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## Pregnant women's acceptance and views on COVID-19 vaccine in Northern Italy

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### Introduction

The rate of COVID-19 associated ICU admissions among pregnant women increased threefold in Italy between February 2021 and June 2021, compared to February 2020 and January 2021 (Donati *et al.* 2022). Similarly, in the UK, a 1.6-times higher rate of ICU admissions among pregnant women was reported during the Delta circulation period compared to the Alpha period (Vousden *et al.* 2022). Based on these findings and with the mounting evidence on vaccine safety, Italy extended vaccine recommendation to all pregnant women in September 2021 (Circolare del Ministero della Salute 2021). Due to the scarcity of European data at the time of the study, we aimed to estimate maternal COVID-19 vaccine uptake as well as vaccination barriers in the Lombardy region.

### Materials and methods

A cross-sectional survey was conducted at five maternity hospitals in Lombardy region of Northern Italy, from April to November 2021. The inclusion criteria included: age  $\geq 18$  years, sufficient command of Italian language, informed consent provided and being eligible for COVID-19 vaccination. The anonymous questionnaire was adapted from previous studies performed by our research group (Vilca *et al.* 2020, 2021). This adapted version was pilot-tested with a convenience sample to ensure clarity and ease of administration and included questions about sociodemographic/clinical characteristics and attitudes regarding COVID-19 vaccination. The results are presented as proportions of respondents to individual questions, excluding nonresponses from the denominators. Chi-square or Fisher's exact tests were performed to compare vaccinated to unvaccinated individuals. Findings were reported as significant at  $p$  value  $< 0.05$  and the statistical package R Core Team (2013) (R Foundation for Statistical Computing, Vienna, Austria) was used. The study

protocol was approved by the Institutional Ethics Committee (prot. number 0032542).

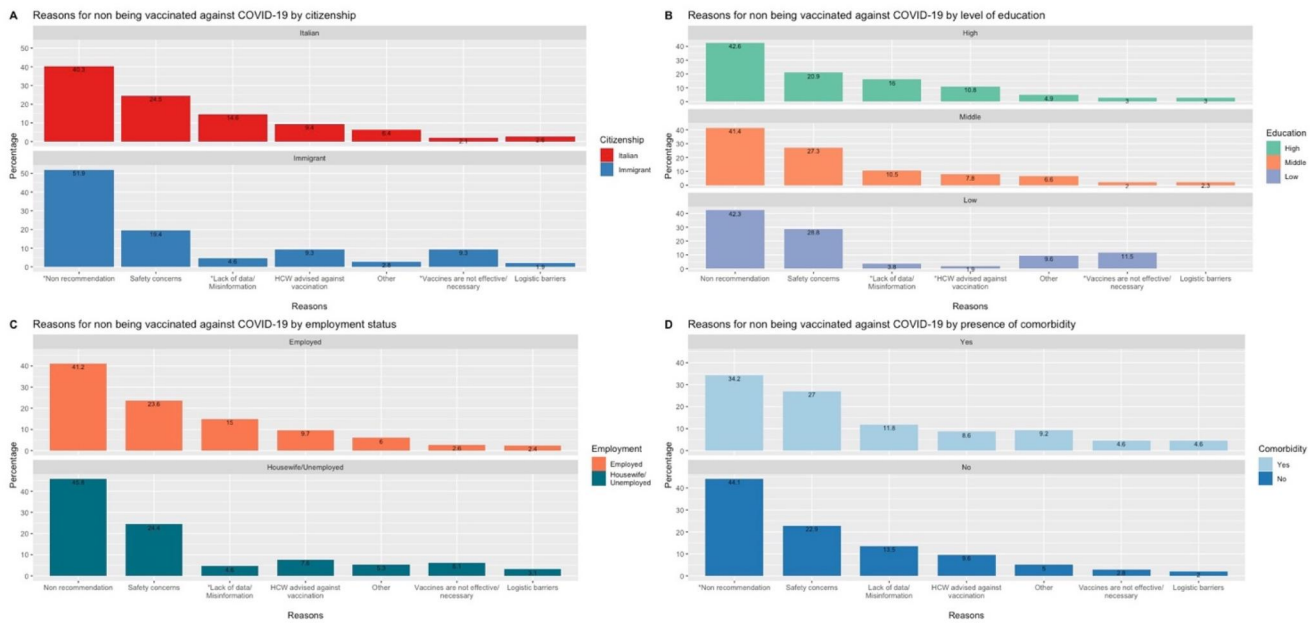
### Results

Overall, 926 women were enrolled in our study and 210 (22.7%) had received at least one vaccine dose. The COVID-19 vaccine uptake was 11.8%, when the Italian vaccination policy recommended the vaccine only to pregnant women with high risk of exposure to the virus (doctors, nurses and caregivers) and women with comorbidities. In contrast, when the vaccine recommendation was extended to all pregnant women during second and third trimester, the coverage reached 49.4% in our study population ( $p < 0.001$ ). COVID-19 vaccine uptake was significantly higher among Italian vs. immigrant women (23.8% vs. 15.6%, respectively;  $p = 0.04$ ). Similarly, women with high and middle education level showed higher vaccine coverages compared to women in the low-level category (26.5% and 18.5% vs. 10.3%, respectively;  $p = 0.003$ ). Furthermore, employed women showed significantly higher uptakes compared to unemployed/housewife women (24.1% vs. 15.5%,  $p = 0.02$ ) as well as women with any comorbidity vs. healthy women (28% vs. 21.1%,  $p = 0.04$ ). Among vaccinated women, 90.5% had received accurate vaccine information, and 92.6% mentioned obstetricians-gynaecologists as their main source of information. With regards to the main reasons for vaccination, 53.3% and 42.9% women stated that they wanted to protect their future newborns or their community. Among the 716 unvaccinated women, 301 (42%) did not receive any recommendation by a health care provider (HCP), followed by 145 (20.1%) who stated safety concerns as the main barrier. Reasons for vaccination refusal according to citizenship, employment status, level of education and comorbidity are presented in Figure 1. A significantly higher percentage of immigrant women, compared to the Italian women, stated that the main reason for not being vaccinated was not receiving any

