



Human Vaccines & Immunotherapeutics

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/khvi20

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To cite this article: Sara Mazzilli, Lara Tavoschi & Pier Luigi Lopalco (2021) Knowledge, attitudes and practices concerning pertussis maternal immunization in a sample of Italian gynaecologists, Human Vaccines & Immunotherapeutics, 17:6, 1681-1685, DOI: 10.1080/21645515.2020.1833580

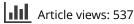
To link to this article: https://doi.org/10.1080/21645515.2020.1833580



Published online: 26 Jan 2021.

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# **RESEARCH PAPER**

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# Knowledge, attitudes and practices concerning pertussis maternal immunization in a sample of Italian gynaecologists

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#### ABSTRACT

Infants are at risk of developing serious diseases as a consequence of pertussis infection. Thus, to protect newborns, many countries, including Italy, have introduced pertussis maternal immunization. However, despite the compelling evidence supporting Tdap vaccinations, the rates of coverage among Italian pregnant women have remained consistently very low. Numerous studies have shown that healthcare providers' recommendations are critical for achieving high maternal vaccination coverages. This study explores Italian gynecologists' knowledge, attitude and practices concerning pertussis maternal immunization. Between July 2018 and September 2018, we performed a national cross-sectional survey administered by e-mail using the mailing list of the Association of Italian Hospital Obstetricians and Gynecologists (AOGOI): the mailing list included more than 3500 members. A total of 451 respondents distributed throughout Italy completed the online survey. Overall, 275 (60.97%) respondents did not routinely recommend pertussis vaccination to pregnant women, mainly for suboptimal knowledge of the maternal pertussis vaccine, protocols, and guidelines: furthermore, 15.44% (69/447) of gynecologists were not aware of the pertussis vaccination program for pregnant women. Gynecologists working in the South or in the Islands of Italy were less aware about the need of administering Tdap in expectant mothers, suggesting that there is a potential risk of health inequalities based on differing levels of vaccine knowledge and recommendations across Italy. In order to enable healthcare professionals to provide accurate and timely information on pertussis immunization to pregnant women, targeted educational programs to improve gynecologists' knowledge on pertussis vaccination are needed.

### 1. Introduction

Despite high vaccination coverage, whooping cough (pertussis) is reemerging, up to the point that it currently represents one of the most prevalent vaccine-preventable diseases in Western countries.<sup>1</sup> Unfortunately, pertussis infection may result in a dangerous disease in infants, with high risk of severe complications, including death.<sup>2</sup> Therefore, providing adequate protection coverage to newborns is a high priority. Several scientific studies have concluded that after the acellular pertussis adult vaccine in combination with tetanus and diphtheria toxoids (Tdap) administration in the third trimester of gestation, pregnant women produce high concentrations of antibodies against pertussis antigens which, through transplacental transfer, pass to the fetus: this ensures that infants are protected at the time of birth and during the first months of life, when they are too young to be vaccinated with the first series of antipertussis vaccination.<sup>3,4</sup> In response to the rise of whooping cough cases observed in the last decade, starting in 2012, many European countries have established the Tdap vaccination for women.<sup>5-7</sup> In 2017, in Italy, according to the World Health Organization,<sup>8</sup> the Ministry of Health stated that women should routinely get Tdap vaccine between the 27th and the 36th week of every pregnancy, regardless of prior Tdap history.<sup>9</sup> However, despite the compelling evidence supporting

**ARTICLE HISTORY** 

Received 24 July 2020 Revised 4 September 2020 Accepted 30 September 2020

#### **KEYWORDS**

Maternal pertussis vaccine; pregnancy; Tdap; gynecologists; attitude; practices; knowledge; survey

Tdap vaccinations, the rates of coverage among pregnant women is still below the recommended threshold.<sup>10,11</sup> A national cross-sectional survey conducted in 600 pregnant women reported 47.2% were aware that Tdap maternal immunization was offered to them free of charge.<sup>10</sup> Moreover, a cross-sectional study performed in the geographic area of Naples (Campania region) reported that of 358 pregnant interviewed none had received Tdap maternal immunization.<sup>11</sup> Numerous studies have shown that healthcare providers' recommendations are critical for achieving high maternal vaccination coverages.<sup>12–16</sup> Therefore, it is extremely important to assess gynecologists' attitudes, experiences, and concerns or barriers that may affect their practices concerning pertussis maternal immunization.

