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# Vaccination of pregnant women in the Valencian Community during the 2014-15 influenza season: a multicentre study

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### ABSTRACT

**Background.** To study influenza vaccination uptake in pregnant women from three Health Departments in the Valencian Community (Spain) during the 2014-15 flu season, to identify degree of knowledge, sources of information and attitudes toward immunization against influenza.

**Methods.** Multicentre cross-sectional descriptive study during the 2014-15 vaccination campaign. Vaccine coverage was determined using the Nominal Vaccination Registry (NVR). Subsequently, a telephone survey was carried out on a sample of vaccinated and unvaccinated postpartum women.

**Results.** The NVR had information on 934 (59.5%) out of 1,569 postpartum women; distribution per Health Departments was: 420 (44.9%), 161 (17.2%) and 353 (37.8%) in La Ribera, Torrevieja and Elx-Crevillent respectively. Vaccine uptake was 27.9% (n = 261). According to the "Country of Origin" variable, 77.5% (n = 724) of women were Spanish, with a vaccination rate of 26.7% (n = 193), compared to 22.5% (n = 210) who were non-Spanish, with a rate of 32.4% (n = 68). The main source of information was midwives for 83.7% (n = 159) of vaccinated pregnant women and for 44.6% (n = 127) of non-vaccinated women. The main reasons for vaccine refusal were lack of awareness (29.5%, n = 84) and not considering it necessary (25.6%, n = 73).

**Conclusion.** Despite their high willingness to be vaccinated after receiving information about the flu vaccine, the vaccination coverage in pregnant women studied is still low and can be improved. Health professionals need new information strategies to extend vaccine uptake to a larger number of pregnant women in Spain. Midwife advice plays

Correspondence: José Tuells Cátedra Balmis de Vacunología. University of Alicante (Spain) Campus de San Vicente Raspeig - Ap.99. E-03080 Alicante (Spain) Phone: O0 34 965903888 Fax: O0 34 965903964 Email: tuells@ua.es an essential role in transmitting information on influenza vaccination in pregnant women and has a significant impact on uptake.

Keywords: Influenza, Pregnancy, Immunization, Vaccine coverage, Vaccination uptake, Midwife, Health professionals.

#### Vacunación de mujeres embarazadas en la Comunidad Valenciana durante la temporada de gripe 2014-15: un estudio multicéntrico

### RESUMEN

**Objetivos.** Investigar la cobertura de la vacunación antigripal en gestantes en tres Departamentos de Salud de la Comunidad Valenciana (España) durante la temporada 2014-15, y evaluar su aceptabilidad, fuentes de información y motivos de rechazo hacia la inmunización contra la gripe.

**Métodos.** Estudio descriptivo transversal multicéntrico en la campaña vacunal 2014-15. La cobertura vacunal se identificó a través del Registro Nominal de Vacunas (RVN). Posteriormente, se realizaron 2 encuestas telefónicas a un mínimo muestral de puérperas vacunadas y no vacunadas.

**Resultados.** De 1.569 puérperas, 934 (59,5%) disponen de información en el RVN; la distribución por Departamentos: 420 (44,9%), 161 (17,2%) y 353 (37,8%) en La Ribera, Torrevieja y Elx-Crevillent respectivamente. Se obtuvo una cobertura vacunal del 27,9% (n=261). Según la variable "País de Origen", el 77,5% (n=724) es española, con una tasa vacunal del 26,7% (n=193), frente al 22,5% (n=210) extranjera, con el 32,4% (n=68). La principal fuente de información fue la matrona en el 83,7% (n=159) de gestantes vacunadas y el 44,6% (n=127) en no vacunadas. Los principales motivos de rechazo fueron el desconocimiento (29,5%; n=84) y el no considerarse imprescindible (25,6%; n=73).

Conclusiones. A pesar de su alta predisposición a

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vacunarse después de recibir información sobre la vacuna contra la gripe, la cobertura de vacunación en mujeres embarazadas estudiadas es aún baja y puede mejorarse. Son necesarias nuevas estrategias de formación e información por parte de los profesionales sanitarios para obtener un mayor número de gestantes vacunadas. El consejo de la matrona es un factor esencial en la emisión de la información sobre la vacunación antigripal recibida por las gestantes estudiadas.

