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ORIGINAL ARTICLES AND REVIEWS

Determinants of COVID-19 vaccination acceptance or hesitancy in Italy: an overview of the current evidence

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Abstract

Introduction. Vaccine hesitancy is a major public health issue and a challenge for the implementation of COVID-19 immunization campaigns. The objective of this study was to address the determinants of COVID-19 vaccination acceptance or hesitancy in the Italian population.

Materials and methods. We conducted a rapid systematic review by searching PubMed until May 3rd, 2022, according to Preferred Reporting Items for Systematic Reviews (PRISMA) guidelines. Articles assessing determinants of Italians' attitudes towards COVID-19 vaccination in terms of hesitancy and/or acceptance were considered eligible. Quality and risk of bias assessment was performed through the Newcastle Ottawa Scale appraisal tool. Determinants were grouped in three categories: contextual, individual and group, and vaccine/vaccination specific influences.

Results. Out of 606 articles, 59 studies were included in the analysis. Included studies demonstrated that, in Italy, COVID-19 vaccination acceptance or hesitancy is mostly influenced by perceived safety, efficacy and usefulness of the vaccine.

Conclusion. These findings should be considered to plan tailored interventions for counteracting COVID-19 vaccination hesitancy in Italy.

Key words

- COVID-19
- vaccine
- vaccination
- adherence
- hesitancy
- Italy

INTRODUCTION

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by SARS-CoV-2, a pathogen that primarily spreads through close contact from person to person and targets the human respiratory system [1]. On January 30th, 2020, the World Health Organization (WHO) declared COVID-19 a public health emergency of international concern. On March 11th, 2020, WHO characterized COVID-19 as a pandemic [2]. Up to July 29th, 2022, there were 572,239,451 confirmed cases and 6,390,401 confirmed deaths worldwide [3, 4].

The development of safe and effective COVID-19 vaccines was the first step toward a long-term solution to the pandemic. The first mass vaccination program started in December 2020. At the date of May 17th, 2022, Italy had one of the highest COVID-19 vaccination coverage in Europe, with only Portugal, Malta and Spain exceeding Italy in terms of percentage of population vaccinated with at least one dose [5, 6]. As of July 27th, 2022, 86.6% of Italian eligible subjects completed the primary vaccination cycle and 83.7% got the booster dose too, with slight differences among Italian regions [7].

Vaccination is recognized as one of the most cost-effective methods of avoiding diseases. The WHO estimated that it currently prevents 2-3 million deaths a year and a further 1.5 million could be avoided if global vaccination coverage improved [8]. A recent study confirmed that COVID-19 vaccination has changed the course of the pandemic, avoiding 14.4 million deaths in 185 countries between December 2020 and December 2021 [9]. However, vaccine hesitancy, defined as a "delay in acceptance or refusal of vaccination despite availability of vaccination services" [10, 11], is a phenomenon that has existed since the first vaccines were administered and has become much more difficult to face in the age of social media. Because it undermines the progress made in addressing vaccine-preventable diseases, vaccine hesitancy was recognized among the top 10 threats to global health by the WHO in 2019 [8].

COVID-19 vaccination campaign achieved overall high coverages in Italy; however, some pockets among

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population did not vaccinate at all or did not get the booster dose. This issue may be attributable to several reasons, including the dynamics of supply and service delivery in the Italian health system, but also people's beliefs, attitudes, and behaviors. Among the barriers to the uptake of COVID-19 vaccination, vaccine hesitancy has been documented by a big body of evidence [12-22] as a key modifiable factor that places critical challenges to the successfully implementation of the COVID-19 vaccination campaign. Vaccine hesitancy is a complex and context-specific issue, varying across time, place, and vaccines [23-34]. According to the SAGE Working Group's Vaccine Hesitancy Determinants Matrix, factors that can influence hesitancy could be grouped in three categories: contextual influences (due to historic, socio-cultural, environmental, health system/institutional, economic or political factors), individual and group influences (arising from personal perception of the vaccine or from the social/peer environment), and vaccine/vaccination-specific issues (directly related to vaccine or vaccination) [11, 23-30].

