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Knowledge, Propensity and Hesitancy among Pregnant Women in the Post-Pandemic Phase Regarding COVID-19 Vaccination: A Prevalence Survey in Southern Italy

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Abstract: The vaccination of pregnant women against influenza and COVID-19 may reduce the risk of severe illness in both the women of this population and their babies. Although the risks of non-vaccination are more serious than the side effects, maternal immunization is still the least-used method of prevention due to a lack of information leading to concerns about the safety and efficacy of vaccines, resulting in a low prevalence rate among pregnant individuals. Our study investigates vaccination coverage and the knowledge, attitudes and perceptions of COVID-19 in pregnant women at a university hospital. A questionnaire was created with the following three scores: a vaccination propensity score, a knowledge score and a hesitancy score. The first observation in the results was the very low number of immunized women (only 4.7% received their first dose). The main barrier towards vaccination was found to be fear of adverse events. We noticed a low percentage of influenza and diphtheria tetanus pertussis vaccination compared to other studies. Vaccination propensity was higher when healthcare workers educated their patients. As immunization is a crucial part of public health policy, measuring coverage to identify gaps and monitor trends, especially for individuals considered at high risk, and developing new strategies in order to increase awareness of vaccination during pregnancy is particularly timely and relevant.

Keywords: socioeconomic factors; knowledge; propensity



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1. Introduction

Vaccination hesitancy is a known phenomenon among various population groups and several socio-cultural contexts [1–4], and it is defined as a delay in accepting or a total refusal of vaccination despite the availability of vaccination services related to information and administration. A particular group for whom hesitancy might be higher is pregnant women. Pregnancy is a particular moment in a woman's lifetime, as she can be exposed to several pathogens affecting both the mother's and the fetus' health, resulting in an increased risk of developing severe disease or complications [5]. Several studies have shown the potential benefits of maternal immunization, mainly related to protection against harmful effects that could be caused by infection such as miscarriage, preterm birth, emergency cesarean section or low birth weight; this protection is effected by inducing the production and transfer of immunoglobulin G through the placenta, as well as expressing secretory antibodies in breast milk [6]. The course of the COVID-19 pandemic, the rapid development of vaccines and a strict immunization campaign have paradoxically led to conflicting opinions, with the end result that acceptance and its predictors among women vary globally [5]. In early 2021, the European Medicines Agency (EMA) approved the following five COVID-19 vaccines: two of them were mRNA vaccines (Pfizer-BioNTech and Moderna), two were viral vector-based vaccines (Oxford-AstraZeneca and Janssen), and

one was a protein subunit vaccine (Novavax) [7]. None of them were tested on pregnant women in preclinical trials or pre-marketing clinical trials [7]. Consequently, the main data for their use in pregnancy come from post-marketing surveillance [8]. Due to a lack of knowledge regarding the safety of vaccines, immunization coverage among pregnant women is low despite the existence of solid scientific data to support its effectiveness and safety [9]. This implies that pregnant women only have the following two options: trust science, family, or any other available source of information and receive the vaccine, even with limited data; or skip the vaccine, leaving themselves and their babies vulnerable to adverse events or severe disease caused by COVID-19. Furthermore, common side effects of the Pfizer-BioNTech vaccination were reported by pregnant [10] and non-pregnant women in similar percentages and the administration of the vaccine is not linked with harmful effects. Few cases of gestational hypertension, childbirth issues, miscarriage and premature birth after receiving the Pfizer-BioNTech vaccine have been reported [10]. The indications for vaccination in pregnant women come from the Obstetrics and Gynecology Societies, which suggest that pregnant women choose whether or not to be vaccinated after consulting with their gynecologists and evaluating the risks and benefits [11].

