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REVIEW

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COVID-19 vaccination hesitancy among Italian parents: A systematic review and meta-analysis

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ABSTRACT

In May 2021, the Italian government extended the COVID-19 vaccination campaign to 12- to 18-year-old subjects and, starting December 2021, vaccines were also offered to children between 5 and 11 years-old. Despite these efforts, suboptimal vaccination coverages are reported. The purpose of this review is to estimate the proportion of parents/caregivers of children and adolescents expressing COVID-19 vaccine hesitancy in Italy. The vaccine hesitation rate among parents of minors was 55.1% (95%CI: 43.8–66.1%). A higher value was evidenced in studies focusing on children (59.9%; 95%CI = 43.7–75.1%) compared to the ones focusing on adolescents (51.3%; 95%CI = 34.5–68.0%). The main reasons for unwillingness were the belief that the vaccine was unsafe or ineffective, fear of adverse events, and considering COVID-19 a non-threatening disease. The implementation of effective communication campaigns and health educational programs on safe pediatric vaccinations is essential to support strategies to bolster vaccination confidence.

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Caregivers; vaccine compliance; SARS-CoV-2; mandatory vaccination; childhood

Introduction

As reported by the U.S. Centers for Disease Control and Prevention (CDC), children and adolescents can be severely affected by Coronavirus Disease 2019 (COVID-19) and can experience ongoing health problems after the infection, similarly to adults. Patients with underlying medical conditions or who have a weakened immune system are especially at risk of severe forms of COVID-19; however, healthy subjects may also experience severe illness and require hospitalization.[1]

Since the development of the first vaccines designed against Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2), both clinical trials and post-marketing studies have been conducted in order to demonstrate these products' efficacy/effectiveness (especially against hospitalization) and safety profile in pediatric patients.[2–6] Moreover, available evidence shows that vaccination helps to prevent COVID-19-associated Multisystem Inflammatory Syndrome in Children (MIS-C), a serious complication that mostly affects children aged 5 through 11.[1]

To deal with the SARS-CoV-2 pandemic, a mass vaccination campaign was launched in European countries on December 27th, 2020.[7] In Italy, the government chose healthcare workers (HCWs) and frail patients as priority targets for vaccination;[7,8] subsequently, in May 2021, the Italian Drug Agency (AIFA) authorized the vaccines' use in all 12- to 18-year-old subjects and, therefore, the vaccine has been offered to this population at risk since June 2021.[9] On December 1st, 2021, AIFA also authorized the administration of the SARS-CoV-2 vaccines to children aged 5 to 11, providing a low-dose version of existing mRNA vaccines (one-third of the dosage authorized for adults and adolescents) with a specific formulation.[10] Despite these recommendations and the good safety and effectiveness profile, a sub-optimal vaccination coverage (VC) is reported in this population sub-group;[10] indeed, data from the Italian Ministry of Health showed an 83.8% VC in 12- to 18-year-olds and a 35.0% VC in 5- to 11-year-olds.[11]

These values, especially the ones regarding children, are likely related to their parents' and/or caregivers' attitude toward vaccination. Vaccine hesitancy (VH) among parents is a well-known phenomenon; In Italy, childhood vaccination coverage rates for various vaccine-preventable diseases have been decreasing since 2013. In 2016, the vaccination coverage rate for poliomyelitis in children at 24 months of age was below 95%. This scenario happened at a time when the World Health Organization (WHO) European Region is at risk for a poliomyelitis outbreak. Moreover, in 2016, the vaccination coverage rate for measles in children at 24 months of age was only 87.3%, and a large measles epidemic occurred in Italy in 2017, with more than 4,885 reported cases from January to December 2017.[12] Consequently, in August 2017, the Italian Government increased mandatory pediatric vaccinations from 4 to 10 through Law-Decree 73.[12]

To estimate the proportion of parents/caregivers of minors expressing COVID-19 vaccine hesitancy in Italy, we conducted a systematic review of relevant literature and a meta-analysis. Determinants of vaccine compliance and options suggested by these studies to deal with vaccine hesitancy were also analyzed.

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The aim of our study was to evaluate this phenomenon from an Italian Public Health perspective and to evaluate possible difference in hesitancy per geographical area.