Uninterrupted efforts should be made to vaccinate everyone who is eligible in every country and an effective vaccination program cannot avoid considering the understanding of concerns and expectations of individuals and communities regarding vaccines and vaccination. In fact, this could help in reaching pockets of unvaccinated people and addressing hard-to-reach populations, through tailored interventions, even in contexts where vaccination coverage is high. The monitoring of vaccination coverage and of reasons for non-vaccination is a required activity to ensure population Essential Levels of Care (LEA) [31]. However, albeit also the Italian Society of Hygiene (Società Italiana di Igiene, Medicina Preventiva e Sanità Pubblica, SItI) underlined the need of monitoring these issues, a national monitoring system has not been implemented yet [35]. Furthermore, despite the increasing body of literature investigating COVID-19 vaccine hesitancy and its determinants in Italy, all available evidence has not been summarized to date. For this reason, the objective of this study was to carry out a systematic literature review of the Italian studies on the topic, in order to collect and summarize the evidence on factors associated with acceptance or hesitancy of COVID-19 vaccination in the Italian population. The synthesis of this evidence will be useful for better understanding the reasons for COVID-19 vaccine acceptance or hesitancy and, consequently, supporting evidence-informed interventions to increase COVID-19 vaccination coverage in Italy.

MATERIALS AND METHODS

A systematic review was conducted and reported according to the Preferred Reporting Items for Systematic Reviews (PRISMA) [36].

Search strategy

PubMed was searched to retrieve potential eligible articles published from the inception until May 3rd, 2022. The PubMed search was pursued with a search string developed on the PICO model (P, population/patient; I, intervention/indicator; C, comparator/control; and O, outcome) and reported below:

((vaccin*[tiab] OR immuniz*[tiab] OR immunis*[tiab]) AND (covid*[tiab] OR sars-cov-2[tiab] OR coronavirus[tiab] OR 2019ncov[tiab])) AND ((adherence[tiab] OR uptake[tiab] OR accept*[tiab] OR intent*[tiab] OR willingness[tiab] OR facilitator*[tiab] OR confiden*[tiab] OR trust[tiab] OR hesita*[tiab] OR refus*[tiab] OR reject*[tiab] OR unwillingness[tiab] OR opposition[tiab] OR barrier*[tiab] OR mistrust[tiab] OR distrust[tiab] OR anti-vaccin*[tiab] OR antivaccin*[tiab] OR exemption*[tiab] OR behaviour[tiab] OR attitude*[tiab] OR determinant*[tiab] OR predict*[tiab])) AND (Ital*).

The reference lists of included articles were hand-searched to look for additional eligible studies.

Inclusion and exclusion criteria

The systematic review included observational analytical studies conducted on the Italian population that assessed acceptance or hesitancy towards COVID-19 vaccination as outcomes and any favorable or unfavorable factor associated to them.

We excluded systematic reviews, non-empirical studies, conference, editorials, commentaries, book reviews, and abstracts without a full text. In addition, studies whose full text could not be retrieved were excluded. International studies that did not analyze and report disaggregated data by countries were also excluded; if disaggregated data were reported, we extracted only separately reported Italian data.

Study selection

The study selection was conducted by one author and further cross-checked by another author for accuracy. Disagreements were iteratively discussed until agreement was reached. The selection of eligible articles was carried out by screening titles and abstracts first and then full texts. The study selection was performed from May 2022 to June 2022.

Data extraction and synthesis

The full text review and data extraction were conducted by one author and further cross-checked by another author for accuracy. Disagreements were iteratively discussed until agreement was reached. The data extraction was performed from June 2022 to July 2022.

A dedicated data extraction form developed on Excel was used to gather the following information for each eligible study:

1) Study identification (first author, title, journal, and publication year);
2) Study characteristics (region/city, period, design and study population);
3) Study population characteristics (sample size, age, gender, and socio-cultural-economic characteristics, presence of any special health conditions, vaccination status);
4) Study outcome(s) (outcomes of the study with relevant descriptive statistics, percentages; factors associated with the outcome).

Because of expected heterogeneity among studies, the synthesis of data was conducted only qualitatively and reported in summary tables.

Factors associated with acceptance or hesitancy towards COVID-19 vaccination were grouped according to the categories identified by the SAGE Working Group in the Vaccine Hesitancy Determinants Matrix [7], namely contextual, individual and group, and vaccine/vaccination-specific influences.

