mainly private	3757	34.5		1.17	1.06-1.28	
Main healthcare provider			<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
Folic acid consumption			<0.0001			<0.0001
No	9246	25.6		0.70	0.63-0.77	
Yes	3286	41.8		1		
Smoking during pregnancy			<0.0001			0.0476
No	11042	31.3		1		
Yes	2387	19.9		0.88	0.77-1.00	
Prenatal classes			<0.0001			<0.0001
No	6941	21.4		0.68	0.62-0.76	
Yes	6473	37.9		1		

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

(2) other occupation or no occupation during pregnancy

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