Although the risks of non-vaccination are more serious than the side effects [7], only 11 of the 20 major countries affected by COVID-19 offer free vaccination to pregnant women. [8]

A meta-analysis conducted on the “Consequences and Implications of Coronavirus Disease (COVID-19) on pregnancy and infants” found that the most common symptoms in pregnant women were fever, cough, chest pain, dyspnea and fatigue. Most newborns were delivered preterm and by cesarean section, which sometimes led to abortion. Neonatal outcomes included fetal suffering, low birth weight, APGAR < 7, hospitalization in the neonatal intensive care unit and fetal mortality [11,12]. In Italy, starting in January 2021, artificial immunization with mRNA vaccines was recommended for pregnant women with comorbidities or an increased risk of disease (i.e., healthcare workers) from the second trimester of pregnancy onwards [13]. Moreover, since the beginning of the pandemic, the Italian Obstetric Surveillance System (ItOSS), directed by the Istituto Superiore di Sanità (Italian National Institute of Health, INIH), launched a national survey to identify the effect of COVID-19 on pregnancy [14]. Vaccinating pregnant women with the flu (influenza) vaccine, tetanus toxoid, reduced diphtheria toxoid, acellular pertussis vaccine (DTaP) and COVID-19 vaccine may reduce their risk and their babies’ risk of developing severe illness or complications from these infections. The Advisory Committee on Immunization Practices (ACIP) recommends that all pregnant or suspected pregnant women receive the flu vaccine during flu season, which can be given at any time during pregnancy [15]. The ACIP also recommends that women receive DTaP during each pregnancy, preferably in the third trimester, between 28 and 32 weeks of gestation [16]. Increasing awareness among pregnant women [15] about vaccinations that can be administered during pregnancy greatly reduces the risk of the mother and child developing not only the acute form of the disease but also its complications. Given the greater likelihood of developing gestational and/or postpartum complications, in Italy, flu vaccination is strongly recommended in pregnant women regardless of trimester [16], as also affirmed by the Ministerial Circular “Prevention and control of flu: recommendations for season 2022–2023”.

Vaccination coverage for COVID-19 is very low in pregnant women; a study conducted in Scotland showed that in the general female population of 18–44 years, only 32.3% of pregnant women had two doses of the vaccine, compared to 77.4% of all women [17]. Moreover, in an American study, only 11.1% of women had completed vaccinations during pregnancy, with differences across age and race. [18]

In a UK study, data were available for 1328 pregnant women, of whom 140 received at least one dose of the COVID-19 vaccine before giving birth and 1188 did not; of those vaccinated, 85.7% received their vaccine in the third trimester of pregnancy and 14.3% in their second trimester of pregnancy. Surprisingly, in an Italian study, vaccination coverage was reported to be equal between pregnant and non-pregnant women for 80% of the

sample [19]. The aims of this study are as follows: a) to investigate COVID-19 vaccination coverage in pregnant women attending prepartum programs, ambulatorial visits or routine visits in the province of Messina at a university hospital; b) to evaluate the knowledge of attitudes towards and perceptions of COVID-19 vaccines in pregnant women and the main drivers that motivate or delay vaccination.

2. Materials and Methods

This study was conducted from November 2022 to December 2022, during the anti-flu vaccination campaign, through an ad hoc survey; it was administered using a computer-assisted web interview technique (via Google[®] forms) to all pregnant women attending prepartum programs, ambulatorial visits or routine visits in the Gynecology and Obstetrics ward of the Polyclinic G. Martino di Messina. All the investigated women chose to participate in the interview (response rate 100%).

The questionnaire had five sections (see Supplementary Material) and was created ad hoc. The first section collected information about socio-demographic status; willingness to undergo recommended vaccinations during pregnancy, such as for DTaP and flu; previous infection with COVID-19; concomitant pathologies; possible drug therapies. The second part was then focused on elements related to knowledge of the vaccine, such as how many doses comprised the primary cycle and knowledge about the possibility of receiving the vaccine during pregnancy and lactation; following this, the third part investigated the most commonly used information sources. In the fourth part, attitude regarding vaccination against COVID-19 was evaluated via short form utilizing the 6-item anti-vaccine scale, which was prepared as a 5-point Likert scale [17]. Women who wanted to receive vaccination or who had already been vaccinated were asked questions regarding their motivations for doing so; women who were not yet vaccinated or unwilling to do so were instead asked questions about their reasons or possible obstacles. A final section gave the opportunity to receive further information on the subject by submitting a telephone number.

The following three scores were designated based on the items posed on the survey: (a) the vaccination propensity score, (b) the vaccine knowledge score and (c) the vaccine hesitancy score.

The vaccine propensity score (VPS) evaluates the propensity and adherence to vaccination using 11 items on the Likert scale. The following scores were assigned based on the given answer: 0 points for disagreement; 1 for a neutral response; 2 for agreement.