Quality assessment and risk of bias

The methodological quality and risk of bias of included articles were assessed through the Newcastle Ottawa Scale - NOS in its original version [37] and in a version adapted for the assessment of analytical cross-sectional studies [38]. The assessment was conducted by one author and further cross-checked by another one. Disagreements were resolved by discussion with a third researcher.

To summarize the results of the quality assessment and risk of bias, the articles were grouped into four categories: excellent (10-11 points), good (9-7 points), sufficient (6-5 points) and poor (4-0 points) quality. The risk of bias decreases as the quality increases.

RESULTS

Results of the search strategy

PubMed search returned 606 articles, of which, after the screening by title and abstract and by full text, 91 papers were retrieved for the assessment of final eligibility. Of these, 59 articles [39-97] met eligibility criteria and were included in the systematic review. The study selection process is reported in *Figure 1*.

Characteristics of the included studies

Among included articles, 27 studies (45.8%) addressed the whole Italian population [43, 44, 47, 48, 51, 59, 61, 63-66, 68, 70, 74, 76, 77, 79, 84, 86, 88-90, 93-97], whereas 12 studies (20.3%) [42, 45, 60, 62, 67, 71, 73, 75, 80-82, 92] were conducted in northern Italy, 5 (8.5%) [40, 41, 54, 83, 87] in central Italy and 12 (20.3%) [39, 46, 49, 50, 52, 53, 55, 56, 58, 69, 85, 91] in southern Italy.

The studies were conducted between February 2020 and January 2022; in particular, 18 [43, 47-50, 55, 59, 60, 63, 65, 73, 76, 78, 79, 88, 90, 95, 97] (30.5%) studies were conducted before the start of the vaccination campaign in Italy, 33 (55.9%) [39-42, 44-46, 51-54, 56-58, 61, 64, 69, 70, 74, 75, 77, 80-83, 85-87, 89, 92-94,