Palabras claves: Gripe, Embarazo, Inmunización, Cobertura Vacunal, Vacunación, Matrona, Profesionales Sanitarios.

#### BACKGROUND

Pregnant women present a higher number and increased severity of diverse infections [1, 2], making them especially vulnerable to influenza [3-5]. This disease is one of the main causes of hospitalization during any pregnancy trimester, as well as respiratory infection in children aged under one year [6, 7].

The need of pregnant women and newborns for immunological protection has led the World Health Organization (WHO) to recommend influenza vaccination in any trimester of pregnancy [8, 9]. This recommendation is supported by results showing a reduction in influenza in 70% of immunized women [10] demonstrating its efficacy and safety [11, 4] as well as extending its protection to infants of up to six months of age [8, 9].

Following the recommendations of the WHO, the Valencian Community (Spain) included pregnant women in the influenza risk group as from 2013 [12]. Spain does not have official influenza vaccination records in pregnant women and the few published studies that do exist reveal vaccine coverage rates below 40% [6, 13, 14]. This figure contrasts with data reported in the United States, where uptake in pregnant women rose to up to 70% following the 2009 influenza pandemic [15].

Fear of possible adverse effects was the most cited reason by pregnant women for avoiding influenza vaccination [16].

Health professionals have a key role in promoting immunization in pregnant women. However, it has been found that a significant percentage of this group is unaware that pregnant women are included in the risk group subject to vaccination [17].

The purpose of this study is to investigate influenza vaccination coverage among pregnant women in three Health Departments of the Valencian Community (Spain): La Ribera (LR), Torrevieja (TV) and Elx-Crevillent (EC) during the 2014-15 season, and identify their degree of knowledge, sources of information and attitudes towards immunization against influenza.

#### METHODS

An observational, multicentre, descriptive and cross-

sectional study was performed among pregnant women who gave birth in the three referral hospitals of the health departments under study (LR, TV and EC) between October 20, 2014 and January 31, 2015. These hospitals provide health care to a total of 570,000 inhabitants (250,000 in LR; 170,000 in TV and 150,000 in EC).

Once the total sample of pregnant women having given birth during the study period was obtained, their vaccination uptake was determined based on the Nominal Vaccination Registry (NVR).

The NVR portal was set up by the autonomous government and it electronically stores information on people vaccinated in hospitals, health centres and clinics in the Valencian Community since 1994 [12].

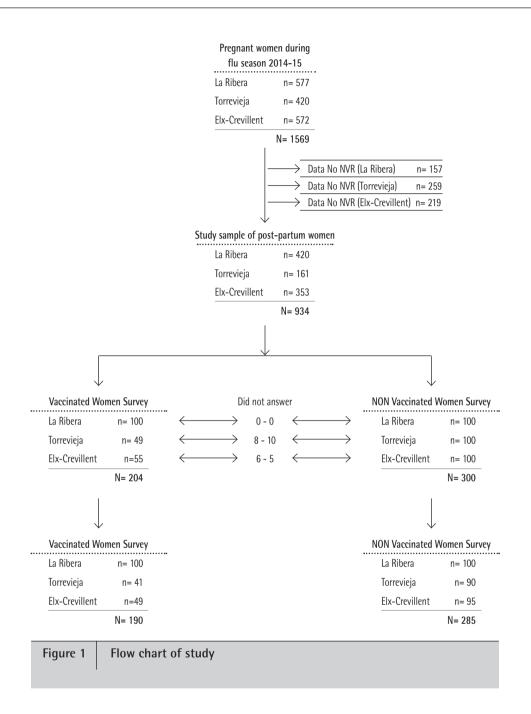
To analyse vaccination coverage and factors influencing vaccination, the following variables were used: health department (LR / TV / EC), age (<25 years, between 25 and 35 years,> 35 years), country of origin (Spain, Others), parity (1 child, 2 children, >3 children) and influenza vaccination status (yes/no/no data in NVR) during the 2014-15 season.

