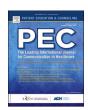
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# Covid-19 vaccination during pregnancy: A mixed-methods study of attitudes in a sample of Italian women and the role of health professionals' communication

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#### ABSTRACT

*Objectives*: We examined Italian pregnant women's attitudes about the diphtheria, tetanus, and pertussis (DTP) vaccine, seasonal influenza, and Covid-19 vaccines, healthcare professionals' (HP) communication, reasons and potential predictors for non-adherence.

Methods: From August 2021 to January 2022, we carried out a cross-sectional study in Italy using an online self-administered questionnaire addressed to women of age and pregnant, designed using LimeSurvey and disseminated through social media. Questions explored vaccination attitude/perceptions, satisfaction, and trust in HPs' information. Thematic analysis of free-text responses was performed using MaxQDA 2022. Statistical analyses were performed using STATA.

Results: 1594 responses were obtained. 52% of women hesitated to be vaccinated against Covid-19 while pregnant. Information received by HPs was deemed incomplete by 56% of participants, unclear by 52%, and untrustworthy by 46%; 49% felt unsupported in their decision-making process. This variable was one predictor of vaccine hesitancy together with concern about vaccine safety in the multivariate model. The analysis of openended questions revealed a pervasive feeling of dissatisfaction.

Conclusion: The perceived lack of adequate communication and support by HPs affected pregnant women's decision-making process on Covid-19 vaccination.

*Practice implications:* HPs need to understand and communicate the importance of vaccination during pregnancy, learning to better tailor their messages.

# 1. Introduction

A number of vaccines are recommended to pregnant women in Italy and offered free of charge by the national health system: the Italian Ministry of Health recommends vaccination against diphtheria, tetanus, and pertussis (DTP) and against influenza (whenever pregnancy occurs during the influenza season) [1]. The medical literature confirms the increased risk of complications and/or severe illness following infection for pregnant women and infant children, and vaccine safety and effectiveness both for the mother and for the child [2–4].

Nevertheless, vaccination uptake among pregnant women often falls short of the required standards in low, medium, and high-income countries alike [5–8]. For example, ECDC data¹ show a 2% influenza vaccine coverage among pregnant women in Italy for the 2017–2018 season. Research has shown that lack of adequate information, concerns about the safety of the foetus, and underestimation of the risks posed by illness and infection are among the most frequent reasons for vaccine hesitancy (VH) among pregnant women. The definition of VH adopted in this study follows Bussink-Voorend et al. (2022) [9]: "a psychological state of indecisiveness that people may experience when making a

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<sup>&</sup>lt;sup>1</sup> Available at: Seasonal influenza vaccination and antiviral use in EU/EEA Member States – Overview of vaccine recommendations for 2017–2018 and vaccination coverage rates for 2015–2016 and 2016–2017 influenza seasons (europa.eu).

decision regarding vaccination", regardless of their final choice. Various studies have highlighted the importance of the role played by health professionals (HPs) in this decision-making process, and they appear to be the most trusted sources of health- and vaccine-related information for pregnant women [10-16].

When Covid-19 vaccines became available in Italy, vaccination campaigns initially focused on high-risk categories: HPs, nursing homes residents, highly vulnerable patients and people aged > 80 years. Pregnant women were not considered a priority class, and given that they are excluded from pre-marketing clinical trials, the Italian Obstetric Surveillance System (ItOSS) did not recommend Covid-19 vaccination for pregnant women. As studies focusing on Sars-Cov-2 infections worldwide began demonstrating that the risk of stillbirth and/or other complications and severe illness is higher among women with Covid-19 [17,18], and as vaccination against Covid-19 was being proven safe and effective both for the mother and for the child [19-22], issued recommendations changed accordingly. Italian women of childbearing age (aged 40-49) started being vaccinated on 20th May 2021, followed by people aged 30-39 (27th May) and 12-29 (2nd June 2021) [23]; and on 24th September 2021, the Italian Ministry of Health published the Circular No.43293 indicating vaccination at any stage of pregnancy and during breastfeeding.

Various recent studies have explored pregnant (and breastfeeding) women's knowledge and attitudes towards the Covid-19 vaccine from different perspectives [24–26]. However, few studies have compared attitudes towards routine vs. Covid-19 vaccines [27–30]; and although the importance of HPs' advice and official recommendations for pregnant women has been established [31–33], the exceptionally critical pandemic situation outlines a specific communication context requiring special communication skills, which is worth analysing.