Material and methods

The protocol of the systematic review was prepared based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist.[13] The protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO) with reference acknowledgment number CRD42022360272. The population, intervention, comparison, and outcome (PICO) framework of a systematic review was used to formulate the review question; the resulting question was "what is the prevalence of parents/caregivers of minors expressing anti-SARS-CoV-2 vaccine hesitancy in Italy?."

Search strategy, selection criteria, and data extraction

The Scopus, MEDLINE/PubMed, and ISI web of knowledge databases were systematically searched. Research articles, brief reports, letters, and editorials published between January 1st, 2020, and July 23rd, 2022, were included in our search. The following terms were used for the search strategy: (adherence OR hesitan* OR compliance OR attitude OR uptake) AND (covid* OR SARS*) AND (vaccin* OR mmune*) AND (parent OR parental OR caregiver OR mother OR father) AND (Ital*). Full-text articles in either English or Italian were included. Abstracts without available full text, reviews, and meta-analyses, papers not reporting epidemiological data, clinical trials, and all studies focusing on questions unrelated to the purpose of this review (vaccine knowledge, seroprevalence, etc.) were excluded. When necessary, study authors were contacted for additional information. References of all articles were reviewed for further study. The list of papers was screened by title and/or abstract independently by two reviewers who applied the predefined inclusion/exclusion criteria. Discrepancies were recorded and resolved by consensus.

Analyzed data included year, sample size, number of vaccinated minors, age of minors, Italian region, potential determinants of vaccine hesitancy, and options for managing hesitant parents.

Quality assessment

The methodological quality of the selected studies was assessed via the Newcastle – Ottawa Scale (NOS), adapted for evaluating cross-sectional studies.[14] It is divided into seven categories checking three quality aspects (selection, comparability, and outcome/exposure), and scores range from 0 to 10. The quality of a study was defined as "high" if the NOS score was 7 to 10, "intermediate" if it was 4 to 6, and "low" if it was 0 to 3.

The risk of bias for each study was independently assessed by two researchers. Discrepancies were recorded and resolved by consensus.

Main outcomes and pooled analysis

A meta-analysis was performed to estimate VH in parents of minors; three sub-analyses were performed in order to estimate VH (i) per age group of the minors (children vs. adolescents), (ii) per study period (before vs. during the immunization campaign), and (iii) per geographical area (North Italy vs. South Italy). The pooled proportion in the meta-analysis was calculated using the Freeman-Tukey double arcsine transformation to stabilize variances, and the DerSimonian-Laird weights for random effects models, with an estimate of heterogeneity obtained from the inverse-variance fixed-effects model.

Odds ratios (ORs) and 95% confidence intervals (Cis) were selected as the general outcome variables for the relationship between VH and the age of minor, sex of parents, education of parents, parents' vaccination status for SARS-CoV-2, fear of COVID-19. Data of ORs and standard errors (Ses) were calculated from 95%CIs, and an additional logarithmic transformation was performed to stabilize the variance and normalize distribution. The ORs in the meta-analysis were calculated using the inverse variance, and the DerSimonian-Laird weights for random effects models, with an estimate of heterogeneity obtained from the inverse-variance fixed-effects model.

The pooled prevalence and the ORs and the associated 95% Wald confidence interval were plotted, and a forest plot was drawn. The I^2 statistic was calculated as a measure of the proportion of the overall variance attributable to heterogeneity between studies rather than to chance. Heterogeneity between studies in different groups was also assessed. A p-value <.05 was considered to indicate the statistical significance of heterogeneity.

Three different sensitivity analyses were conducted to evaluate stability:

- Sub-analysis considering high-quality studies only;
- Sub-analysis per study sample (≥1,000 vs. <1,000 subjects);
- Exclusion of one study at a time; the conclusion based on the others was then reevaluated to avoid severe distortions.

Statistical analysis was conducted using STATA MP17.

Strategies to increase vaccination compliance among parents and suggested strategies to address vaccine hesitancy were collected from all available studies, and their respective findings were compared, with particular attention to evidence presented in several of the included papers.