To identify the degree of knowledge, sources of information and attitudes towards the immunization of pregnant women, a subgroup of 100 pregnant vaccinated women and a subgroup of 100 non-vaccinated women were selected within each department. Inclusion in these two subgroups was determined randomly from among the studied population, in order to identify possible differences between them, with a level of significance of <0.05. The subgroup of vaccinated pregnant women did not reach the minimum sample of 100 women in two health departments (TV, 49 and 55, EC) due to a lack of records in the NVR or because of its low vaccination coverage.

The study was conducted according to the Declaration of Helsinki and current legislation and was approved by the Research Commission of the participating centres after obtaining authorization from the Spanish Agency of Medicinal Products and Medical Devices ("Agencia Española del Medicamento y Productos Sanitarios", AEMPS) (number Cl2015-20).

Both subgroups were interviewed by telephone using a closed ad hoc survey, a survey conducted by authors of the current manuscript published in similar studies [14]. Telephone calls were made between March and May 2015, respondents were informed about confidentiality, protected anonymity, as well as the right not to answer questions.

We asked vaccinated women about the source of the information of influenza vaccine, the health provider involved in recommending the vaccination, and whether they would opt to be vaccinated again in their next pregnancy the health provider involved in recommending the vaccination, and whether they would be vaccinated again in their next pregnancy. For the group of women who did not receive vaccines, asked if they had heard about the vaccine and, if so, which healthcare provider recommended it, the reasons Vaccination of pregnant women in the Valencian Community during the 2014-15 influenza season: a multicentre study



for vaccine rejection, their knowledge about the vaccine and whether they would have the vaccine given in their next pregnancy.

The inclusion criteria in the study consisted in being pregnant and cared for by the Primary Health Care centres, as well as being assisted with labour diagnosis in the health departments (LR, TV and EC). Women having given birth in other hospitals were excluded, as well as those with contraindications to influenza vaccination, occurrence of antenatal death or who refused the telephone survey.

Statistical analysis was performed using the statistical

software SPSS version 20.0. Quantitative and qualitative variables were expressed as absolute frequencies, mean and ratios. Vaccination coverage was calculated as the percentage of women vaccinated with respect to the total number of pregnant women, and their 95% confidence interval (CI) was calculated. The Chi-square test was used to analyse the statistical significance of differences in vaccine coverage percentages between the categories of variables. To evaluate the adjusted effect of age, parity, country of origin and health department variables on non-vaccination, multivariate logistic regression models were constructed, taking non-vaccination as a response variable and the rest as explanatory variables.

# Table 1Pregnant women according to study variables and data in<br/>the Nominal Vaccination Registry (NVR).

	-	No NVR information		NVR information		
		n	%	n	0/0	Total
Total		635	40.5	934	59.5	1,569
Health department	La Ribera	157	27.2	420	72.8	577
	Torrevieja	259	61.7	161	38.3	420
	Elx-Crevillent	219	38.3	353	61.7	572
Country of Origin	Spain	374	34.2	724	65.8	1098
	Not Spain	261	55.4	210	44.5	471
Parity <sup>a</sup>	1	158	30.7	356	69.3	515
	2	224	40.5	329	59.5	553
	3 or more	253	49.2	248	50.2	286
Age	<25 years	73	33.2	147	66.8	220
	25-35 years	409	40.8	593	59.2	1002
	>35 years	153	44.1	194	55.9	347

<sup>a</sup>Total number of pregnancies, including the current pregnancy.

Table 2Influenza vaccination coverage among pregnant women during the 2014-15 season					
		n	Vaccinated women	0/0	IC95%
Total		934	261	27.9	[25.0-30.7]
	La Ribera	420	157	37.4	[33.1-42.3]
Health department	Torrevieja	161	49	30.4	[23.3-37.5]
	Elx-Crevillent	353	55	15.6	[11.8-19.4]
Country of origin	Spain	724	193	26.7	[23.5-29.9]
Country of origin	Not Spain	210	68	32.4	[26.1-38.7]
	1	357	96	27.8	[22.4-31.6]
Parity <sup>a</sup>	2	329	93	28.3	[23.4-33.2]
	3 or more	248	72	29.0	[23.3-34.6]
Age	<25 years	147	38	25.9	[18.8-32.9]
	25-35 years	593	162	27.3	[23.7-30.8]
	>35 years	194	61	31.4	[24.8-37.9]

<sup>a</sup>Total number of pregnancies, including the current pregnancy.