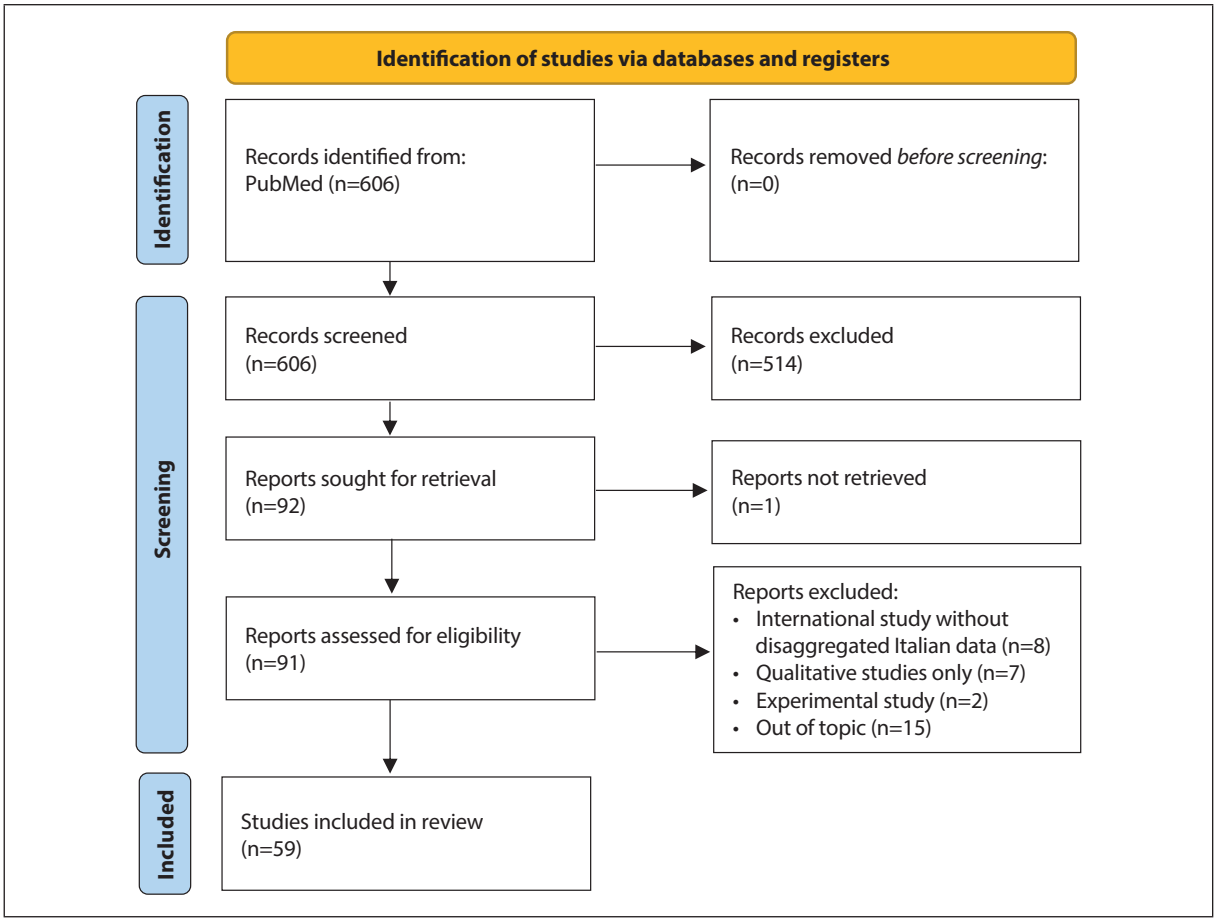

Figure 1

Preferred reporting items for systematic reviews (PRISMA) flowchart of the search strategy. *From*: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:71. doi: 10.1136/bmj.n71. For more information, visit: http://www.prismastatement.org/.

96] after the start of the vaccination campaign and 8 (13.6%) [62, 66-68, 71, 72, 84, 91] straddling the two periods. Twenty-five (41.7%) [41, 42, 47, 51, 56, 59-61, 63, 65, 66, 72, 74, 76, 79, 80-82, 84, 86, 88, 89, 95-97] studies investigated the attitudes of general adult population towards COVID-19 vaccination, and two [43, 58] (3.3%) the attitude of the elderly. Ten (17%) [44, 45, 52, 54, 64, 68, 69, 75, 87, 91], focused on potentially more fragile and/or at-risk population groups (patients with chronic diseases, persons previously tested positive for SARS-CoV-2, prisoners, migrants). Eight studies (13.3%) [46, 48, 50, 62, 70, 77, 90, 93] investigated the attitudes towards vaccination of healthcare workers. Eight (13.3%) [39, 40, 49, 57, 67, 73, 78, 85] involved students and/or university staff. Seven studies (11.7%) [53, 55, 69, 71, 83, 92, 94] investigated parents' attitudes towards COVID-19 vaccination of their children, one [55] of which also assessed parents' propensity to vaccinate for themselves.

In 25 studies (42.4%), the study population was balanced between females and males, 28 (47.4%) study populations were predominantly formed by females (>60% of the sample) while only two (3.4%) [52, 62] were predominantly formed by males; eventually four articles (6.8%) [46, 66, 76, 84] did not report gender distribution of the study population.

Two studies (3.4%) [39, 56] evaluated populations that had already undergone a full cycle of vaccination.

A full description of the characteristics of the included studies is given in *Table 1*.

Only 3 studies (5.1%) [41, 54, 82] assessed actual vaccine uptake as an outcome, while the others investigated attitudes towards vaccination considering the intention to vaccinate.

Table 1
Description of the characteristics of the studies included in the systematic review, about COVID-19 vaccination acceptance or hesitancy in Italy

