

## BRIEF ORIGINAL

Receipt: 2017 July 25  
Accepted: 2018 March 6  
ePublished: 2018 March 16

## CONSISTENCY BETWEEN THE INFLUENZA VACCINATION HISTORY RELATED BY PREGNANT WOMEN AND THAT INDICATED ON THE CLINICAL RECORD OF CATALONIA

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The authors declare that there was no conflict of interests on performing this work

### ABSTRACT

**Background:** Sometimes and when a registry is not available, influenza vaccination (IV) is based on vaccination records reported by citizens, and there may be discrepancies between the two sources of information. The objectives of this study were: to know the IV coverage in pregnant women (both referred and recorded in the clinical history), to determine the concordance between both sources of information and to quantify the lost opportunities of IV due to errors in verbalization.

**Methods:** From June to September after the IV campaigns 2013/2014 and 2014/2015, a cross-sectional survey was carried out to a random sample of 657 pregnant women assisted in seven ASSIR (public centers for sexual and reproductive care) in Catalonia. The history of IV referred by the pregnant women and those of the vaccination record of the computerized clinical history were collected. Vaccination coverage was calculated for each source of information, it was also calculated the concordance between both (Kappa index) and the proportion of pregnant women who reported receiving the IV without having received it. This indicator was analyzed according to the different variables compared to globality through the Chi-square test. The accepted statistical significance level was  $p < 0.05$ .

**Results:** The referred vaccination coverage was 22.2% (95% CI: 19.0%-25.4%) and 15.4% (95% CI: 12.6%-18.2%) according to the vaccination record ( $p = 0.0019$ ). Despite the good concordance between both sources (Kappa = 0.738), one out of every three pregnant women who said they were vaccinated was not according to the registry. The lower concordance and the lost opportunities of IV occurred in the upper social strata, at intermediate fertile ages and when there was previous knowledge and experience of IV.

**Conclusions:** The coverage of IV in pregnant women continues to be low. In spite of the good concordance between both sources of information, one out of three unvaccinated believe that they have been vaccinated, as result they can lose a vaccination opportunity.

**Key words:** Vaccination coverage, Influenza vaccine, Pregnant women, Vaccine records, Practices, Vaccination.

### RESUMEN

#### Concordancia entre los antecedentes de vacunación antigripal referidos por las gestantes en Cataluña y los registrados en la historia clínica

**Fundamentos:** En ocasiones y cuando no se dispone de un registro, la vacunación antigripal (VAG) se fundamenta en los antecedentes vacunales referidos por los ciudadanos. Cuando existe la posibilidad de comparar ambas fuentes de información, a veces se han observado discrepancias entre las mismas. Los objetivos de este estudio fueron: conocer la cobertura de VAG en gestantes tanto referida como registrada en la historia clínica, determinar la concordancia entre ambas fuentes de información y cuantificar las oportunidades perdidas de VAG debidas a los errores en la verbalización.

**Métodos:** De junio a septiembre después de las campañas de VAG 2013/2014 y 2014/2015 se aplicó una encuesta transversal a una muestra aleatoria de 657 gestantes atendidas en siete ASSIR (Centros Públicos de Atención Sexual y Reproductiva) de Cataluña. Se recogieron los antecedentes de VAG referidos por las gestantes y los del registro de vacunaciones de la historia clínica informatizada. Se calcularon la cobertura vacunal para cada fuente de información, la concordancia entre ambas (índice Kappa) y la proporción de gestantes que manifestaron haber recibido la VAG sin haberla recibido. Este indicador se analizó según las distintas variables comparándose con la globalidad a través de la prueba de Ji cuadrado. El nivel significación estadística aceptado fue de  $p < 0,05$ .

**Resultados:** La cobertura vacunal referida fue del 22,2% (IC 95%: 19,0%-25,4%) y del 15,4% (IC 95%: 12,6%-18,2%) según el registro de vacunaciones ( $p=0,0019$ ). A pesar de la buena concordancia entre ambas fuentes (Kappa=0,738), una de cada tres gestantes que manifestaron estar vacunadas no lo estaba según el registro. La menor concordancia y las oportunidades perdidas de VAG se produjeron en los estratos sociales altos, a edades fértiles intermedias y cuando se tenían conocimientos y experiencias previas de VAG.

**Conclusiones:** La cobertura de VAG en gestantes continua siendo baja. A pesar de la buena concordancia entre ambas fuentes de información, una de cada tres no vacunadas cree estarlo, pudiendo perder una oportunidad de vacunación.