Our study seeks to explore Italian pregnant women's knowledge and attitudes towards the Covid-19 vaccine, considering also their knowledge and attitudes towards the routine DTP vaccine and the seasonal influenza vaccine. Furthermore, we seek to understand their evaluation of the advice received by HPs and caregivers during pregnancy. Our goal is to better understand how to support pregnant women's vaccination decisions in such a delicate phase of their life.

# 2. Methods

# 2.1. Participants and procedure

From August 2021 to January 2022, we carried out a cross-sectional study using an online self-administered questionnaire addressed to women living in Italy, aged  $\geq$  18 years old and pregnant at the time of the survey. The questionnaire was designed using LimeSurvey (Lime-Survey GmbH, Hamburg, Germany) and made accessible via a link disseminated through Facebook (including Facebook groups devoted to maternal health), Instagram, and WhatsApp. In all cases it was asked to re-share the survey link with friends and acquaintances for snowball sampling. Participation was voluntary and anonymous, without any possibility to trace back who filled in the questionnaire. Purposes of the survey were described in the first part of the questionnaire. Participants could withdraw consent at any time prior to submitting responses. According to the Italian Data Protection Authority 2012 [34], this study did not require approval by the Ethics Committee. The questionnaire was designed with different sections including sociodemographic information; DTP, influenza, and Covid-19 vaccinations attitude and perceptions; and satisfaction/level of trust in HPs' information concerning Covid-19 vaccinations. The questionnaire included binary, multiple-choice closed-ended questions, open- ended questions, and 1-5-point Likert-type scales.

#### 2.2. Measures

The sociodemographic characteristics included age, education level,

residence, working status, marital status, and number of children. Participants were also asked to state whether they were studying or working in healthcare. Presence of diseases related to pregnancy was assessed by a self-reported answer (yes/no). Previously published questionnaires administered in the USA [35] and in Italy [36] were used to survey participants about their perceptions and attitude to DTP, influenza and Covid-19 vaccinations. The former investigates influenza and DTP vaccine perceptions and is made of three sections, each containing nine questions: the first two sections, examining patients' vaccination behaviours and provider support concerning the influenza and the DTP vaccine, were included. The latter questionnaire investigates Covid-19 vaccine perceptions and is made of 16 questions exploring knowledge about the disease, knowledge about vaccine safety and effectiveness, and intention to vaccinate during pregnancy. Items 3–15 were included in our survey.

Trust and perceptions towards information concerning the Covid-19 vaccine provided by different HPs (gynecologist, midwife, GP, and healthcare assistant) in addition to perceived support were assessed using a 5-point Likert scale (1 = "not at all" to 5 = "extremely"). To increase the sample size of categories we collapsed the responses as follows: "Not at all/Little" scored 1 through 2 points, and "Quite/Very" scored 3 through 5 points. Respondents who rated a score of 3 or less were asked to indicate the critical issues through an open-ended optional question.

To investigate HPs' various positions about the Covid-19 vaccine in relation to possible doubts expressed by pregnant women, participants were asked to indicate the answer that most closely matched the one they received from their gynecologist, GP, health assistant and midwife. The questions were: 1) "Can/should I get the anti-covid vaccine?" 2) "Could the anti-covid vaccine have harmful effects on my child?" and 3) "Could the anti-covid vaccine have harmful effects on the progress of my pregnancy?". For each question four answers were possible in addition to "not asked". Possible answers to question 1 were: "Better not"; "I'm not sure that the data available so far are sufficient to decide"; "Based on the data available so far the risk/benefit ratio is in favour of the vaccine so I'd say yes"; "Absolutely yes". Possible answers to questions 2 and 3 were: "I cannot exclude it"; "There is no sufficient data so I wouldn't know how to give you an answer"; "To date, there are no reports of harmful effects on the child"; "Don't worry because there is no risk".

# 2.3. Main outcome

Intention to receive the Covid-19 vaccine during pregnancy was evaluated through the question "Will you get the Covid-19 vaccination in this pregnancy?". The answers "No" and "Yes, but not before the birth of my baby" were categorized as "hesitancy". The other two options were "Yes, as soon as possible" and "I have already been vaccinated".

## 2.4. Thematic analysis

Thematic analysis of the free text responses was carried out using MaxQDA 2022 (VERBI Software). Texts were codified independently by two researchers looking for the factors which most impacted on the participants' wellbeing and satisfaction with the care and support received, assessed following the participants' own wordings. The two researchers then met to discuss discrepancies until a final agreement was reached.