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**Figure 1.** Reasons for COVID-19 vaccination refusal according to citizenship, employment status, level of education and comorbidity (women who did not provide any reason for vaccination refusal were not included). \* $p < 0.05$ .

recommendation (51.9% vs. 40.3%;  $p = 0.02$ ). Similarly, a significantly higher proportion of healthy women, compared to women with comorbidities, did not receive any recommendation (44.1% vs. 34.2%;  $p = 0.03$ ). Safety concerns were reported more frequently by primiparous vs. multiparous women (27% vs. 20%, respectively,  $p = 0.03$ ) and lack of sufficient data was reported more frequently among highly educated vs. women with middle or low education level (16% vs. 10.6% vs. 3.9%, respectively;  $p = 0.03$ ).

## Discussion

Our findings show a suboptimal COVID-19 maternal vaccine coverage (22.7%) in Northern Italy during the whole study period, lower than other European estimates (Stock *et al.* 2022), likely due to the late issuing of national recommendations for all pregnant women. Although SARS-CoV-2 prevalence among pregnant women reported by Donati *et al.* (2022), during the Alpha circulation period was lower than the prevalence reported during the wild-type period (Franchi *et al.* 2020, Donati *et al.* 2022), the ItOSS study also detected a significant increase in resort to ventilatory support and/or ICU admission in the case of pneumonia during the Alpha-variant period (Donati *et al.* 2022). Due to those findings and the poorer maternal outcomes observed during the Alpha wave, such as increase in preterm births, the Italian National Institute of Health recommended on 22 September 2021, that all pregnant women during second/third trimester of pregnancy should receive the COVID-19 vaccine (Circolare del Ministero della Salute 2021). Our results demonstrated that this change in the vaccination policy was associated with a significant increase in vaccination uptake, from only 11.8% (when the vaccine was recommended to women considered at high risk of exposure or women with comorbidities) to 49.4% when the vaccine was recommended to all pregnant women during second and third gestational trimester.

Although this increase in vaccine coverage observed in the second study period was encouraging, the fact that the new vaccine policy recommended an individual-level benefit-risk assessment during the first trimester might have prevented many women with early pregnancies from being vaccinated. A secondary analysis of the World Association of Perinatal Medicine (WAPM) cohort identified that infection during the first trimester was associated with adverse perinatal outcomes in fetuses (Di Mascio *et al.* 2021). This finding suggests that women should not delay COVID-19 vaccine until late pregnancy.

To improve maternal health outcomes, not only the COVID-19 vaccination policies should align with the current available evidence, but also maternal vaccination programs should be tailored according to the main vaccination barriers identified in this vulnerable population. For instance, Egloff *et al.* (2022) reported that European women and with at least one child had higher COVID-19 vaccine uptake. Similarly, in our study, immigrant women had a lower vaccine uptake and, interestingly, a higher proportion of these women did not receive any vaccine advice compared to Italian women. Even though we did not identify differences in vaccine coverage according to parity, more primiparous than multiparous unvaccinated respondents were more concerned about vaccine adverse events. Despite participants with comorbidities had higher vaccination uptake, this finding should be interpreted with caution because COVID-19 vaccine policies changed during the study period and this change might also explain why healthy participants reported more frequently not receiving any vaccine advice compared to women with comorbidities.

Since the beginning of the COVID-19 pandemic in Italy, maternity care units have been facing several challenges related to providing effective control measures (Franchi *et al.* 2020) and offering, at the same time, quality obstetrical care to their pregnant patients. Furthermore, the emergence of

new viral strains could result in more severe illness among pregnant women, creating constant new challenges to maternal care providers. Our findings showed that surveyed women considered their ob-gyns as their main source of COVID-19 vaccine information, but they also mentioned the lack of vaccine recommendation and safety concerns as the main vaccination barriers. These results, which are in line with previous studies about influenza and pertussis maternal vaccination (Vilca *et al.* 2020, 2021), reinforce the crucial role of ob-gyns and midwives in maternal vaccine acceptance and why vaccination policies and operational procedures should support their role as vaccinators.

This study has some limitations. We used a self-administered questionnaire that could be prone to response bias. Also, the survey was anonymous to increase participation and we were not able to verify the vaccine records of each survey participant due to confidentiality of health-related data. On the other hand, our study has several strengths. First, since scarce data were available about COVID-19 vaccine coverage during the Alpha and Delta circulation periods in Italy, we were able to provide unique information about vaccine coverage during diverse pandemic waves. Another strength includes assessing the main COVID-19 vaccination barriers in a large study sample of pregnant women residents of the most populous region in Italy, Lombardy, which has also been considered the pandemic epicentre in this country.

In conclusion, our findings might be useful to guide future vaccines strategies directed to pregnant population, especially with more COVID-19 booster doses to be offered in the forthcoming months.

### Disclosure statement

All authors have no conflicts of interests to declare.

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