The same method was used for the 9 questions asked to create the vaccine hesitancy score (VHS). This score and the corresponding questions were directed at pregnant women who did not receive vaccination for COVID-19.

Regarding the knowledge score (KS), 4 multiple choice questions were constructed where basic knowledge about the COVID-19 vaccine was evaluated. Zero points were given to incorrect or negative answers and one point was given to correct or positive answers.

Statistical Analysis

The median and IQR were calculated for the quantitative variables (age and score), while the absolute and relative frequencies were obtained for the categorical data (vaccination status).

All possible associations between score and the collected data were investigated.

Scores were assessed by evaluating normality verifications through the Shapiro–Wilk test, which allowed us to ascertain the non-normality of the three scores. Comparisons between covariates with two encodings were assessed using the Mann–Whitney test; for covariates with three factors (age and gestational period), comparisons were performed using the Kruskal–Wallis test and its post hoc nonparametric (Conover’s test). The threshold for statistical significance was set at $p = 0.050$; p -values of less than 0.050 on two-tailed tests were considered statistically significant. The summary and inferential statistics were analyzed using R software.

3. Results

The sample consisted of 127 women with a mean age of $30.91 \pm \text{SD } 5.42$. The main socio-demographic data are represented in Table 1.

Table 1. Distribution of the study sample according to sociodemographic data.

	N	%
Mean age \pm SD	$30.91 \pm \text{SD } 5.42$	
Employment		
Public employee	21	16.5
Private Employee	48	37.8
Housewife	33	26
Other	4	3.1
Freelance	21	16.5
Educational attainment		
Less than 8 years	14	11
More than 8 years	113	89
Living in . . .		
Suburbs	81	63.8
Center	46	36.2
Gestational age		
1st	12	9.6
2nd	28	22.4
3rd	85	68
Level of COVID-19 vaccine received		
No doses	14	11
1st dose	6	4.7
2nd dose	49	38.6
3rd dose	58	45.7

In our sample, 11% of the pregnant women did not undergo vaccination and 4.7% were partially artificially immunized. In our sample, the percentage of vaccinated subjects was higher in the healthy group (72.8%) than in the sick one (5.6%), with significant statistical differences ($p < 0.05$). Moreover, the uptake of flu (28.4%) and DTaP (27.2%) vaccinations among pregnant women was investigated, and among the not-vaccinated group, only 16.5% ($n = 17$) wanted to receive the flu vaccine and 31.1% ($n = 28$) wanted to receive the DTaP vaccine.

Based on education level and age, the occurrence of statistically significant differences in COVID-19 vaccination status was examined. Significant associations were found between the level of education and patient adherence to vaccinations, with a greater number of vaccinated persons with higher levels of education ($p < 0.01$).

The main information sources used were radio and television ($n = 69$; 54.3%), followed by official sources such as the Ministry of Health ($n = 14$; 11%) and healthcare workers (i.e., obstetricians, gynecologists, general practitioners and hygienists) ($n = 35$; 31.59%).

Another emerging trend was the presence of a correlation between the sources of information and the propensity for vaccination as follows: a greater number of unvaccinated pregnant women were informed by the media ($p < 0.01$), while the main source of information for vaccinated subjects was healthcare workers. Regarding knowledge about vaccination, most of the subjects (73.8%) did not know the correct schedule for the COVID-19 vaccine. That being said, most of the interviewees recognized its value and the importance of receiving the vaccination during pregnancy and breastfeeding.

The analysis of the data showed that the motivational factors comprise the geographical accessibility and availability of vaccination centers (70.5%) and willingness to pay or the presence of a free vaccination program (69.1%). More than half of the sample considered it

essential to protect themselves from infection (58.1%) and then transmit immunity to the child (60.1%). In addition, in more than 70% of cases, there was a strong recommendation from the gynecologist and midwife. Additionally, 69.9% of the sample recommended vaccination to friends and relatives (Table 2).

Regarding the factors hindering vaccination in women who were not immunized, there was a willingness to await data concerning the effects of vaccination on pregnant and breastfeeding women (70.5%). In particular, 47.4% referred to the lack of data on the effects of COVID-19 vaccination in pregnant women. As observed in another Italian study [18], 70.1% of the unvaccinated pregnant sample would prefer to immunize themselves naturally via COVID-19 infection instead of by vaccination. Accessibility to vaccination centers was not an impeding factor in 75% of the unvaccinated women examined, demonstrating that the main factor of vaccination hesitancy is not a lack of accessibility due to logistical or physical difficulties but rather concerns regarding the long-term effects of vaccination (Table 3).