# 2.5. Statistical analyses

The analyses included descriptive statistics (i.e., frequencies and percentages for categorical variables and mean values with standard deviations for continuous variables). Comparisons between groups were made using the  $\chi 2$  test or Fisher's exact probability test for categorical variables and t-test for continuous variables. A binary logistic regression model was carried out, with Covid-19 VH as the dependent variable. The

covariates to be included into the final model were selected on the basis of univariate analysis with a univariate p value <0.05 as the main criterion. Then, using a backward selection process, statistically non-significant variables were excluded. To check for collinearity among variables, the Spearman correlation test was used. The results of logistic regression are reported with adjusted odds ratios and 95% confidence intervals. A p-value less than 0.05 was considered as statistically significant for all analyses. Statistical analyses were performed using STATA (Stata Statistical Software: Release 14.0 College Station, TX: Stata Corporation).

#### 3. Results

1594 pregnant women completed the online survey. Overall, 52% (n =823) of participants declared to be unwilling to be vaccinated during pregnancy. Table 1 shows participants' characteristics according to Covid-19 VH.

Compared to women who had already received the vaccine or were willing to be vaccinated during pregnancy, hesitant women were on average younger (p <0.0001), with a lower level of education (p <0.0001), unemployed (p =0.02), housewives (p <0.0001), and not working or studying in the healthcare field (p <0.0001). Most women (58%) in the third trimester expressed Covid-19 VH, compared to 48% of women in the second and 37% of women in the first trimester (chisquare (2)  $=33.6,\ p <0.0001$ ). Covid-19 VH was higher in the first period of recruitment (August) (62%) compared to September-November (49%) and December-January (28%) (chi-square (2)  $=104.8,\ p <0.0001$ ). Previous Sars-Cov2 exposure and presence of chronic diseases including diseases related to pregnancy did not affect Covid-19 vaccine acceptance.

Women who reported that they did not intend to get vaccinated against DTP (34%) and seasonal influenza (75%) during pregnancy were more unwilling to receive the Covid-19 vaccine (p < 0.0001) (Table 2). All the other questions shown in Table 2 used a Likert scale model. The answers were collapsed as follows: "No/very little" and "Quite/Very much"; "Surely not/I don't think so/I don't Know" and "I think so/Surely".

Covid-19 VH was mainly expressed by women concerned about abortion (69% vs 21%), baby malformation (70% vs 16%), premature birth (71% vs 19%) and fetal growth restriction (71% vs 19%) as possible consequences of the Covid-19 vaccine, compared to less worried women (p < 0.0001). Most participants were aware of the infectiousness (92.9%) and possible severity (96.8%) of Covid-19 disease; 50.6% of those who were aware of Covid infectiousness and severity (chi-square (1) = 43.2, p < 0.0001) and 49.6% of respondents who thought that Covid infection can lead to hospitalization (chi-square (1) = 28.3, p < 0.0001) were also more willing to get vaccinated. Participants convinced that the risk of complications from Covid-19 infection is the same in pregnant and non-pregnant women were more reluctant to get the Covid-19 vaccine (55% vs 45%, p < 0.0001). Around 55% of women agreed that each anti-Covid-19 vaccine approved in Italy was safe and effective; however, less than 50% thought that it was safe in pregnancy. The perception of the vaccine's unsafety was associated with increased Covid-19 VH. Women who declared that they did not receive support by HPs in deciding whether to get the Covid-19 vaccine were also more hesitant (69% vs 35%, p < 0.0001).

Women were asked to rate the information they received about the Covid-19 vaccination by HPs as exhaustive, clear and trustworthy using a Likert scale. Fig. 1 shows the distribution of responses according to the different source of information, excluding, for each evaluation, women who reported not to have received any information from their gynecologists, GPs, and perinatal care staff. The denominators used for calculating proportion for each category are reported in Fig. 1.

Most women judged the information received from their gynecologist as trustworthy (68%), clear (60%), and exhaustive (57%). GPs and perinatal care staff were considered trustworthy by 52% and 54% of

Table 1
Participants' characteristics according to Covid-19 vaccine hesitance.