Author, year	Region/ city	Period	Study population	Sample size (N)	Sex (female %)	Age	Study outcomes and results				Quality score
							Hesitancy	%	Acceptance	%	
Aliberti 2022 [39]	Salerno	May-August 2021	University lecturers undergoing full cycle of Vaxzevria	500	59.20	range: 26-66	Vaccine hesitancy (Vaxzevria)	32.70			7
Baccolini 2021 [40]	Roma	March-June 2021	University students unvaccinated	5,369	61.50	mean (SD): 23.5 (4.5)	Vaccine hesitancy	26.00			5
Barello 2022 [51]	Italia	March 2021	Adult population	866	50.80	range: 18-70	Delay in vaccination while waiting for a 'better' vaccine	46.00			9
Belingheri 2021 [62]	Monza-Brianza	December 2020-January 2021	Health workers	421	28.50	≥25			Intention to vaccinate	82.20	7
Belingheri 2021 [73]	Lombardia	December 2020	Healthcare students	422	82.90	median (IQR): 21 (20-22)			Intention to vaccinate	80.80	5
Bucchi 2022 [84]	Italia	October 2020	Adult population	991	NA	>15			Intention to vaccinate (as soon as possible)	36.02	7
		January 2021		987						59.90	
		May 2021		977						83.80	
Buonsenso 2022 [94]	Italia	November 2021-January 2022	Parents of children/ adolescents with a previous diagnosis of COVID-19	121	81.20	median (IQR): 42 (38-47)			Intention to vaccinate one's children	56.20	7
Caserotti 2021 [95]	Italia	February-June 2020	Adult population	2,267	69.90	mean (SD): 38.1 (14.0)			Intention to vaccinate	40.10	6
Caserotti 2022 [96]	Italia	January-February 2021	Adult population	5,006	50.00	range: 18-70			Intention to vaccinate	88.00	9
Caserotti 2022 [97]	Italia	May-June 2020	Adult population	448	70.80	mean (SD): 33.8 (13.9)			Intention to vaccinate	NA	5
Cesaroni 2022 41]	Lazio	December 2021	Adult population	3,186,728	54.00	mean (SD): 58.9 (14.3)	Non-vaccination	10.30			11
Cocchio 2022 [42]	Veneto	January 2021	Adult population	4,467	51.10	mean (SD): 46.8 (16.0), median (IQR): 48 (34-59)	Vaccine hesitancy	15.70			6

Continues

Table 1
Continued

Author, year	Region/ city	Period	Study population	Sample size (N)	Sex (female %)	Age	Study outcomes and results				Quality score
							Hesitancy	%	Acceptance	%	
Contoli 2021 [43]	Italia	August-December 2020	Elderly population	1,876	53.60	≥65	Vaccine hesitancy	45.00			10
							Vaccine refusal	16.00			
Costantino 2021 [44]	Italia	February 2021	Patients suffering from inflammatory bowel disease	1,252	58.20	median (IQR): 48 (37-58)	Vaccine hesitancy	18.10			7
							Vaccine refusal	2.70			
Costantino 2021 [45]	Milano	February 2021	Patients suffering from coeliac disease	103	78.60	range: 18-77	Vaccine hesitancy	25.20			7
							Vaccine refusal	4.80			
Costantino 2022 [46]	Palermo	January-March 2021, October 2021	Health workers	1,450; 1,391	64.70	mean (SD): 46.3 (15.7);			Intention to vaccinate	64.00	9
Del Riccio 2021 [47]	Italia	December 2020	Adult population	7,605	65.50	median (IQR): 47 (34-58)			Intention to vaccinate	81.90	5
Di Gennaro 2021 [48]	Italia	October 2020	Health workers	1,723	57.70	mean (SD): 35.5 (11.8)	Vaccine hesitancy	33.00			5
Di Giuseppe 2021 [49]	Caserta-Napoli	September-November 2020	University staff	1,501	60.80	mean (SD): 36 (14.2); range: 18-73			Intention to vaccinate	84.10	9
Di Giuseppe 2021 [50]	Caserta-Napoli	September-November 2020	Health workers	738	42.30	mean (SD): 40.4 (12.8); range: 19-70			Intention to vaccinate	80.70	9
Di Giuseppe 2022 [52]	Campania	March-April 2021	Prisoners	865	0.00	mean (SD): 42.4 (11.9); range: 18-78			Intention to vaccinate	63.90	8
Di Giuseppe 2022 [53]	Napoli	April-May 2021	Parents of children/ adolescents	607	82.40	mean (SD): 42.3 (6.5); range: 22-63			Intention to vaccinate one's children	68.50	10
Di Noia 2021 [54]	Roma	March 2021	Patients suffering from oncological diseases	914	61.00	range: 21-97			Vaccinated	88.80	6
Di Valerio 2021 [93]	Italia	1 January-16 February 2021	Healthcare professional members of a Facebook private group	10,898	77.90	≥18	Vaccine hesitancy	1.10			4
Fedele 2021 [55]	Napoli	November 2020	Parents of children/ adolescents	640	73.90	NA	Vaccine hesitancy regarding the vaccination of one's children	82.80			5
							Vaccine refusal regarding the vaccination of one's children	34.50			
							Vaccine hesitancy	73.40			
							Vaccine refusal	23.40			
Folcarelli 2022 [56]	Napoli	November-December 2021	Adult population vaccinated with full cycle	615	57.40	mean (SD): 32.1 (15.9); range: 19-76	Vaccine hesitancy on booster dose administration	24.70	Intention to vaccinate (booster dose)	85.70	10
Gallè 2021 [57]	Bari, Napoli, Roma	February-April 2021	University students	3,226	56.00	mean (SD): 23.3 (3.9); median (IQR): 22 (21-25); range: 18-45			Vaccinated or Intention to vaccinate	92.90	8
Gallè 2021 [58]	Apulia	June-August 2021	Elderly population	1,041	58.30	mean (SD): 76.6 (6.5)			Vaccinated or Intention to vaccinate	92.70	8