Results

Identification of relevant studies

The flow-chart, constructed following the PRISMA guide[13] (Figure 1), shows the process of article selection. According to the inclusion criteria, 12 articles were identified in MEDLINE/PubMed, 11 in Scopus, and 12 in Web of Science. After exclusion of duplicate articles in the three databases, there were 12 eligible studies. Of these, two were excluded because they did not fulfill the inclusion criteria. Thus, overall, 10 studies were included, of which 9 were

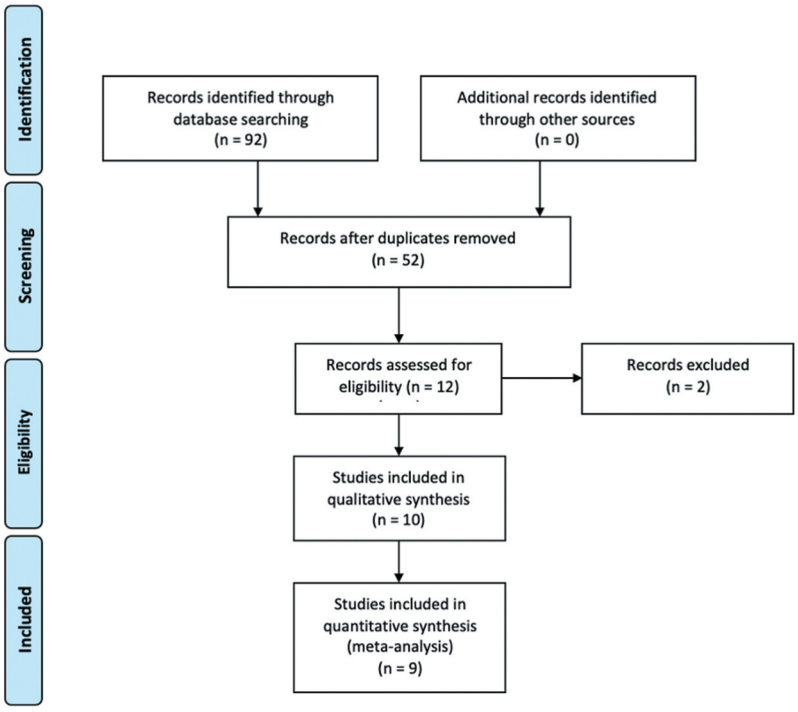

Figure 1. Flowchart of the bibliographic research.

Table 1. Characteristics of the selected studies included in meta-analysis and systematic review.

Author	Year	Quality	Total sample	n. of hesitants	Italian Region	Age of minors	Study period
Quantitative							
Bianco A	2022	h	394	287	Campania	12–17	April–May 2021
Buonsenso D	2022	h	121	53	Lombardy	1–17	November 2021–January 2022
Di Giuseppe G	2022	h	607	191	Campania	1–18	April–May 2021
Lecce M	2022	h	601	290	Lombardy	5–11	September–October 2021
Miraglia del Giudice G	2022	h	430	263	Campania	5–11	December 2021–January 2022
Fedele F	2021	h	640	530	Campania	1–14	November 2020
Montalti M	2021	h	4993	1976	Emilia-Romagna	1–18	December 2020–January 2021
Russo L	2021	h	1696	1145	Latium	1–17	July–August 2021
Zona S*	2021	h	1799	796	Emilia-Romagna, Lombardy	12–17	July–August 2021
Qualitative							
Savarese G	2022	h	-	-	Campania	12–17	January–March 2022

*short report.

quantitative and one was qualitative[15–24] (Table 1). The remaining 42 studies did not match the inclusion criteria.

Quality assessment

The NOS was applied appropriately to the included studies, and all of them were determined to be high-quality (Table 1).

Pooled analysis

Meta-analysis of all studies showed that the prevalence of vaccine hesitancy among parents of minors was 55.1% (95%CI: 43.8–66.1%; $I^2 = 99.2\%$; p-value for heterogeneity <.0001; Figure 2).

The prevalence of vaccine hesitancy investigated before and during the start of vaccination campaign for the specific subgroup population was 55.6% (95%CI = 36.9–73.5%; $I^2 = 99.4\%$; $p < .0001$) and 54.5% (95%CI = 40.2–68.4%; $I^2 = 98.6\%$; $p < .0001$), respectively, according to a p-value in the test of heterogeneity between sub-groups of .927 (Figure 3).