		Covid-19 v hesitancy		
	Overall	Yes	No	P value
	n = 1594	n = <b>823</b>	n = <b>771</b>	
	n (%)	n (%)	n (%)	
Age, mean (SD)	31.5	30.9	32.0	<
	(4.9)	(4.8)	(4.9)	0.0001
Country of origin				0.99
taly	1505	777	728	
	(94.4)	(51.6)	(48.6)	
Other	89 (5.6)	46	43	
		(51.7)	(48.3)	
Area of residence				0.034
Northern Italy	802	389	413	
	(50.3)	(48.5)	(51.5)	
Centre Italy	293	156	137	
	(18.4)	(53.2)	(46.8)	
Southern Italy and isles	499	278	221	
	(31.3)	(55.7)	(44.3)	
Marital status				0.18
Married/ cohabiting partner	1559	801	758	
	(97.8)	(51.4)	(48.6)	
Divorced/Separated/Single	35 (2.2)	22	13	
		(62.9)	(37.1)	
ducation				<
		40:		0.0001
ligh school or less	824	494	330	
	(51.7)	(60.0)	(40.1)	
Jniversity degree	770	329	441	
	(48.3)	(42.7)	(57.3)	
Vorking status				<
				0.0001
Employed	996	488	508	
	(62.5)	(49.0)	(51.0)	
Self-employed	196	90	106	
	(12.3)	(45.9)	(54.1)	
Jnemployed	193	115	78	
	(12.1)	(59.6)	(40.4)	
Iousewife	166	108	58	
	(10.4)	(65.1)	(34.9)	
Student	43 (2.7)	22	21	
		(51.2)	(48.8)	
Work/Study in healthcare field				<
(n = 1235)*	000	114	016	0.0001
'es	330	114	216	
_	(26.7)	(34.6)	(65.4)	
No	905	486	419	
	(73.3)	(53.7)	(46.3)	
Gestational age (weeks)				<
. 10	100		100	0.0001
0–12	189	69	120	
0.07	(11.8)	(36.5)	(63.5)	
.3–27	605	290	315	
00	(38.0)	(47.9)	(52.1)	
> 28	800	464	336	
	(50.2)	(58.0)	(42.0)	
Number of children				0.68
)	1136	581	555	
	(71.3)	(51.1)	(48.9)	
	368	190	178	
_	(23.1)	(51.6)	(48.4)	
≥ 2	90 (5.6)	52	38	
		(57.8)	(42.8)	_
Chronic diseases				0.47
l'es .	268	133	135	
	(16.8)	(49.6)	(50.4)	
No	1326	690	636	
	(83.2)	(52.0)	(48.0)	
Chronic diseases related to pregnancy				0.28
Zes .	218	120	98	
	(13.7)	(55.1)	(45.0)	
No	1376	703	673	
	(86.3)	(51.1)	(48.9)	
	(86.3)		(48.9) continued on	next pa

Table 1 (continued)

			Covid-19 vaccine hesitancy		
Tested positive for Sars-Cov2 by swab before pregnancy				0.23	
Yes	177	99	78		
	(11.1)	(55.9)	(44.1)		
No	1417	724	693		
	(88.9)	(51.1)	(48.9)		
Tested positive for Sars-Cov2 by swab during pregnancy				0.70	
Yes	62 (3.9)	35	27		
		(56.4)	(43.6)		
No	1532	788	744		
	(96.1)	(51.4)	(48.6)		
Period of recruitment				<	
				0.0001	
August	789	491	298		
	(49.5)	(62.2)	(37.8)		
September-November	514	252	262		
	(32.2)	(49.0)	(51.0)		
December-January	291	80	211		
•	(18.3)	(27.5)	(72.5)		

 $<sup>\</sup>ensuremath{^{\circ}}$  The question was addressed to women who reported to be working or studying.

women, respectively. Information received from their GP was considered clear by 43% and exhaustive by 39%; information received from perinatal care staff was deemed clear by 48% and exhaustive by 44% of participants.

The distribution of answers in relation to the attitude shown by different HPs to patients' doubts about the Covid-19 vaccine is shown in Fig. 2.

Most (70%) of women reported a favorable attitude to the vaccine displayed by their gynecologist; 60% declared this tendency in case of their GP, health assistant and midwife. Concerning the possible negative consequences of the vaccine on their baby, 64% of participants reported a favorable attitude shown by their gynecologist, and around 50% by their GP, health assistant and midwife. Similar percentages were found when HPs were asked about possible side effects of the vaccine on pregnancy.

Table 3 shows all variables statistically associated with Covid-19 VH after the backward selection process and their relative adjusted and unadjusted Odds ratios. The following variables did not significantly predict VH: area of residence, education, working status, DTP and influenza VH, perception related to Covid-19 contagiousness and severity in adults and young children. The perception that the Covid 19 vaccine is not safe in pregnancy (aOR=43.0; 95%CI: 28.9–64.1) was the main factor associated with VH.

The multivariate analysis was carried out also using an independent variable excluding women who stated that they had already been vaccinated and the results were overlapping (Data not shown).

Fig. 3 shows the list and frequency of the themes identified in the thematic analysis of the free-text answers to the question "In what ways were the HPs you approached for the anti-Covid vaccination deficient?". 403 out of 757 women who stated that they did not feel supported by their HPs in the decision to get the Covid-19 vaccine agreed to provide a written answer. Of these, 40 were excluded from the thematic analysis because they did not provide a relevant and consistent answer to the question. Of the 363 valid answers, 37% described inadequate, incomplete, hasty explanations received by HPs; 32% received contrasting, inconsistent information from different professionals or from the same professional at different times; 17% stated that HPs were not able to reassure them. 14% of answers were grouped into the category "other", as they mentioned aspects which were less frequent in the overall corpus: for example, 3 women wrote that HPs were "lacking in everything" and 6 women wrote that they were "unprofessional".