### RESULTS

After applying the exclusion criteria (figure 1), a total of 934 patients were finally selected out of a total of 1.569 postpartum patients. A total of 635 (40.4%) postpartum women were discarded from the study because they did not have any data recorded in the NVR. In this respect, the TV

department stood out because it disposed of no recorded data on 61.7% of postpartum women (table 1). The final sample under study turned out not to be homogeneous across the different health departments (LR, 420 (44.9%); TV, 161 (17.2%); and EC, 353 (37.8%)). Vaccination coverage was 27.9% (n=261 [Cl 95%: 25.0-30.7]), with a higher coverage in LR, with 37.7% (n = 157) and TV, with 30.4% (n = 49) (table 2).

Table 3	3
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# Attitudes and information sources on influenza vaccination in pregnant women vaccinated and not vaccinated during the 2014-15 season

Pregnant women vaccinated	Total (n=190) %	CI (95%)	Pregnant women not vaccinated	Total (n=285) %	CI (95%)
Have you heard of influenza vaccinati	on during pregnancy?	)			
			SI	67.7	[62.3-73.1]
			No	32.3	[26.9-37.7]
Where did you receive information?					
Primary Care Centre	94.7	[91.5-97.8]	Did not receive	31.9	[26.4-37.3]
Media	2.1	[0.1-4.1]	Media	8.8	[5.5-12.1]
Private consultation	2.6	[0.3-4.8]	Family/Friends	7.7	[4.6-10.8]
The pregnant woman is a health care professional	0.5	[0.0-1.5]	At work	0.7	[0.0-1.6]
Who recommended the influenza vaco	cine?				
Family doctor	7.9	[4.1-11.7]	Midwife	44.6	[38.8-50.4]
Midwife	83.7	[78.4-88.9]	Gynaecologist	0.4	[0.0-1.1]
Health care professional	1.6	[0.0-3.4]	Primary Care doctor	2.1	[0.4-3.8]
Gynaecologist	4.2	[1.3-7.0]	The pregnant woman is a health care	3.9	[1.6-6.1]
Other	4.2	[1.3-7.0]	professional		
If you became pregnant again at the same time of year, would you get vaccinated again?		If you became pregnant again at the same time of year, would you get vaccinated then?			
Yes	96.8	[94.3-99.3]	Yes	61.8	[56.1-67.4]
No	3.2	[0.7-5.7]	No	31.6	[26.2-36.9]
			Not sure	6.7	[3.8-9.6]

Spain was the country of origin accounting for 77.5% (n=724) of the sample, presenting vaccination coverage of 26.7% (n = 193 [95% CI: 23.5-29.9]). The remaining 22.5% (n=210) were non-Spanish, with a coverage of 32.4% (n=68 [CI 26.1-38.7]) (table 2).

Concerning the parity variable, higher coverage was observed in multiparous pregnant women (> 3 children), 29.0% (n = 72 [95% Cl: 23.3-32.9]). This result is inversely related to the distribution of the study's population, since the number of first parity (38.1% (n = 356)) or Second parous (35.2% (n = 329)) women predominated.

Women between 25 and 35 years represented 63.5% (n = 593) of the total, followed by 20.7% (n = 194) of pregnant women> 35 years. Vaccination coverage in the > 35 years group was highest, with 31.4% (n = 61 [95% Cl: 24.8-37.9]); this data had a descending orientation, 27.3% (n=162) and 25.9% (n=38), according to the established age segments (table 2).

Out of a total number of 190 surveys carried out on vaccinated pregnant women aiming at identifying the degree of knowledge, attitudes and sources of information, 52.6% (n=100), 21.6% (n=41) and 25.8% (n=49) corresponded to LR,

TV and EC respectively (table 3).