**Palabras clave:** Cobertura de vacunación, Vacuna antigripal, Mujeres embarazadas, Registros vacunales, Prácticas, Vacunación.

## INTRODUCTION

According to the World Health Organization (WHO) and various scientific societies, pregnant women are a priority risk group for influenza vaccination (IV)<sup>(1,2,3)</sup>. This is a safe and effective vaccine<sup>(4)</sup>, being beneficial for pregnant women, and this benefit even extending to breastfed infants up to the age of six months<sup>(5)</sup>. Despite this, IV coverage in pregnant women in Catalonia is very low, ranging from 3,7% to 5,6% in the season from 2008/2009 to 2012/2013, and reaching a maximum level of 8,3% in the pandemic 2009/2010 season<sup>(6,7)</sup>. One of the factors associated with non-vaccination is not having a vaccination card or record and deciding in accordance with the background expressed by the user, giving rise to an overestimation of vaccine coverage<sup>(8,9)</sup> and, therefore, to a loss of vaccine opportunities<sup>(10,11)</sup>.

The ASSIR are public sexual and reproductive health centres which attend to pregnant women. These centres perform preventive actions, including vaccination of pregnant women. The midwife is the healthcare professional who most recommends IV (28,9%) in this group<sup>(6)</sup>.

The vaccination procedure is a process which includes the prior history of the patient's vaccine background in order to decide on the administration of the vaccine in question. On occasions, and when there is no record, this decision is based on the history indicated by the pregnant woman. The objectives of this study were: know IV coverage in pregnant women both as expressed and as indicated on the clinical record, determine the consistency between these two sources of information and quantify the IV opportunities lost due to verbalization mistakes.

## SUBJECTS AND METHODS

Between the months of June and September following the 2013/2014 and 2014/2015 IV campaigns, a cross-sectional survey was applied to pregnant women who undertook

monitoring and control of the pregnancy exclusively in the ASSIR of the Barcelona Sur, Camp de Tarragona, Terres de l'Ebre and Lleida Healthcare Regions. Those with language difficulties not solved by a proxy (family or friend), those who completed the pregnancy with a bad obstetric outcome (miscarriage or stillbirth) and those who had IV contraindicated were excluded. The following assumptions were made to calculate the sample size: a confidence level of 95%, vaccine coverage of 5% and a desired precision of  $\pm 2,0\%$ , 657 pregnant women being required for this. An expected response level of 50% was moreover taken into account, and 10% of pregnant women with exclusion criteria. The sample was obtained by random sampling proportional to the population assigned to be ASSIR starting from the pregnant women registered in these centres.

Having received IV during pregnancy (yes/no) was collected in two variables, one depending on whether expressed by the pregnant woman and the other on reviewing the vaccination record in the computerized clinical record. The socio-demographic variables were: age, high or low-income country of origin (according to the World Bank<sup>(12)</sup> and OECD<sup>(13)</sup> classification), immigrant, time spent in our country and social class according to REI Model<sup>(14)</sup>, which includes level of education, per capita family income and crowding index. Under obstetric background, the number of miscarriages, pre-term and full-time births and the number of previous live births were collected. In relation to IV, the personal vaccination history was obtained, whether they vaccinated previous children and whether they intended to vaccinate the newborn in relation to systematic vaccinations. As regards knowledge on influenza and IV during pregnancy, they were asked about the severity of influenza during pregnancy and the safety and benefits of IV. Finally, they were asked whether the male or female midwife had recommended IV. The information was collected in telephone interviews (three attempts) by a duly trained midwife. A pilot

test was undertaken with 51 pregnant women. The approval of the project was obtained from the Clinical Research Ethics Committee of the Instituto de Investigación en Atención Primaria Jordi Gol i Gurina (IDIAP).

The qualitative variables were described by means of percentages and the quantitative variables through the arithmetic mean and standard deviation ( $\bar{X} \pm SD$ ) and the range. Vaccine coverage (related or recorded) was defined as the number of pregnant women vaccinated divided by the total number of pregnant women, expressed in percentages and accompanied by a confidence interval of 95% (CI 95%). The consistency between the verbalization of the vaccine status and its observation on the record was measured using the Kappa index. The proportion of pregnant women who related having received IV and for whom the opposite appeared on the record was moreover calculated. This indicator was accompanied by the corresponding CI 95%. Finally, this indicator was analyzed in accordance with the different variables of the study, comparing with the whole by means of the chi-squared test. The statistical significance level accepted was  $p < 0,05$ .