Underlying most answers is a pervasive feeling of disquiet, anxiety,

**Table 2**Participants' perception of vaccination/disease and Covid-19 vaccine hesitancy.

		Covid-19 hesitano		
	Overall	Yes	No	P valu
	n =	n =	n =	
	1594	823	771	
DTP vaccine hesitancy in	n (%)	n (%)	n (%)	<
pregnancy				0.0001
Yes	538	349	189	
	(33.8)	(64.9)	(35.1)	
No	1056	474	582	
C1	(66.2)	(44.9)	(55.1)	
Flu vaccine hesitancy in pregnancy (n = 1125)*				< 0.0001
(ii = 1123) Yes	838	444	394	0.0001
	(74.6)	(53.0)	(47.0)	
No	285	65	220	
	(25.4)	(22.8)	(77.2)	
Worry about abortion as possible				<
consequence of Covid-19 vaccine	207	00	207	0.0001
No/very little	387 (27.8)	80 (20.7)	307 (79.3)	
Quite/Very much	1007	695	312	
<u> </u>	(72.2)	(69.0)	(31.0)	
Worry about baby malformation as		•	•	<
possible consequence of Covid-				0.0001
19 vaccine	051	F.6	005	
No/very little	351 (25.4)	56 (16.0)	295 (84.0)	
Quite/Very much	1029	(16.0) 719	310	
Quite/ very much	(74.6)	(69.9)	(30.1)	
Worry about premature birth as	,	( ,	()	<
possible consequence of Covid-				0.0001
19 vaccine				
No/very little	600	115	485	
Ouito Work much	(37.6) 994	(19.2) 708	(80.8) 286	
Quite/Very much	(62.4)	(71.2)	(28.8)	
Worry about foetal growth	(02.1)	(71.2)	(20.0)	<
restriction as possible				0.0001
consequence of Covid-19 vaccine				
No/very little	597	113	484	
Out of the out	(37.4)	(18.9)	(81.1)	
Quite/Very much	997 (62.6)	710 (71.2)	287 (28.8)	
Covid-19 infection is highly	(02.0)	(/1.2)	(20.0)	<
contagious				0.0001
Surely not/I don't think so/I don't	113	92	21	
Know	(7.1)	(81.4)	(18.6)	
I think so/Surely	1481	731	750	
Consid 10 infeation	(92.9)	(49.4)	(50.6)	_
Covid 19 infection can sometimes be severe enough to require				< 0.0001
hospitalization				0.0001
Surely not/I don't think so/I don't	51 (3.2)	45	6	
Know		(88.2)	(11.8)	
I think so/Surely	1543	778	765	
	(96.8)	(50.4)	(49.6)	
Young children are at higher risk of				< 0.0001
having to be hospitalized due to Covid 19 infection than adults				0.0001
Surely not/I don't think so/I don't	1290	707	583	
Know	(80.9)	(54.8)	(45.2)	
I think so/Surely	304	116	188	
•	(19.1)	(38.2)	(61.8)	
Pregnant women run the same risk				<
of complications from Covid 19				0.0001
infection as women who are not				
pregnant Surely not/I don't think so/I don't	540	242	298	
Know	(33.9)	(44.8)	(55.2)	
I think so/Surely	1054	581	473	
•	(66.1)	(55.1)	(44.9)	
All anti-Covid 19 vaccines				<
approved in Italy are safe				0.0001

Table 2 (continued)

		Covid-19 vaccine hesitancy		
Surely not/I don't think so/I don't	711	533	178	
Know	(44.6)	(75.0)	(25.0)	
I think so/Surely	883	290	593	
•	(55.4)	(32.8)	(67.2)	
All anti-Covid 19 vaccines				<
approved in Italy are effective				0.0001
Surely not/I don't think so/I don't	679	522	157	
Know	(42.6)	(76.9)	(23.1)	
I think so/Surely	915	301	314	
	(57.4)	(32.9)	(67.1)	
The anti-Covid 19 vaccine is safe in pregnancy (excluding contraindications)				< 0.0001
Surely not/I don't think so/I don't	847	719	128	
Know	(53.1)	(84.9)	(15.1)	
I think so/Surely	747	104	643	
	(46.9)	(13.9)	(86.1)	
Perceived support by health				<
professional in deciding whether to do Covid-19 vaccine				0.0001
No/little	757	538	233	
	(47.5)	(64.3)	(30.8)	
Quite/very/very much	837	285	524	
•	(52.5)	(35.7)	(69.2)	

<sup>\*</sup>The question was addressed to women who reported to be pregnant during the ensuing flu season.