Continues

Table 1
Continued

Author, year	Region/ city	Period	Study population	Sample size (N)	Sex (female %)	Age	Study outcomes and results				Quality score
							Hesitancy	%	Acceptance	%	
Genovese 2022 [59]	Italia	February-July 2020	Adult population	4,116	64.10	mean (SD): 33 (13)			Intention to vaccinate	76.00	8
Gerussi 2021 [60]	Udine	September-November 2020	Adult population with a previous diagnosis of COVID-19	599	53.40	mean (SD): 53 (15.8); range: 19-76	Vaccine hesitancy	59.10			5
							Vaccine refusal	24.90			
Giuliani 2021 [61]	Italia	January-February 2021	Adult population	1,074	67.50	range: 18-88			Intention to vaccinate	85.40	5
Graffigna 2020 [63]	Italia	May 2020	Adult population	1,004	50.90	mean (SD): 44 (14); range: 18-70			Intention to vaccinate	58.60	8
Guaraldi 2021 [64]	Italia	January 2021	Patients sufferingfrom diabetes	1,176	73.10	>18	Vaccine hesitancy	15.70			5
Heyerdahl 2022 [65]	Italia	December 2020	Adult population	1,000	50.40	range: 18-65			Vaccination acceptance	66.00	5
Lindholt 2021 [66]	Italia	September 2020-February 2021	Adult population	2,411	NA	>18			Vaccination acceptance	60.00	9
Lo Moro 2022 [67]	Torino	November 2020-February 2021	Health students	902	63.50	median (IQR): 24 (23-26)	Vaccine hesitancy	6.70			6
							Vaccine refusal	0.50			
Magon 2021 [68]	Italia	June-August 2020, October 2020-March 2021	Patients undergoing anticoagulant therapy	288	50.50	mean (SD): 58 (20)	Vaccine hesitancy	35.60			7
Miraglia del Giudice 2022 [69]	Napoli	December 2021-January 2022	Parents of children/ adolescents with chronic diseases	430	86.50	mean (SD): 40.5 (6.1); range: 25-57	Vaccine hesitancy regarding the vaccination of one's children	26.30	Intention to vaccinate one's children	38.80	10
Monami 2021 [70]	Italia	January 2021	Health workers	7,881	76.30	NA	Vaccine hesitancy	2.40			5
Montalti 2021 [71]	Bologna	December 2020-January 2021	Parents of children/ adolescents	4,993	76.60	NA	Vaccine hesitancy regarding the vaccination of one's children	39.50			5
							Vaccine refusal regarding the vaccination of one's children	9.90			
Montalti 2021 [72]	Bologna, Palermo	December 2020-February 2021	Adult population	443	56.40	>18			Intention to vaccinate	75.60	5
Moscardino 2022 [74]	Italia	June 2021	Adult population	1,200	49.40	mean (SD): 29.8 (6.5); range: 18-40	Vaccine hesitancy	25.10			9
							Vaccine refusal	7.50			
Page 2022 [75]	Milano	February-May 2021	Migrants	126	67.20	median (IQR): 41 (20)			Vaccination request	52.00	8
Palamenghi 2020 [76]	Italia	May 2020	Adult population	1,004	NA	NA			Intention to vaccinate	59.00	6
Papini 2021 [77]	Italia	February-April 2021	Health workers	2,137	71.70	NA	Vaccine hesitancy	6.70			7
Pastorino 2021 [78]	Milano, Brescia, Piacenza, Cremona, Roma	June-July 2020	University students	436	70.40	median (IQR): 23.1 (21.3-24.7)			Intention to vaccinate	94.70	6
Prati 2020 [79]	Italia	April 2020	Adult population	624	54.00	mean (SD): 32.3 (12.7); range: 18-72			Intention to vaccinate	75.80	6
Reno 2021 [80]	Emilia-Romagna	January 2021	Adult population	1,011	55.20	mean (SD): 46.9 (11.5); range: 19-70			Intention to vaccinate	68.90	8