A difference was evidenced considering the sub-analysis per age of minors with a pooled prevalence of 59.9% (95%CI = 43.7–75.1%; $I^2 = 98.8\%$; p-value <.0001) in studies focused on children and of 51.3% (95%CI = 34.5–68.0%; $I^2 = 98.5\%$; p-value <.0001) in studies focused on adolescents, with the heterogeneity between groups p-value equal to .472.

A difference was evidenced considering the sub-analysis per geographical area with a pooled prevalence of 49.1% (95%CI = 28.5–69.8%; $I^2 = 99.4\%$; p-value <.0001) in studies set in South Italy and of 43.7% (95%CI = 39.5–48.0%; $I^2 = 87.8\%$; p-value <.0001) in studies set in North Italy, with the heterogeneity between groups p-value equal to .628.

Estimates of OR values when comparing vaccine hesitation for different determinants are described in Table 2.

Considering the sensitivity analyses, the exclusion of one study at a time did not show severe distortions from any specific paper, with the exception of the evaluation of VH

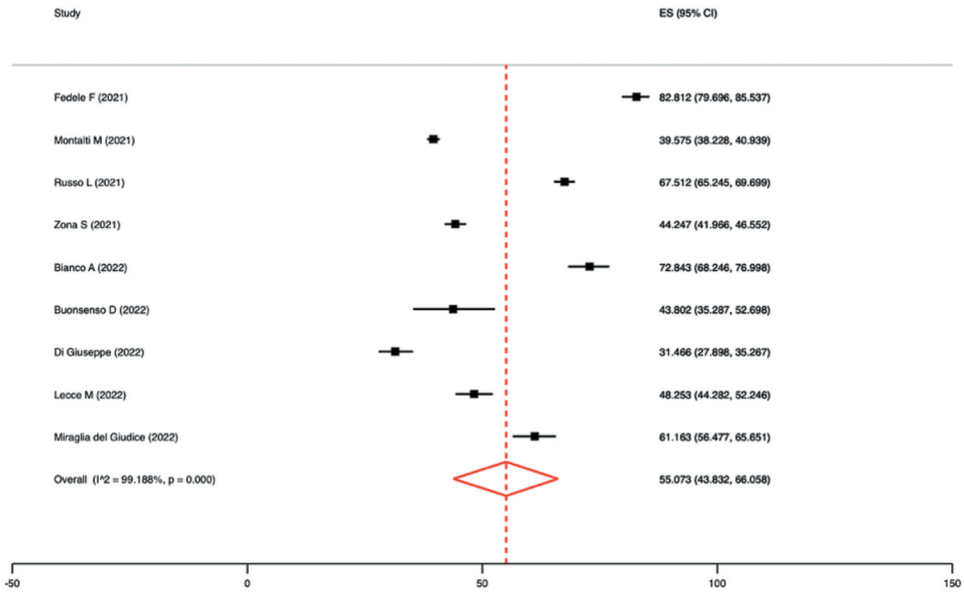

Figure 2. Forest plot of the pooled prevalence of vaccine hesitancy.