### 2. Methods

# 2.1. Study setting and sample

This study is based on a national cross-sectional survey conducted between July 2018 and September 2018. We sent two e-mails to each member of the Association of Italian Hospital Obstetricians and Gynecologists (AOGOI), that counts 3500 subscribers: the first e-mail was sent at the beginning of the study, whilst the second one was sent after one month. In both

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e-mails, we invited gynecologists to participate in an online survey conducted using Google Forms<sup>®</sup>. The e-mails included detailed explanation regarding the purpose and the noncompulsory nature of the study and clarifying that respondents' anonymity was guaranteed.

#### 2.2. Survey instrument

The questionnaire, which was developed by the research team, consisted of five parts. After informed consent, reflecting the anonymous nature of the study was obtained through a question, the first part of the questionnaire was focused on gynecologists' personal information (age, gender, geographical area of service and place of service). The second part investigated general knowledge and practices concerning pertussis vaccination for pregnant women. The third part examined doctors' perceptions and attitudes about vaccination and Tdap. The fourth part investigated gynecologists' selfperceived knowledge about Tdap vaccination in pregnancy. The fifth part asked gynecologists whether they were willing to be involved in the implementation strategy.

The survey included categorical responses and 5-points Likert scale (2 levels of agreement, 1 neutral choice, 2 levels of disagreement). To evaluate the effectiveness of our survey, especially in terms of questions' comprehensibility, we conducted a pilot with 10 gynecologists purposively selected among our acquaintances: we revised the questionnaire in line with their suggestions.

### 2.3. Statistical analysis

The software Stata (version 13.0) was used for the entirety of our statistical analyses. We started with a descriptive analysis of the main characteristics of the sample. The second level of analysis has been completed in three stages. First, comparison between proportions of each potential risk factor categories by gynecologists' knowledge or practices on Tdap administration in pregnancy were carried out using the Chi-square test of Pearson or Fisher exact test, in case any expected frequency was lower than five. Then, a univariate analysis was carried out to explore the association between each independent variable and the different outcomes of interest using logistic regression. All independent variables found to be associated with p-value less than 0.05 during the univariate analyses were entered in the multivariate logistic regression. Finally, a multivariate logistic regression model was constructed to identify factors significantly and independently associated with the following binary outcome variable: having heard about Tdap vaccination during pregnancy.

To build multivariate models a manual stepwise variables' selection procedure was used, in order to assess confounding and effect modification. To select the variables included in the models, we ran the Likelihood-ratio test. All reported values are two-sided, and a value of  $p \le 0.05$  was used as a threshold for statistical significance for all analyses.

#### 2.4. Ethics approval and consent to participate

During the study planning period, we checked the requirements of the competent Ethics Committee of the University of Pisa (https://www.unipi.it/index.php/etica-nella-ricerca /itemlist/category/1322-comitato-bioetico-dell-universita-dipisa). The guidelines for seeking ethics approval clearly identify the type of studies for which the Ethics Committee's review and approval are required. Our study did not require the involvement of patients, medical interventions of any sort, or the conduct of experiments on animals. Hence, according to the competent Ethics Committee, we did not require its approval. The guidelines are publicly available here: https://alboufficiale. unipi.it/wp-content/uploads/2017/12/regolamento.pdf.

We did comply with the requirements of informed consent and anonymization: we obtained consent from each respondent following the written explanation of the study's aims and objectives.