Continues

Table 1
Continued

Author, year	Region/ city	Period	Study population	Sample size (N)	Sex (female %)	Age	Study outcomes and results				Quality score
							Hesitancy	%	Acceptance	%	
Reno 2021 [81]	Emilia-Romagna	January 2021	Adult population	1,011	55.20	mean (SD): 46.9 (11.5); range: 19-70			Intention to vaccinate	68.90	8
Russo AG 2021 [82]	Milano-Lodi	September 2021	Adult population	2,981,997	52.10	>18			Vaccinated	84.40	11
Russo L 2021 [83]	Roma	July-August 2021	Parents of children/ adolescents	1,696	81.60	median (IQR): 42 (37-47)			Vaccinated or Intention to vaccinate one's children	32.20	6
Salerno 2021 [85]	Palermo	May 2021	University students unvaccinated	2,667	68.10	mean (SD): 22.74 (3.81)	Vaccine hesitancy (mRNA vaccine)	8.20			5
							Vaccine refusal (mRNA vaccine)	1.00			
							Vaccine hesitancy (viral vector vaccine)	42.60			
							Vaccine refusal (viral vector vaccine)	12.20			
Santirocchi 2022 [86]	Italia	March-May 2021	Adult population	971	57.60	>18			Intention to vaccinate	78.50	7
Scoccimarro 2021 [87]	Firenze	January-April 2021	Patients suffering from diabetes	502	60.20	>18	Vaccine hesitancy	18.30			7
Simione 2021 [88]	Italia	April 2020	Adult population	350	8.00	mean (SD): 40.8 (10.8)			Intention to vaccinate	NA	7
Steinert 2022 [89]	Italia	June 2021	Adult population	1,087	51.20	>18	Vaccine hesitancy	15.00			8
Trabucco Aurilio 2021 [90]	Italia	December 2020	Health workers	531	73.40	NA			Intention to vaccinate	91.50	6
Viola 2021 [91]	Messina	October 2020-June 2021	Patients suffering from inflammatory bowel disease	470	43.60	mean (SD): 48 (18)			Vaccination acceptance (vaccinated or vaccine booking)	85.00	7
Zona 2021 [92]	Modena	July-August 2021	Parents of children/ adolescents	1,799	76.40	mean (SD): 45 (5.8)			Intention to vaccinate one's children	26.50	7

Vaccination hesitancy: refers to delay in acceptance or refusal of vaccination despite availability of vaccination services.
Vaccination acceptance: refers to vaccinated subject, subject who has already booked to vaccinate and intention to receive vaccination.
SD: standard deviation; IQR: interquartile range.

The majority of the articles referred to COVID-19 vaccination in general, except for three studies (5.1%) which referred to Vaxzevria, [39], to mRNA [85] and viral vector [56] vaccine type; moreover, one study (1.7%) [56] specifically assessed the attitude towards the administration of the booster dose.

Among studies investigating COVID 19 acceptance and /or hesitancy, there is a considerable variability in definition of outcomes, in study population type and in periods assessed (*Table 1*). Vaccination hesitancy showed the highest values in a study conducted in November 2020 on a population of parents, who stated that they were not positively inclined to vaccinate themselves in 73.4% of cases or to vaccinate their children in 82.8% [55]. Regarding hesitancy about vaccinating children, a lower percentage (26.3%) was found among parents of children with chronic diseases between December 2021 and January 2022 [69]. The lowest percentage of vaccination hesitancy (2.4%) was recorded among healthcare professionals [70]. The vaccination acceptance ranged from 94.7% in a study conducted among students of the Catholic University of the Sacred Heart in July 2020 [78] to 36.2% in a study performed on the general population in October 2020 [84]; this study found an increase in acceptance rate up to 83.8% in May 2021 too [84].