A total of 94.7% (n = 180 (95% Cl: 91.5-97.8) received information on the influenza vaccine at their Primary Health Care Centre, and the LR and EC departments stood out with 98% (n = 98) and 96 % (N = 47) respectively. Midwives accounted for 83.7% of the total number of health professionals involved (n = 159 [95% Cl: 78.4-88.9]) and played a major role in recommending the vaccine to pregnant women. The 96.8% of vaccinated pregnant women (n = 184 [95% Cl: 94.3-99.3]) would get vaccinated again if they got pregnant again during the seasonal period of the vaccination campaign (table 3).

A total of 285 non-vaccinated pregnant women were contacted for the telephone survey, with a distribution of 35.1% (N = 100), 31.6% (n = 90), and 33.3% (n = 95), in LR, TV and EC respectively. Of these, 67.7% (n = 193 [95% CI: 26.4-73.1]) had heard of influenza vaccination during pregnancy, EC showing the lowest level of information with 45.3% (n = 43) (table 3). Midwives, with 44.6% (n = 127), were again the main source of information in all three departments studied (table 3).

The main arguments put forward for rejecting

Table 4	Reason for influenza vaccine refusal in pregnant women not vaccinated during			
	the 2014-15 season			

Pregnant women not vaccinated	Total (n=285) %	CI (95%)
Could you indicate your reason for refusal?		
Unawareness	29.5	[24.2-34.8]
Not necessary	25.6	[15.5-35.6]
Not receiving information from a health worker	12.3	[8.5-16.1]
Giving birth soon	8.1	[4.9-11.3]
Fear of adverse effects	8.1	[4.9-11.3]
Not effective	6.7	[3.8-9.6]
Never get vaccinated	3.9	[1.6-6.1]
Advised against by doctor	2.8	[0.9-4.7]
Have a cold	2.1	[0.4-3.7]
Long waiting list	1.1	[0.0-2.3]

administration of the vaccine were: unawareness of the recommendation of influenza vaccination during the gestational period with 29.5% (n = 84 [95% Cl: 24.2-34.8, EC data standing out with 44.2% (n = 42); and 25,6% (n=73 [IC95%: 15,5-35,6], not considering it necessary as a preventive measure, especially in the LR department with a total of 39% (n=39) (table 4).

A total of 61.8% (n = 176 [95% Cl: 56.1-67.4]) of unvaccinated pregnant women interviewed showed a predisposition to get vaccinated against influenza in the case of a new pregnancy.

An analysis of the logistic regression model of the department, country of origin, age and parity (modelling the probability of non-vaccination) variables, showed that there was no statistically significant relationship between influenza vaccination and the rest of the variables, except for the department variable. The EC department showed worse vaccination coverage than the LR department, these differences being statistically significant and adjusted by the multivariate model.

Differences with the TV department were not significant, although this may be due to lack of data on pregnant women profiles in the NRV; the latter were significantly elder than those in the RN department, with a greater number of children and a much higher percentage of non-Spanish women.

#### DISCUSSION

Vaccination coverage registered in the Valencian Community during the 2014-15 season in the so-called risk groups was less than 80% of the immunization rates recommended by the WHO. Vaccination coverage of 50% was obtained in the population with cardiac pathology, 43% in health professionals and 17.4% in pregnant women [18].

Although vaccination is an essential recommendation to prevent and combat maternal and neonatal morbidity [1], vaccination coverage of pregnant women was low, showing unequal behaviour across the three health departments under study. The EC department, with 15.6%, presented the lowest rates, a figure similar to the 17.4% obtained in the southern area of Madrid during the 2004-05 season [6].

In Europe, data on vaccine coverage of pregnant women are disparate. A study conducted in Germany during the 2012-13 season turned out a coverage of 15.9% [19], another in the UK showed a coverage between 14.9% and 21.6% during the 2009-10 season [20] and in Belgium a rate of 42.8% for the 2013-14 season [21] was found. These latter figures are similar to those in different areas of the United States (41%) during the same season [22].

Although they are far from acceptable, our results reveal higher coverage rates than those in other similar studies, such as those described in the Barcelona health department (5%) during the 2007-08 season [13].