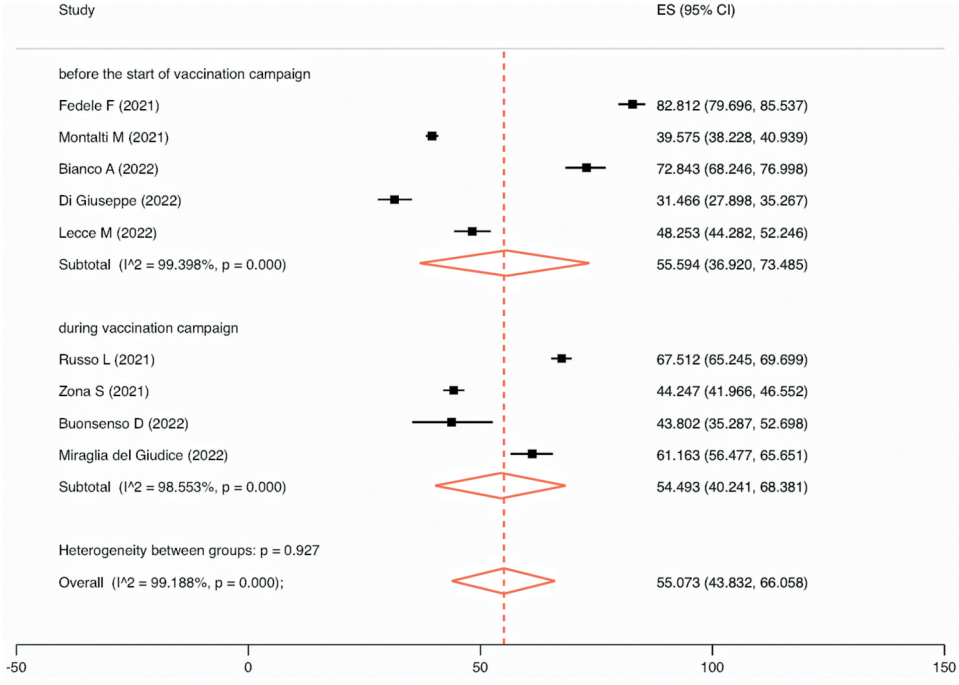

Figure 3. Forest plot of the pooled prevalence of vaccine hesitancy as determined by the different timing of survey administration (before vs. during the vaccination campaign).

Table 2. Estimates of the or in a comparison of the willingness of parents to vaccinate minors with respect to several determinants.

Determinants	n. of studies	OR (95%CI)	I^2	*p*-value for heterogeneity
Age of minor	4	1.38 (1.12–1.69)	91%	<.0001
Sex (female vs. male)	4	1.22 (0.63–2.37)	94%	<.0001
Education of parents (higher degree vs. lower)	3	1.50 (1.19–1.90)	58%	.090
Parents vaccinated against COVID19	3	2.82 (0.95–8.33)	73%	.020
Fear of COVID19	3	1.32 (1.13–1.55)	0%	.430

per parents' sex; indeed, excluding the results of Zona S et al.[23] the estimated OR was 1.61 (95%CI = 1.38–1.87) with I^2 equal to 0% (*p*-value = .670). A not significative distortion was evidenced considering the sample size, and the sub-analysis per study quality was not performed considering that all studies were classified as high-quality.

Determinants of vaccination compliance and suggested strategies to address vaccination hesitancy

Most studies reported that the main reasons to express VH were lack of information about vaccination, opinion that the vaccine was unsafe or ineffective against the disease, fear of adverse events, and considering COVID-19 a non-threatening disease for subjects under 18.[15–24] The role of pharmaceutical companies in influencing vaccine policy decisions and the uncertainty associated with the fast anti-SARS-CoV-2 vaccine development process[20] were also determinants of poor attitude toward vaccination. Buonsenso D. et al.[16] reported that parents of children who had experienced "long COVID" symptoms were more likely to be in favor of the vaccination, while parents of minors with no records of long COVID were more frequently against the vaccination. Zona S. et al.[23] reported that vaccine hesitancy toward vaccinations in general was associated with higher "anti-SARS-CoV-2-specific" vaccine hesitancy, and Di Giuseppe D. et al.[17] reported that having undergone vaccination in the past increased acceptance of the anti-SARS-CoV-2 vaccine.

Family members and friends of patients play a primary role in vaccination compliance; in fact, the vaccination status of relatives,[17,18] knowing subjects who have already experienced COVID-19,[15,19] and having had a child previously hospitalized with COVID-19[16] increased the parents' willingness to vaccinate their children. Concerns about the risk associated with COVID-19 disease and its impact on the health of their offspring was another determinant of better attitude.[15,19] Many studies reported that higher education and availability of information from scientific sources and institutional websites were associated with greater vaccination acceptance.[15,18,21,23,24] Regarding information sources about vaccines and COVID-19, the role of social media was discussed; three studies[15,19,21] reported that subjects who used social media or the Internet as their main source of information showed higher levels of hesitancy, due to the frequently inaccurate, misleading, and unconfirmed information circulating online.

Parents of adolescents are more prone to vaccinate them than parents of younger children.[17,21] This phenomenon was linked to considering the latter at a higher risk of side effects after vaccination. Younger caregivers expressed higher hesitation levels;[20–23] two studies[20,21] identified mothers as more hesitant, while one study[22] observed higher hesitancy in fathers.