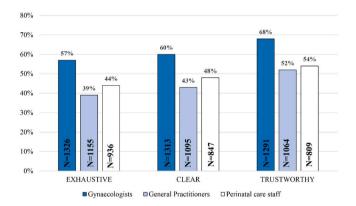


Fig. 1. Evaluation of information received about the Covid-19 vaccine by different healthcare professionals based on Likert scales.\*. \*Figure shows the distribution of responses categorized as "quite/very". NB: Percentages were calculated excluding women who reported not to have received any information from each health professional shown in the figure. The denominators are reported within the columns.

and fear, which is not eased by the HPs' recommendations, especially when the patients received conflicting advice (example 1. Literal translations from Italian into English are provided that attempt to remain as faithful as possible to the original text, even reproducing grammatical and lexical errors and inaccuracies. The original Italian examples can be read in the supplementary materials.).

This is also confirmed by our results showing that some participants did not receive a clear recommendation in favour of the vaccine by their operators, and that there was a small but significant level of disagreement among practitioners, who provided patients with discordant advice (k=32%). This level of disagreement was denounced by our participants regardless of the period of recruitment.

These examples also show that pregnant women's main concerns were safety for the foetus and possible long-term side effects of the vaccine, which exceeded concerns about the possible effects of Covid-19 on the foetus and pregnancy (example 2):

- Too many different opinions created confusion, uncertainty and fear. Consequently, my choice not to vaccinate either during pregnancy or while breastfeeding.
- Bad information, because they really don't even know the effects a vaccine might have over time

Other examples express the desire to be reassured in the decision to vaccinate during pregnancy which is shared by most of our participants, but unmet by many HPs:

- They are not able to reassure you completely. This is also what momentarily keeps me from deciding whether or not to do it during pregnancy.
- 4. No one really and clearly explained the possible future side-effects of the vaccine. No one tried to reassure.

Examples 5–6 illustrate more precisely that the communication problem between practitioner and patient is rooted in different expectations and registers used to convey a message. Sometimes patients recognise this dissonance (example 5), while in other cases they merely judge the communicative encounter as unsuccessful (example 6):

- 5. In general, the answers were 3: 1st Yes, get the vaccine because vaccines are useful; 2nd I don't know talk to your gynaecologist and decide together; 3rd The new guidelines recommend the vaccine during pregnancy, too. [...]. It is understandable that for a doctor these answers may be exhaustive, but for a person who has spent two months locked up at home [...], such absolute but almost superficial answers are not at all reassuring.
- They say there are no contraindications but they don't tell you don't worry you can do it.

Note, however, that in order to be effective, communication cannot be reduced to a fixed set of rules, but must always be tailored on the individual patient. This is evident when comparing example 6 above with example 7:

During my search for pregnancy I was dismissed with a "don't worry".

It is however encouraging to notice that pregnant women in our study consider HPs to be more experienced and knowledgeable on the subject:

8. We are increasingly worried and confused, but obviously we rely on our gynaecologist, not being competent in the matter.

# 4. Discussion and conclusion

#### 4.1. Discussion

Our sample mainly comprised educated women with a good perception of the severity of the disease and its risks for pregnant women and their babies. However, this awareness did not necessarily lead them to vaccinate, because the main reason for their VH was their overwhelming concern about the vaccine's alleged side effects. This is in line with previous literature, such as Kilich et al.'s [37] 2020 study. Carbone et al.'s systematic review [24] also uncovered that the most pressing concerns for pregnant women worldwide are the possible side effects of the vaccine on the foetus and new-born baby, coupled with a limited preoccupation with the effects of the Covid-19 disease [25]. Similarly, Skjefte et al.'s [26] survey of 16 different countries found that the top three reasons for pregnant women to decline Covid-19 vaccination were worries about possible side-effects, concern that approval of the vaccine had been rushed for political reasons, and the perceived need of more data on vaccine safety and effectiveness. We expanded this finding