Table 2. Motivators to receive vaccination from interviews with immunized subjects. ^: the sum of the numbers does not correspond to the sample total due to the absence of some answers.

	Certainly Not % (n)	Probably No % (n)	Maybe Yes Maybe No % (n)	Probably Yes % (n)	Yes of Course % (n)
Protect myself from infection	9.2 (11)	14.1 (17)	13.3 (16)	27.3 (33)	30.8 (37)
Transmission of maternal immunity to my children	5.7 (7)	16.9 (21)	16.3 (20)	21.1 (26)	39 (48)
Availability of free vaccination	8.1 (10) ^	7.4 (9)	15.4 (19)	36.6 (45)	32.5 (40)
Accessibility of vaccination center to get vaccine	4.1 (5)	15.6 (19)	9.8 (12)	24.6 (30)	45.9 (56)
Recommendation from my own gynecologist	1.8 (2)	5.3 (6)	15.9 (18)	40.7 (46)	36.3 (41)
Recommendation from my own obstetric	4.5 (5)	3.6 (4)	20.5 (23)	39.3 (44)	32.1 (36)
It gives more benefits rather than risk	1.8 (2)	4.4 (5)	29.2 (33)	30.1 (34)	34.5 (39)
It is a social liability	1.8 (2)	1.8 (2)	22.1 (25)	28.3 (32)	46 (52)
I would like to get COVID-19 vaccine	9.2 (11)	14.1 (17)	13.3 (16)	27.3 (33)	30.8 (37)
I would like propose vaccination to my friends and relatives	8.1 (10) ^	7.4 (9)	15.4 (19)	36.6 (45)	32.5 (40)

Table 3. Obstacles to receiving vaccination from interviews with non-immunized subjects. ^: the sum of the numbers does not correspond to the sample total due to the absence of some answers.

	Certainly Not % (n)	Probably No % (n)	Maybe Yes Maybe No % (n)	Probably Yes % (n)	Yes of Course % (n)
I am in the 1st trimester of pregnancy ^	39.4 (13)	30.3 (10)	3 (1)	21.2 (7)	6.1 (2)
Difficult access to vaccination center^	33.3 (12)	41.7 (15)	16.7 (6)	5.6 (2)	2.8 (1)

Table 3. *Cont.*

	Certainly Not % (n)	Probably No % (n)	Maybe Yes Maybe No % (n)	Probably Yes % (n)	Yes of Course % (n)
Inefficacy or defective of vaccine ^	21.1 (8)	18.4 (7)	21.1 (8)	23.7 (9)	15.8 (6)
The clinical trials did not include pregnant and breastfeeding women ^	5.3 (2)	21.1 (8)	26.3 (10)	26.3 (10)	21.1 (8)
I think that there is an effect on my own child through breastfeeding ^	7.9 (3)	31.6 (12)	18.4 (7)	28.9 (11)	13.2 (5)
The vaccine was promoted for financial reasons by pharmaceutical companies ^	27 (10)	18.9 (7)	13.5 (5)	18.9 (7)	21.6 (8)
I prefer to get natural immunity rather than to get vaccine ^	5.7 (7)	16.9 (21)	16.3 (20)	21.1 (26)	39 (48)
I would like to get vaccine after the evaluation of side effects in pregnancy women and breastfeeding ^	4.1 (5)	15.6 (19)	9.8 (12)	24.6 (30)	45.9 (56)

Further data were obtained by comparing the knowledge score and the propensity score (Table 4). Uncovering a trend of increasing value with increasing age. It also emerged that the propensity score increased for older subjects with a higher level of education (more than 8 years of study). The hesitation score was only highly associated with COVID-19 vaccination status ($p < 0.001$) in non-vaccinated subjects.

Table 4. Knowledge, propensity and hesitancy scores (median, 25° percentile and 75° percentile) by age, educational degree, COVID-19 status, gestational age and comorbidities.