Several authors[15,17,19,23] have focused on the role of healthcare providers; indeed, the degree of confidence in healthcare professionals to provide reliable and trustworthy information regarding anti-SARS-CoV-2 vaccines' safety seems to be a strong predictor of vaccine acceptance. Moreover, most parents reported having been informed by physicians, followed by social media, friends, and the Internet.[15,19] It is henceforth important that healthcare providers, especially physicians, are constantly informed about the latest scientific updates regarding anti-SARS-CoV-2 vaccination, as well as current data regarding the risks of infection for minors.

Most authors reported that communication and public health interventions emphasizing scientific evidence should be intensified to enhance the attitude and to help parents on deciding on COVID-19 vaccination of adolescent children.[15–17,19,22–24] Furthermore, better use of mass media, social media, and the internet to disseminate evidence-based facts about the vaccine and COVID-19 is advocated.[15]

Discussion

Our meta-analysis estimated vaccine hesitancy among Italian parents in Italy to be 55% (95%CI = 44–66%); this value is consistent with two systematic reviews published in 2022 that investigated the phenomenon worldwide and that assessed it to 39–46%.[25,26] No changes in the vaccine attitude before and during the vaccination campaign were evidenced; this phenomenon seems peculiar of this population subgroup, considering that variations in VH were reported in HCWs[27] and pregnant and breastfeeding women[28] following the beginning of the vaccination campaign. This may be due to the different timing of the start of vaccination campaign for these subgroups.

Parents seem to be more hesitant regarding younger minors, as older age was a determinant of better vaccine compliance; moreover, our meta-analysis showed a higher expression of VH among parents of children (60%) compared to parents of adolescents (51%), which was confirmed by the systematic review. This behavior may be due to the perception that the younger children are, the more immature their organism is, thus increasing the risk of adverse events following the vaccination. A similar behavior was found among pregnant and breastfeeding women for which one of the main determinants of low compliance to vaccination was the fear of harm coming to their offspring.[28] On the other hand, however, scientific evidence shows that the vaccine is safe for younger children and adolescents (as well as infants and fetuses), who also have a higher risk of SARS-CoV-2 infection (although serious complications are rarer than in adults).[29,30]

Regarding sex, our systematic review did not clearly report if mothers are more or less hesitant compared to fathers;[20–22] in this light, not even the results of our metanalysis are helpful (female vs. male OR = 1.22; 95%CI = 0.63–2.37), even if the sensitivity analysis showed a statistically significant OR (1.61; 95%CI = 1.38–1.87). Nevertheless, the topic is debated in the scientific community, and more studies are needed to clarify it.[31–33]

Northern Italian parents seem to be slightly less hesitant compared to Southern Italian parents (43% vs. 49%); scientific literature recognizes socio-economic status as a determinant of VH[34] and it may justify the above described difference, considering that the regions of southern Italy tend to be poorer than those of northern Italy.

Lack of information about vaccination, opinion that the vaccine is not safe and/or effective, and fear of adverse events are well-known determinants of vaccination refusal in scientific literature;[35–38] indeed, our research confirmed evidence

that has already been acquired for other high-risk groups.[28,29,39] Interestingly, younger parents showed higher levels of VH; indeed, this may be a form of optimism bias, i.e., the tendency to be more optimistic about a particular health risk, believing it is greater for other people than for themselves. Optimism bias was in fact reported to be higher in younger people than in older subjects.[40,41]

Having suffered from COVID-19 or previous infections among family members and friends, as well as fear of complications related to COVID-19, seemed to increase willingness to vaccinate. Higher education and scientific sources played a fundamental role in the attitudes of this population; trust in the scientific community has already been identified as a major determinant of vaccination compliance in the general population[28] and also seems to play a key role for this sub-group. Misinformation spreading across mass and social media facilitates distrust of vaccines,[42,43] and our systematic review confirmed this mechanism in parents of minors.[15,19,21]

Having received the vaccine seems to increase the attitude of parents toward vaccination of their offspring; this is probably caused by lower levels of concern after the absence of serious side effects following the parents' immunization; similar behaviors have already been described for other population sub-groups.[28,29,44,45]