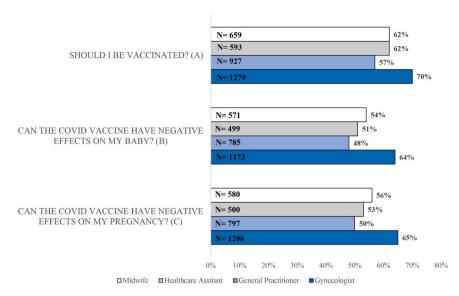


Fig. 2. Distribution of answers about favorable attitude\* of different health professionals to three possible questions on the Covid-19 vaccine and pregnancy. NB: Percentages were calculated excluding women who reported they did not ask information to one of the healthcare professionals mentioned here. The denominators are reported within the columns. \* (A) "Favorable attitude" includes the following responses: "Based on the data available so far the risk/ benefit ratio is in in favor of the vaccine so I would say yes" and "Absolutely yes"; "unfavorable attitude" refers to "Better not" and "I am not sure that the data available so far are sufficient to decide". (B) and (C) "Favorable attitude" includes the following responses: "To date, there are no reports of harmful effects on the child" and "Don't worry because there is no risk"; "unfavorable attitude" refers to "Better not" and "I'm not able to exclude it" and "There is no sufficient data so I wouldn't know give you an answer"

**Table 3**Variables affecting Covid-19 vaccination hesitancy based on multivariate analysis.

Variable	Covid-19 vaccine hesitancy					
	Univariate analysis			Multivariate analysis		
	OR	95% CI	P value	Adjusted OR	95% CI	P value
Age	0.95	0.93-0.97	< 0.0001	0.95	0.92-0.99	0.012
Working/studying in healthcare field						
Yes	Reference			Reference		
No	2.20	1.69-2.86	< 0.0001	2.53	1.69-3.79	< 0.0001
Gestational age						
1st trimester	Reference			Reference		
2nd trimester	1.60	1.14-2.24	0.006	2.42	1.37-4.22	0.002
3rd trimester	2.40	1.73-3.33	< 0.0001	7.72	4.35-13.70	< 0.0001
Period of recruitment						
December-January	Reference			Reference		
September-November	2.54	1.86-3.46	< 0.0001	2.06	1.22-3.49	0.007
August	4.35	3.24-5.84	< 0.0001	7.46	4.43-12.57	< 0.0001
Perceived support by health professional in deciding whether to do Covid-19 vaccine						
Quite/very/very much	Reference			Reference		
No/little	4.05	3.28-4.99	< 0.0001	2.09	1.45-3.0	< 0.0001
Pregnant women run the same risk of complications from Covid 19 infection as women who are not pregnant						
Surely not/I don't think so/I don't know	Reference			Reference		
I think so/Surely	1.51	1.23-1.86	< 0.0001	1.66	1.15-2.40	0.007
The anti-Covid 19 vaccine is safe in pregnancy (excluding contraindications)						
I think so/Surely	Reference			Reference		
Surely not/I don't think so/I don't know	34.73	26.25-45.94	< 0.0001	43.02	28.89-64.06	< 0.0001

through the analysis of the free-text answers written by participants who reported HP's inability to adequately reassure them given their concerns. Our participants also signalled that HPs gave them contrasting advice without satisfactorily explaining the reasons behind each recommendation and did not unanimously recommend the Covid-19 vaccine. Indeed, the attitudes shown by the different professionals towards the Covid vaccine varied: from a slim majority of GPs in favour of the vaccine to a large majority of gynaecologists. Concerning HPs' attitudes towards the vaccine's possible side effects, gynaecologists seem to come out more strongly in favour of the Covid-19 vaccine especially when compared to GPs. This is relevant also in light of the perceived trustworthiness, clarity, and exhaustiveness of the information provided by the various HPs: gynaecologists appear to be judged more favourably than GPs, and more favourably than other peri-natal care staff. This result can possibly be explained by their different competencies and responsibilities in peri-natal care delivery.

This finding is particularly worrying in light of previous literature

highlighting the influential role played by HPs: Huddleston et al. [31] discovered that being counselled about the Covid-19 vaccination by a provider was a strong predictor of getting vaccinated compared with receiving no counselling among a population of pregnant women in the USA. Similarly, Stuckelberger et al. [32] in Switzerland and Tao et al. [33] in China found that pregnant women who had an obstetrician follow their pregnancy or who received a vaccine recommendation from their doctors were more likely to be willing to receive the Covid-19 vaccine; Cetin et al. [23] highlighted how the Covid-19 vaccine uptake rate in northern Italy increased significantly after the issuing of official recommendations.