	Age			<i>p</i> Value
	18–24	25–34	>35	
Knowledge Score	1 (1;1)	3 (1;3)	3 (2;3)	0.001
Propensity Score	12(10;16)	19 (11;21)	20 (17;22)	0.003
Hesitancy Score	4 (4;8)	4 (2;4)	4 (1;4)	0.073
	Educational degree			
	Less than 8 years	More than 8 years		
Knowledge Score	1 (1;2)	3 (1;3)		0.005
Propensity Score	11 (2;12)	20 (14;21)		0.001
Hesitancy Score	6 (3;14)	4 (2;4)		0.066
	COVID-19 vaccination status			
	Vaccinated	Not vaccinated		
Knowledge Score	1 (1;2)	4 (2;4)		0.001
Propensity Score	20 (16;21)	3.5 (0.5;6.5)		0.001
Hesitancy Score	4 (2;4)	11.5 (6;14)		0.001
	Gestational age			
	1st trimester	2nd trimester	3rd trimester	
Knowledge Score	3 (1;3.50)	3 (1;3)	2 (1;3)	0.664
Propensity Score	15.50 (11;19.50)	20 (11;21)	19 (11;21)	0.535
Hesitancy Score	4 (2;6)	4 (1;10)	4 (3;4)	0.823
	Comorbidities			
	Yes	No		
Knowledge Score	3 (1;3)	3 (1;3)		0.847
Propensity Score	18 (10.50;20)	20 (12;21)		0.401
Hesitancy Score	3 (2;4)	4 (3;4)		0.172

4. Discussion

Maternal immunization and the cocooning strategy are fundamental tools used to protect newborns from vaccine-preventable infections. However, not all healthcare workers and people who take care of newborns recommend immunization for these “at-risk categories”. This is reflected in the low prevalence of COVID-19 vaccination among pregnant women observed worldwide [1].

This study was planned to assess (a) the rate of COVID-19 vaccination among pregnant women and (b) the knowledge, attitudes, perceptions and concerns of pregnant women about COVID-19 vaccination.

This survey provides insight into the coverage, hesitancy and willingness to receive the COVID-19 vaccination among pregnant women in Italy and also identifies the factors that are related to an individual’s decision.

A first observation in the results of this study was the very low number of women (11%) who claimed that they received at least one dose of the COVID-19 vaccine. Moreover, 4.7% of the sample had received only one shot. These data are similar to those of a systematic review that reported vaccine acceptance rates ranging between 3% and 65%. Studies conducted before the COVID-19 vaccine became available in the United States showed that 41% to 47.80% of pregnant people would be interested in receiving the vaccine [19]. However, after vaccination became available, the rates of acceptance decreased or remained equal [20]. Despite the decreased rate of acceptance, most of the interviewees recognized the value and importance of vaccination [21,22]. Our results show a high vaccination rate, reaching 90%, most likely derived from the distribution of the sample. In fact, we found that educational degree and age had a high impact on the acceptance of vaccination, as indicated by Del Giudice et al. [23], and similar to another study, our sample was predominantly composed of people with higher educational attainment compared to those with medium-low instruction levels [24].

Ethnic discrepancies are clearly influenced by socioeconomic level because it affects a person’s ability to pay for and receive vaccinations [25]. Moreover, we noticed among pregnant women a low percentage of flu and DTaP vaccine uptake compared to other studies. In fact, according to data from the CDC, flu and DTaP vaccination coverage was highest among women who reported receiving a provider offer or referral for vaccination (63.5% and 62.2%, respectively) [14–16].

Factors that could influence vaccine uptake are socio-demographic factors, individual factors (personal beliefs, political views and risk perception), and finally, social or organizational factors such as social media [26].

Our study also highlights that women with comorbidities, despite being more vulnerable to disease, have a lower vaccination rate, similar to the data obtained by Snajider et al. [24]. We also evaluated the role of information sources related to active immunization and found that HCWs played a large part in the empowerment and adherence of pregnant women with higher vaccination coverage, as indicated in other studies [27].