# 3. Results

# 3.1. Characteristics of gynecologists

A total of 451 gynecologists completed the survey; 186/411 (45.3%) of them worked in the north of Italy, 95/411 (23.1%) in the center, 80/411 (19.5%) in the South and 50/411 (12.2%) in the islands. These percentages correspond roughly to the population's distribution in the four different areas of Italy. Among the respondents, 30/444 (6.8%) were less than 40 years old, 75/444 (17.0%) were between 40 and 50 years old and 339/444 (76.4%) were over 50 years old. These percentages correspond roughly to the age distribution of medical doctors in Italy<sup>17</sup>. 276/442 (62.4%) of the gynecologists interviewed worked in a hospital, 6/442 (1.4%) in a public clinic, 120/442 (27.2%) in a private clinic, 33/442 (7.5%) in a counseling service and 7/442 (1.6%) in more than one of the mentioned places.

# 3.2. Gynecologists' general knowledge and practice on maternal Tdap

Overall, 84.79% (379/447) of the respondents knew about the existence of the pertussis vaccination program for pregnant women. According to Pearson's Chi Square test or Fisher's Exact test, three variables were found to be associated with the knowledge of Tdap vaccination during pregnancy: region, area, and place of service (Table 1).

According to the results of the logistic regression model, the respondents who worked in the North of Italy had a higher likelihood of having been informed about pertussis vaccine for pregnant women compared to those working in the South or in the islands of Italy. In addition, respondents working in counseling had a higher likelihood of having been informed about maternal Tdap. Of the gynecologists aware of pertussis vaccination for pregnant women 31.6% (120/379) reported recommending the vaccine to their patients always, 21.9% (83/379) often, 23.0% (87/ 379) occasionally while 23.5% (89/379) never recommended it. Between those who recommended the vaccine occasionally or did not recommend it, 75.8% (125/165) did not consider themselves properly informed about the pertussis vaccine, 7.3% (12/165) did not believe that pertussis may be a danger for newborns, 3.0% (5/ 165) thought that the vaccine could interfere with the proper development of the fetus, 13.9% selected the answer "other reasons". Among the gynecologists in our study who gave vaccines to

	Did you hear about the Tdap administration in pregnancy?					Did you recommend the Tdap to pregnant women?								
	No n		Yes			No		Yes						
		(%)	n	(%)	p <sup>a</sup>	n	(%)	n	(%)	$p^{\mathrm{a}}$				
Age	N = 444				0.8620	N = 376				0.7400				
30-40	5	16.67	25	83.33		13	52.00	12	48.00					
40–50	10	13.33	65	86.67		28	43.08	37	56.92					
>50	53	15.63	286	84.37		133	46.50	153	53.50					
Gender	N = 443				0.0680	N = 375				0.6760				
Male	41	18.47	181	81.53		86	47.51	95	52.49					
Female	27	12.22	194	87.78		88	45.36	106	54.64					
Area	N = 411				0.0210	N = 350				0.3700				
North	16	16.84	79	83.16		42	53.16	37	46.84					
Center	11	22.00	39	78.00		22	56.41	17	43.59					
South	17	9.14	169	90.86		75	44.38	94	55.62					
Islands	17	21.25	63	78.75		28	44.44	35	55.56					
Service place	N = 442				0.0230	N = 374				0.0380				
Hospital	43	15.58	233	84.42		120	51.50	113	48.50					
Public Practice	3	50.00	3	50.00		1	33.33	2	66.67					
Private Practice	17	14.17	103	85.83		38	36.89	65	63.11					
Counseling Service	2	6.06	31	93.94		11	35.48	20	64.52					
More than one	3	42.86	4	57.14		3	75.00	1	25.00					

<sup>a</sup>P-value from the Pearson chi-squared test or from the Fischer's exact test.

their patients, only 7/80 (8.7%) reported always administering the pertussis vaccine to their pregnant patients, whilst 8/80 (10.0%) did it often, 22/80 (27.5%) occasionally and 43/80 (53.8%) never.