The role of healthcare professionals in promoting immunization has been reported to be crucial in achieving high VCs; the degree of confidence in healthcare professionals providing reliable information about the safety of anti-SARS-CoV-2 vaccines appears to be strong predictors of vaccine acceptance; moreover, it must be considered that a hesitant HCW may decrease parents' willingness to let their children get vaccinated.[46–48] This evidence is also confirmed when considering the literature for other high-risk infection populations.[28,29,41]

The main limitation of this meta-analysis was the high heterogeneity across studies, as indicated by the I^2 values; however, the use of a random-effects analysis minimized this bias. Another weakness was the fact that the definition of "vaccine hesitation" is rather heterogeneous among the included studies; however, they all investigated the same topic, and therefore this does not seem to be a critical issue. Moreover, the small number of selected studies did not allow us to define adequate determinants to perform sub-analyses. However, the strength of our review was the sample size resulting from selected papers, which improved the statistical analysis and provided a better view of anti-SARS-CoV-2 vaccine hesitancy among parents of minors in Italy. In addition, all studies have been published in 2021 and 2022, so this view is up-to-date and reliable. Finally, to our knowledge, ORs for vaccination hesitancy have never been calculated considering the age of minors, education status, having been vaccinated, and fear of COVID-19.

The main auspicated strategy to deal with this issue was the improvement of communication and health education campaigns by Italian health institutions and policymakers. Indeed, the evidence available in literature has shown that fighting vaccine resistance is difficult, and too slow of a process considering the fast spread and unpredictability of a pandemic. The introduction of mandatory vaccination in Italy for adolescents aimed at overcoming this phenomenon in a situation as challenging as the pandemic emergency,[49] and managed to reach a vaccine coverage >80% in Italy. Moreover, it must be considered that vaccine uptake has been found to be beneficial to people's health.[46]

However, VCs for pediatric vaccines decreased during the SARS-CoV-2 pandemic,[50,51] a phenomenon which has been associated both to an increase in vaccine hesitancy[52] and to the fear of contagion, which led Italian parents to postpone their children's scheduled vaccinations.[53]

The implementation of effective communication campaigns and educational programs about the safety of childhood vaccinations is essential in order to reinforce vaccination confidence and behaviors. Widespread actions on multiple fronts are therefore needed to achieve good outcomes in these patients, including a better communication by the Italian Government and public health institutions and the fight against misinformation spreading across mass and social media.

Finally, the role of HCWs, especially pediatricians, is fundamental. Currently, the lack of recommendation by pediatricians and the absence of a clear communication circuit between the pediatrician and the parents are some of the main reasons for these patients' vaccine hesitancy. In fact, parents tend to identify the pediatrician as the most important physician for their children, thus granting this professional a high deal of influence on their attitude toward vaccination. In this light, pediatricians must be aware that although COVID-19 in younger subjects can rarely get complicated, it is possible that a small percentage of infected people can also have fatal outcomes. Furthermore, children represent a privileged source of infection for the adults and the elderly with whom they come into contact. For this reason, the vaccine in this category of population is not only an individual protection tool but above all a collective protection tool (although vaccination has not demonstrated a very high efficacy in reducing the transmission of the virus[54,55]). Pediatricians must stay up-to-date with the latest evidence, but depending on the evidence, recommendations for vaccination of children may change.

In conclusion, vaccination hesitancy toward anti-SARS-CoV-2 vaccines among parents of minors in Italy is an existing phenomenon. Achieving high vaccination coverages requires a multifactorial approach that demands major social, scientific, and health efforts. The success of vaccination campaigns in this population depends on the capillarity and consistency of the implemented interventions. Moreover, strategies developed to deal with COVID-19 VH can be adapted to fight VH toward other pediatric vaccinations. Italian Public Health institutions should embrace the results of this meta-analysis and the suggestions of the several authors that focused on this topic to manage the phenomenon of VH and set up the best strategies to set up effective education and communication campaigns in order to increase parents' confidence in their children's immunization.

Abbreviations

SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus-2
COVID-19	Coronavirus Disease 2019
HCW	Healthcare worker
CDC	Centers for Disease Control and Prevention
VH	Vaccine hesitancy
WHO	World Health Organization

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Informed consent statement

As this study constituted a non-original research, ethical approval from institutional review board was not required. All data were provided and analyzed anonymously.

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