Mixed attitudes towards the Covid-19 vaccine and the inadequacy of the support received by HPs were reported by women in our study regardless of the period of recruitment, even as studies were being published on the safety and effectiveness of the vaccine during pregnancy and official recommendations were being issued stressing the importance of vaccination for pregnant women and their babies. This

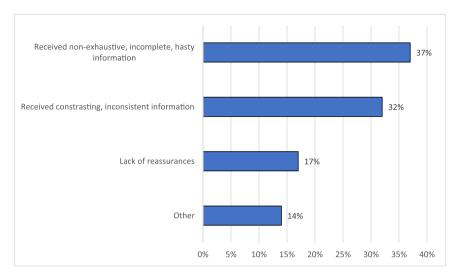


Fig. 3. Themes emerging from the thematic analysis of the free-text answers to the question: "In what ways were the health professionals you approached for the anti-Covid vaccine deficient?".

further suggests that HPs' level of preparation and/or ability to communicate effectively were lacking.

Going one step further, our analysis of the free-text questions showed that the effectiveness or otherwise of communication may take different forms: for some patients it may be important to receive empathic reassurances appealing to their emotions, while others need more detailed explanations. Still, patients' willingness to receive extensive information and reassurances suggests that there is room for improvement in their relationship with HPs.

The lower rate of Covid VH in the first trimester of pregnancy seems to contradict results from the previous literature: for example, both Stuckelberger et al. [32] and Tao et al. [33] found that women in their second or third trimester were more likely to accept the Covid vaccine. However, Goncu Ayan et al. [38] also found that women in their first trimester in Turkey expressed greater interest in receiving the Covid vaccine. The authors explain their finding with data showing that women who were in their first trimester of pregnancy during the Covid pandemic experienced greater psychological distress [39], suggesting that this feeling of vulnerability may have led them to accept the Covid vaccine to protect both themselves and their baby. Another possible explanation concerns the attitudes of women in their second and third trimester, who may consider themselves less vulnerable and less likely to infect their baby with Covid. Consequently, they may decide to wait for their child's birth before getting vaccinated.

These results cannot be easily generalised: our sample (though large) cannot be considered representative of the entire population because of a possible selection bias resulting from the means used to spread the questionnaire (social media), and from snowball sampling whereby initial subjects may tend to nominate people they know very well. One-third of the population (26.7%) in the sample were studying or working in the healthcare field. 48.3% of the women in our sample were highly educated. Therefore, we might have underestimated VH, given that VH often correlates with a low level of education. Moreover, our period of recruitment covered a limited time span, and the thematic analysis of the free-text answers is necessarily based on a small sample.

These limitations notwithstanding, we believe our study to have some value in uncovering some potentials and pitfalls of vaccine communication to pregnant women by HPs in Italy.

#### 4.2. Conclusion

It appears from our results that peri-natal care staff need to be better informed about the safety and effectiveness of vaccinations for pregnant

women, to be alert to their patients' worries and communicative needs, and conscious of the importance of establishing a functional relationship with them.

#### 4.3. Practice implications

The implications of our study are twofold: first, there appears to be a need to focus more on healthcare staff's education concerning the safety and effectiveness of vaccination during pregnancy (both routine and anti-Covid vaccines), also raising awareness about the importance of effective communication for their patients' health. Second, our findings seem to suggest that communication to hesitant patients can be improved by adequately training HPs on how to deal with worried patients, and especially pregnant women who feel forced to take difficult decisions affecting their own and also their child(ren)'s health. We suggest tailoring a message which not only emphasises the dangers of catching a disease, but also the safety of the vaccine. This message should also consider women's previous knowledge and the information they have been exposed to, and can be conveyed successfully only if perinatal care staff carefully appraise their patients to try and understand whether they need empathic reassurances, medico-scientific accurate explanations, or both, paying attention to the patient's expectations in any given situation.

#### CRediT authorship contribution statement

Conceptualization; Loredana Covolo and Umberto Gelatti. Methodology; Loredana Covolo and Carlotta Fiammenghi. Formal analysis; Loredana Covolo. Data curation; Loredana Covolo and Carlotta Fiammenghi. Writing—original draft preparation; Carlotta Fiammenghi. Writing—review and editing; Carlotta Fiammenghi and Loredana Covolo. Investigation; Nene Alassane Mbaye and Debora Pelleri. Visualization; Nene Alassane Mbaye, Debora Pelleri and Elisabetta Ceretti. Supervision; Umberto Gelatti and Elisabetta Ceretti. All authors have read and agreed to the published version of the manuscript.

#### CRediT authorship contribution statement

Gelatti Umberto: Supervision, Conceptualization. Covolo Loredana: Writing – review & editing, Methodology, Formal analysis, Data curation, Conceptualization. Pelleri Debora: Visualization, Investigation. Ceretti Elisabetta: Visualization, Supervision. Mbaye Nene Alassane: Visualization, Investigation. Fiammenghi Carlotta: Writing

– review & editing, Writing – original draft, Methodology, Data curation.

#### **Declaration of Competing Interest**

None.

#### Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.pec.2023.107929.

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