Overall, the biggest barrier to vaccination was represented by the fear of adverse effects in women who preferred to acquire disease rather than receive the vaccine. We must remember that there are records in VAERS, the Yellow Card Reporting System, and other official databases of adverse events following immunization (AEFIs), both in the general population and in pregnant women. In particular, a study reported that among 1,315,315 Individual Case Safety Reports (ICSRs) related to COVID-19 vaccines, 3252 (0.25%) were related to vaccinations during pregnancy. Although the majority (87.82%) of ICSRs concerned serious AEFIs, their outcomes were mostly favorable. In this study, 85.0% of total ICSR referred to pregnant women ($n = 2764$), while 7.9% referred to fetuses/newborns ($n = 258$). They identified 16,569 AEFIs. Moreover, 55.16% were AEFIs not related to pregnancy (mostly headache, pyrexia and fatigue), while 17.92% were pregnancy-, newborn- or fetus-related AEFIs. The most common type of pregnancy-related AEFI was spontaneous abortion. Messenger RNA (mRNA) vaccines had a lower reported probability of spontaneous abortion than viral-vector-based vaccines (ROR 0.80, 95% CI 0.69–0.93). Moderna and

Oxford-AstraZeneca vaccines had a higher reported probability of spontaneous abortion (ROR 1.2, 95% CI 1.05–1.38 and ROR 1.26, 95% CI 1.08–1.47, respectively), while a lower reported probability was found for the Pfizer-BioNTech vaccine compared with all other COVID-19 vaccines (ROR 0.73, 95% CI 0.64–0.84) [28].

On the other hand, women who are pregnant or were recently pregnant are at increased risk of severe illness with COVID-19. Severe illness means that a woman might need to be hospitalized, receive intensive care, or be placed on a ventilator to help with breathing. Pregnant women with COVID-19 are also more likely to deliver a baby before the start of the 37th week of pregnancy (premature birth). Pregnant women with COVID-19 might also be at increased risk of problems such as stillbirth and pregnancy loss. Pregnant women who are Black or Hispanic are more likely to be affected by infection with COVID-19. Pregnant women who have other medical conditions, such as diabetes, might be at an even higher risk of severe illness due to COVID-19 [29].

The limitations of our study are its observational nature, the lack of investigation into COVID-19 and the implementation of the study only after the introduction of vaccination for COVID-19. Another limitation of this study is the use of self-reported data that could not be independently verified. The results could be affected by several biases (limited by the online survey), such as selection bias and social desirability bias. Furthermore, we did not evaluate the uptake of a fourth shot of the vaccine.

Another limitation is that the prevalence of COVID-19 vaccination in Italy could be dominated by the mandatory nature of the vaccinations in numerous workplaces, with the result that people's knowledge, hesitancy and barriers do not matter when it comes to the vaccination rate.

5. Conclusions

According to the WHO, vaccination is the primary method for preventing and controlling infectious disease epidemics. As a result, it is crucial to measure vaccination coverage and take population empowerment measures in order to spot any gaps and track trends [14]. Understanding the factors that contribute to the non-adherence and/or refusal of vaccination as well as the deployment of specific monitoring programs is crucial given the significance of primary prevention via vaccination. In particular, the availability of a global pharmacovigilance or post-marketing surveillance network that evaluates the effects of vaccination on pregnant women and newborns in the medium and long term is essential [30–33]. Another possible solution is the presence of a national recommendation approving the administration of the COVID-19 vaccine during pregnancy.

According to the international literature and our findings, vaccination bias is not the result of a single cause but rather the consequence of a complex intersection of several factors, probably as a result of a lengthy and intricate history of vaccine hesitation.

Other studies claim the presence of several risk factors to the development of vaccine hesitancy, with the role of many determinants [34,35]. For this reason, adequate vaccine counseling can be an important building block for increasing trust in the healthcare system, which will be essential in countering disinformation and misinformation about the COVID-19 vaccine for pregnant women [36–44]. Further research is necessary to test our results and explore additional questions.

Supplementary Materials: The following supporting information can be downloaded at: <https://www.mdpi.com/article/10.3390/women3030028/s1>, Questionnaire S1: Knowledge, attitude and perception of sars cov2 vaccination in pregnant women.

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Institutional Review Board Statement: This study was carried out in accordance with the Declaration of Helsinki's ethical standards. The study needed no formal approval by the local Ethics Committee, though a formal communication of the study start was given (notification with a request for acknowledgement). All the subjects who accepted voluntary participation in the survey provided informed consent. Participation was voluntary and without compensation and the survey was anonymous.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data presented in this study are available on request from the corresponding author.

Conflicts of Interest: The authors declare no conflict of interest.

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