## RESULTS

We started from a sample of 1593 pregnant women, 176 of whom were excluded (11,0%). Of the remaining 1417, a total of 657 (46,4%) accepted to participate, their description being presented in **table 1**.

Almost a third were immigrants, basically from low-income countries, two thirds had essential knowledge on influenza and IV and less than a tenth declared that they had been previously vaccinated against influenza.

Vaccine coverage related by the pregnant women was 22,2% (CI 95%: 19,0%-25,4%) and 15,4% (CI 95%: 12,6%-18,2%), according to that indicated on the vaccination record of the Catalan Health Institute ( $p=0,0019$ ).

IV was observed on the record of 97 of the 146 pregnant women who related having received this vaccine (66,4%) and, from among the 511 who related the opposite, 4 appeared on the record as vaccinated (0,8%), with a Kappa index of 0,738. The consistency analyzed according to the different variables mainly obtained a Kappa index between 0,600 and 0,799 (good consistency). Women

**Table 1**  
**Description of the pregnant women participating in the study**

Characteristics	$\bar{X} \pm SD / \% (n)$	Range
Age (years)	31,8 $\pm$ 4,9	(18-47)
Previous live births	0,5 $\pm$ 0,7	(0-3)
Immigrant	32,9 (216)	na
Time spent in Spain (years)	9,5 $\pm$ 4,3	(1-25)
Immigrant from low-income country	30,4 (200)	na
Education complete up to secondary	63,9 (420)	na
Social class IV and V	13,9 (64)	na
Up to a maximum of two people/bedroom (crowding)	82,2 (526)	na
Know the risk of complications due to influenza	71,7 (471)	na
Know the safety of the influenza vaccine	62,6 (411)	na
Have been previously vaccinated against influenza	7,9 (52)	na
The male or female midwife did not recommend influenza vaccination	39,1 (328/609)	na

X: arithmetic mean; SD: standard deviation; na: not appropriate

under 25 years old obtained a Kappa index equal to or above 0,8 (very good consistency) (Kappa = 0,874), as did those over 34 (Kappa = 0,827), with a per capita family income equal to or less than €240 per month (Kappa = 0,844), with incomplete primary education (Kappa = 0,821), with more than two people per bedroom (Kappa = 0,879), with social class IV (Kappa = 0,824) and having had two previous full-term pregnancies (Kappa = 0,808). On the contrary, the following obtained a Kappa index equal to or below 0,6 (moderate consistency): women with a per capita family income of €241 to €370 per month (Kappa = 0,592), those who had

been previously vaccinated against influenza (Kappa = 0,497), those who had been previously vaccinated on being healthcare professionals (Kappa = 0,303), those who do not know the safety of IV (Kappa = 0,519) and those for whom the male or female midwife did not recommend IV (Kappa = 0,545).

In relation to potentially lost vaccination opportunities, from among the total number of pregnant women 7,5% (49) with a CI 95% (5,5%-9,5%) responded that they had received IV when, on the contrary, the record indicated that they had not received it. Table 2 presents the subgroups of pregnant women in which

**Table 2**  
**Influenza vaccination opportunities potentially lost in pregnant women situated above the overall value (7.5%)**

Characteristics of the pregnant women	Vaccination opportunities potentially lost*		p-value**
	% (n/N)	CI 95%	
Age from 25 to 34 years old	9,4% (38/403)	6,6%-12,2%	NS
Originating from low-income country	8,8% (40/457)	6,2%-11,4%	NS
Autochthonous	8,6% (38/441)	6,0%-11,2%	NS
Per capita family income > €240	7,7% (36/468)	5,3%-10,1%	NS
University education complete	8,4% (20/237)	6,5%-10,3%	NS
1-2 people per bedroom (crowding index)	8,3% (42/504)	5,9%-10,7%	NS
Social class I-III	9,0% (36/398)	6,2%-11,8%	NS
Previous full-term birth	9,3 (19/204)	5,3%-13,3%	NS
No previous miscarriage	8,5% (44/515)	6,1%-10,9%	NS
Does not vaccinate her children	100% (4/4)	-	0,0000
Does not plan to vaccinate the newborn	100% (8/8)	-	0,0000
Was previously vaccinated against influenza	20,9% (14/52)	9,8%-32,0%	0,0001
Was previously vaccinated on being a healthcare professional	39,1% (9/23)	20,0%-58,2%	0,0000
Was previously vaccinated due to chronic pathology	14,3% (1/7)	-11,6%-40,2%	NS
Knows the risk of complications from influenza	8,5% (40/471)	6,0%-11,0%	NS
Knows the safety of influenza vaccination	10,9% (45/411)	7,9%-13,9%	NS
Knows the benefits of influenza vaccination	9,6% (45/467)	6,9%-12,3%	NS
The male or female midwife did not recommend vaccination against influenza	18,1% (43/238)	13,2%-23,0%	0,0000