# **3.3.** Gynecologists' perception and attitudes and about vaccination and maternal Tdap

In general, gynecologists have shown a good attitude about vaccination and maternal Tdap. Indeed, 285/421 (67.7) strongly agreed with the sentence: "I consider all vaccinations mentioned in the National Vaccinal Prevention Plan necessary", 106/421 (25.2%) agreed, 21/421 gave a neutral answer and only 9/421 (2.1%) disagreed or strongly disagreed with the sentence. The 47.7% (197/413) of respondents strongly agreed with the sentence "I think that pertussis vaccination for pregnant women is important", 36.1% agreed (149/413), 13.3% (55/ 413) gave a neutral answer, 1.7% (7/413) disagreed and 1.2% (5/413) strongly disagreed. Moreover, gynecologists recognized that pertussis may be a severe disease for infants; indeed, 345/411 (83.9%) agreed or strongly agreed with the sentence: "I believe pertussis is a danger for the newborn", 49/411 (11.9%) gave a neutral response, while 17/411 (4.1%) respondents strongly disagreed or disagreed (Table 2).

# 3.4. Gynecologists' self-perceived knowledge on maternal Tdap

Even if the majority of respondents are convinced that their knowledge on Tdap vaccine is adequate, a sizable portion of gynecologists would like to receive more information on this vaccination. Indeed, 61.5% (244/397) of respondents strongly agreed or agreed with the sentence: "I think I have enough knowledge about Tdap vaccine for pregnant women", 19.6% (78/397) gave a neutral response, while 18.9% (75/397) disagreed or strongly disagreed. Nonetheless, only 16/416 (3.8%) of respondents strongly disagreed or disagreed with the sentence: "I am interested in getting more info about Tdap vaccination during pregnancy", while 37/416 (8.9%) gave a neutral

answer and 363/416 (87.3%) agreed or strongly agreed with the sentence. 176/357 (49.3%) of the respondents would like to be informed about Tdap vaccine for pregnant women through e-mail, 55/357 (15.4%) would like to be informed during courses or online courses, 30/357 (8.4%) would like to receive articles on the topic, 22/357 (6.2%) would appreciate to be informed through internet webpages, 18/357 (5.0%) through their professional organizations, 16/357 (4.5%) through leaflets, 12/357 (3.4%) would like to talk about the topic during congresses, 5 (1.4%) state that they did not need more information and 23/357 (6.4%) answered "others".

# 3.5. Gynecologists' willingness to be involved in Tdap implementation

Despite the fact that most of the gynecologists are willing to recommend Tdap to pregnant women, and think that his/her recommendation is important, the majority of respondents do not want to be directly involved in the vaccine administration. Overall, 257/420 (61.2%) respondents strongly agreed with the sentence "I believe it is my responsibility to inform pregnant women about whooping cough vaccination", 123/420 (29.3%) agreed, 32/420 (7.6%) gave a neutral answer and 8/420 (1.9%) disagreed or strongly disagreed. Furthermore, 241/410 (58.8%) strongly agreed with the sentence "I believe my advice is important for my pregnant patients", 157/410 (38.3%) agreed, 10/410 (2.44%) gave a neutral answer and 2/410 (0.5%) strongly disagreed.

Instead, 228/383 (59.5%) strongly disagreed or disagreed with the sentence: "I believe it should be me who get the Tdap vaccine to pregnant women", 70/383 (18.3%) agreed or strongly agreed with the sentence and the remaining 85/383 (22.2%) gave a neutral answer.

# 4. Discussion

Numerous studies have shown that healthcare providers' recommendations are critical for achieving high maternal