The influenza surveillance program developed in the Valencian Community shows a progressive increase in the number of influenza vaccine doses administered to pregnant women compared to previous seasons (7.6%; 9.2% and 14.8% for season 2011-12; 2012-13 and 2013-14 respectively) [12, 18, 23].

These reports do not give real figures on the total number of pregnant women, but they do provide an estimate, so this study allows updating the situation of influenza immunization in the group of pregnant women in the Valencian Community.

Significantly, non-Spanish pregnant women had better vaccination coverage than Spanish pregnant women.

Data relating to age and parity variables were similar across studied departments, presenting a pattern of higher vaccination rates in pregnant women who were elder and had previously been mothers. This result coincides with that revealed in a recent systematic review of studies predominantly in Europe and America. This latter review concludes that older ages of pregnant women, previous experiences and recommendations of medical staff were the most influential factors in the acceptance of the vaccine against seasonal influenza [24].

Vaccinated pregnant women reported receiving information on the vaccine at their health centre and their midwife recommending it. The bond of trust established between midwives and pregnant women during the months of pregnancy could explain these results [14]. In addition, these data coincide with a similar study conducted in London [25], where recommendation by midwives accounted for 76% of cases. However, at the international level, the family doctor is found to be the health professional having the greatest impact in recommending influenza vaccination [20, 26]. Almost all

vaccinated pregnant women surveyed said that in the case of a new pregnancy, they would get vaccinated again. Nonetheless, the behaviour of unvaccinated pregnant women was uneven according to the department, where a higher percentage of pregnant women were located in EC and TV, with the intention of not being vaccinated again. One study identified a greater predisposition to immunization in women who had already been vaccinated prior to their pregnancy during other flu seasons [27].

Unawareness that influenza vaccination is recommended during pregnancy is the main reason vaccine administration is rejected, thus corroborating data from previous studies. [28]. Other arguments against vaccination were that of considering it as non-effective and non-essential, which is part of the perception of lack of scientific evidence about the efficacy and safety of the vaccine [18, 29, 30].

Nevertheless, the safety of the influenza virus vaccine in pregnant women has been evaluated in observational studies [31] and to date, there is no evidence of an increase in adverse effects such as late antenatal death, miscarriage or congenital malformations [32]. Nor is there any evidence that pregnant women immunized against influenza develop a greater number of adverse effects compared to those who are not pregnant and are vaccinated [33].

The importance of information strategies during the vaccination season highlights the key role that health professionals have in transmitting such information [34] in socio-sanitary contexts as disparate as the United Kingdom [35] or Pakistan [36]. However, in other studies, the effectiveness of these interventions to increase vaccination coverage is put into question, and health professionals in contact with pregnant women are recommended to verbalize the benefits of the vaccine for newborns [37]. In this line of research, the majority of studies was situated in North America and was published in 2011, as a consequence of the 2009 influenza pandemic. From that year onwards, a decrease of interest in scientific literature can be observed on influenza vaccination among pregnant women [30].

The recent inclusion of the dTpa vaccine as a recommendation for pregnant women may improve adherence to influenza vaccination. Both can be administered simultaneously and are safe for the mother and the child [38].

The study has some limitations since pregnant women without data in the RVN have been excluded from the study. A greater participation of the health professionals in charge of the registration of vaccines in the RVN would imply a considerable improvement of the vaccination program.

Vaccination coverage among the studied population of pregnant women was low and could be improved. In order to reach higher coverage rates, new strategies are needed to encourage health professionals to inform pregnant women, minimize excessive self-confidence and perceptions of the vaccine as dispensable. Disseminating scientific evidence available on the risks of influenza and the safety of the influenza vaccine as a Public Health preventive measure is essential. In Spain, midwife advice is a crucial factor in transmitting information to pregnant women on the influenza vaccine.

Both vaccinated and non-vaccinated pregnant women are highly predisposed to accepting immunization against influenza in the case of a new pregnancy, and this fact reinforces the importance of communication strategies directed at this group.

Finally, in the light of the lost records observed, the NVR should be used with caution when determining the vaccination status of pregnant women. The duty of professionals to record each vaccination should be reinforced.

# CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest

### FUNDING

None to declare

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