\* Pregnant women who declared that they were vaccinated against influenza but did not appear on the vaccination record of the Catalan Health Institute among total pregnant women;  
\*\*Compared with the overall value (7,5%)

these lost opportunities were greater than 7,5%. Among them, the following were observed as statistically higher than this overall percentage: the subgroups in which the woman had not vaccinated previous children, did not intend to vaccinate the newborn, had been vaccinated in previous pregnancies, when the reason for prior vaccination was being a healthcare professional and when the male or female midwife had recommended IV.

## DISCUSSION

In this study, IV coverage in pregnant women increased threefold compared with that obtained in the last 14 years<sup>(6,7)</sup>, according to the information of the vaccination records, and fourfold according to the information verbalized by them. Even so, IV coverage in pregnant women is clearly insufficient.

Despite the good consistency between what they recall and what appears on the records, one out of three non-vaccinated pregnant women believes that she is vaccinated and may, therefore, lose the opportunity of being vaccinated. Overall, this figure would correspond to one out of every 13 pregnant women. Verbalization would inflate correct vaccine status by 44.2%, this being observed in other studies<sup>(8,9)</sup>. In this respect, and in order to reduce lost vaccination opportunities, various scientific institutions and societies (the Task Force and the National Vaccine Advisory Committee of the CDC - Centers for Disease Control and Prevention) made a series of recommendations based on scientific evidence, including the correct recording of vaccines administered and consulting vaccine records and documents prior to vaccination<sup>(15,16)</sup>.

The loss of vaccination opportunities and the lower consistency occurred essentially in the higher social classes and at intermediate ages, which could be related to the higher insertion and involvement of these pregnant women in the labour market, leaving less time for these women for their own care. In any case, the survey on healthcare knowledge,

competencies and skills indicates women from 35 to 49 years old as the group most interested in looking after their own health<sup>(17)</sup>. In view of all this, it would be convenient to undertake in-depth research on the social and economic aspects of this group.

Previous IV knowledge and experiences could give rise to a negative attitude in relation to this vaccine. Thus, the fact of being a healthcare professional, previous vaccination and an a priori decision not to vaccinate the newborn or not having vaccinated previous children, also give rise to lost vaccination opportunities due to a lack of interest of the pregnant woman in this vaccine. In this respect, some authors insist on analyzing these beliefs and on designing strategies to change the attitude of healthcare professionals<sup>(18,19)</sup>. Furthermore, there were also more lost opportunities with those pregnant women whose male or female midwife did not recommend IV and when there was a lack of information on the safety of the vaccine, which could highlight the abilities of these professionals to collect information on the vaccination history and to give information on IV, as demonstrated in other studies<sup>(6)</sup>.

The study was performed in two IV seasons, between which there were no changes in IV strategies or in the other vaccines indicated during pregnancy. The fact that the study was performed in the ASSIR could represent a bias of underrepresentation of pregnant women seen in other public centres such as hospitals and those who attend private centres. Carrying out the interview by telephone, although by an educated and trained midwife, may not achieve the same level of attention in relation to that which would have been obtained in a face-to-face manner in the surgery, which could give rise to a presumably random error. Moreover, having undertaken the interviews a few months after the vaccination period would make it easier to recall whether they had been vaccinated and which vaccines they had received. Also, it is not possible to guarantee the validity of the vaccine records,

especially when a vaccine appears as not administered, which could overestimate the findings of this study.

In conclusion, systematizing a review of vaccine records within the vaccine procedure in pregnant women would be a non-negligible way of contributing to the improvement of low vaccine coverage in this group.

## ACKNOWLEDGEMENTS

The male/female midwives of the ASSIR of the Barcelona Sur, Camp de Tarragona, Lleida, Terres de l'Ebre Healthcare Regions and the pregnant women seen by them.

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