		Strongly agree		Agree		Neutral		Disagree		Strongly disagree	
	Ν	n	%	n	%	n	%	n	%	n	%
I consider all vaccinations mentioned in the National Vaccinal Prevention Plan necessary	421	285	67.70	106	25.18	21	4.99	4	0.95	5	1.19
I think that pertussis vaccination for pregnant women is important	413	197	47.70	149	36.08	55	13.32	7	1.69	5	1.21
I believe pertussis is a danger for the newborn	411	205	49.88	140	34.06	49	11.92	11	2.68	6	1.46
I think I have enough knowledge about Tdap vaccine for pregnant women	397	103	25.94	141	35.52	78	19.65	55	13.85	20	5.04
I am interested in getting more info about Tdap vaccination during pregnancy	416	210	50.48	153	36.78	37	8.89	9	2.16	7	1.68
I believe it is my responsibility to inform pregnant women about whooping cough vaccination	420	257	61.19	123	29.29	32	7.62	5	1.19	3	0.71
I believe my advice is important for my pregnant patients	410	241	58.78	157	38.29	10	2.44	0	0.00	2	0.49
I believe it should be me who get the Tdap vaccine to pregnant women	383	16	4.18	54	14.10	85	22.19	131	34.20	97	25.33

Table 2. Answers' distribution in five-points Likert scales to questions aiming to assess gynecologists' perception, attitudes, self-perceived knowledge on maternal Tdap and willingness to be involved in Tdap implementation.

immunization rates.<sup>10,12,16</sup> According to the results of the survey done by Marchetti et al., gynecologists were the most trusted healthcare professionals for the provision of maternal immunization information to Italian pregnant women.<sup>10</sup> To the best of our knowledge, ours is the first study offering insights into gynecologists' knowledge, attitude and practices regarding pertussis recommended vaccination. Furthermore, this study found considerable gaps in the level of gynecologists' knowledge related to Tdap vaccination for pregnancy. According to our results around 15% of the gynecologists interviewed were not aware of the pertussis vaccination program for pregnant women; moreover, among the ones who were aware, just 44% routinely recommended the vaccination to pregnant women (around the 39% of the total). These percentages are smaller compared with those measured in the UK or the US<sup>18,19</sup> and this could be one of the reasons explaining Italy's lower Tdap vaccination rates compared to these countries.7,20

Even if 96.92% of our respondents were willing to recommend Tdap for pregnant women, ultimately only 39% did it. The first reason why gynecologists did not give advice about Tdap to their pregnant patients is inadequate knowledge of Tdap immunization, protocols and guidelines. Indeed, 87% of our study population would like to have more information about Tdap vaccination in pregnancy. This is in line with other researchers' findings.<sup>18,21</sup>

In order to enable healthcare professionals to provide accurate and timely information on pertussis immunization to pregnant women, educational programs to improve their knowledge, vaccine confidence and target their reasons for hesitancy are needed. In our study e-mails and courses/online courses were highlighted as the preferred means for receiving information.

Only around 18% of our respondents were willing to directly administer the vaccine to pregnant women and only a small proportion routinely gave Tdap vaccine to their pregnant patients. However, not offering vaccine administration in the gynecologist's office is a known barrier to vaccine uptake as expectant mothers need to arrange extra appointments at vaccination services.<sup>22</sup> A more convenient approach might be to routinely administer Tdap vaccination at the time of antenatal appointments.

The likelihood of having heard about maternal immunization varied significantly by working area. Gynecologists working in the South or in the Islands of Italy were less aware about the need of administering Tdap in expectant mothers, suggesting that there is a potential risk of health inequalities based on differing levels of vaccine knowledge and recommendations across Italy.

Overall, the gynecologist has shown a positive attitude to the vaccine and this is in line with what was shown in prior studies.<sup>19,23</sup>

The main limitation of this study is the high number of gynecologists that did not reply to our e-mails and were impossible to reach. It is possible that our respondents represent the most informed group, with respect to the Tdap vaccination, across the gynecologists' population: if that was the case, our sample may not be representative.

In conclusion, although most gynecologists have a positive attitude to maternal immunization, vaccination coverage rates are still low in Italy. Filling providers' knowledge gap is a necessary step in order to increase the number of pregnant women who get Tdap vaccine during pregnancy.

# Acknowledgments

We would like to thank the Italian gynaecologists' association for allowing us to conduct the study. We would also like to thank all the participants in this study.

# Disclosure of potential conflicts of interest

Pier Luigi Lopalco has received during the last two years research grants and/or personal fees to participate to advisory boards from GSK, MSD, Pfizer, Sanofi and Seqirus.

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