Results of the quality assessment and risk of bias

The details of the quality assessment are shown in detail in the *Supplementary Material* available online

whereas the overall scores are reported in *Table 1*. The quality scores ranged from 4 to 11 (median: 7; mean: 7.05). The quality was evaluated as "very good" for 6 studies (10.2%) [41, 43, 53, 56, 69, 82], "good" for 29 studies (49.2%) [39, 44-46, 49-52, 57-59, 62, 63, 66, 68, 74, 75, 77, 80, 81, 84, 86-89, 91, 92, 94, 96] and "sufficient" for 23 studies (39.0%) [40, 42, 47, 48, 54, 55, 60, 61, 64, 65, 67, 70-73, 76, 78, 79, 83, 85, 90, 95, 97], while for only one study (1.7%) [93] was evaluated as "low". With regard to risk of bias, thirteen studies [40, 47, 48, 55, 61, 64, 70-73, 85, 93, 97] could be considered at high risk of selection bias as they were scored zero in three out of four items considered, namely *representativeness of the sample, sample size and non-respondent*. Three studies [54, 60, 65] have a zero score in the item of comparability, while no article has a zero score in the domain referred to outcome assessment. Special attention should be paid to the article of Di Valerio, 2021 [93], which totalized a NOS score of 4, so it is reasonable to assume that it is at high risk of bias. Nevertheless, the evidence on factors associated with acceptance or hesitancy of COVID-19 vaccination, that are hereafter summarized, came from many studies, thus minimizing the hazard of making conclusions based only on studies at high risk of bias.

Factors associated with COVID-19 vaccine acceptance or hesitancy

The complete matrix of factors associated with COVID-19 vaccination acceptance or hesitancy is reported in *Table 2* and, hereafter, summarized according to the groups of influences.

Contextual influences. Among the contextual influences, socio-demographic and cultural factors have been the most investigated. Age was associated with adherence to vaccination, with a greater propensity to be vaccinated among older subjects than younger ones [41, 42, 52, 55, 56, 60, 64, 66, 71, 72, 74, 76, 79, 82, 84, 86, 88, 89, 91, 92, 96]. Similarly, a significant association was found between the higher age of children/adolescents and the propensity of parents to vaccinate them [53, 69, 71, 94]. Only few studies have come to opposite conclusions. In all except than two studies [40, 49] female gender was found to be associated with hesitancy [41-44, 47, 50, 55, 60, 61, 66, 71-73, 77, 80, 82, 84, 86, 88-90, 92, 96]. A medium/higher level of education was overall associated with a greater propensity to vaccination [40, 44, 55, 58, 61, 64-66, 69, 73, 84, 86, 88, 89, 96, 97], while a low educational level was associated with hesitancy [41-43, 71, 72, 74, 80, 81]. The evidence about health workers showed that they are more predisposed to accept vaccination [40, 48, 50, 61, 77, 96]. With regard to the source of information, there is a clear relation between the consultation of scientific/institutional information and the acceptance of vaccination [50, 55, 56, 81, 96], while the collection of information from mass media is associated to hesitancy [48, 58, 66, 71, 75, 81, 86, 96]. In the political sphere, both trust in government and institutions [47, 61, 74, 79, 86, 97] and support for health policies [66, 71, 96] are predictors of vaccination acceptance.

Individual and group influences. Beliefs, attitudes, and knowledge/awareness were the factors mostly addressed among individual and group influences. In particular, the attitude to preventive behaviours (such as use of masks, adherence to therapies, adherence to the flu vaccination campaign and cancer screening) was significantly associated with COVID-19 vaccination acceptance in half of the studies [40, 42, 43, 45-48, 51, 53, 57, 59, 60, 62, 64, 66, 67, 70, 72, 73, 76, 78, 82, 83, 86, 90, 91, 95, 97]. Twenty-five articles [39, 44-47, 57, 59, 61, 63, 66, 69, 71, 74, 76, 80, 81, 83, 84, 86, 88, 89, 92, 95-97] investigated the relationship between vaccination and confidence in science, medicine, health institutions and healthcare professionals, as well as confidence in vaccines in general; in contrast, propensity to alternative medicine [44] and previous experience of adverse events linked to vaccinations [67, 70, 93] were related to hesitancy. A positive association with acceptance was also found in relation to health literacy and health engagement [63, 68]. With regards to the perception of risk of disease, some studies showed a significant association between the perception of risks of COVID-19 and vaccination acceptance [40, 43, 44, 46, 49, 50, 52, 53, 61, 63, 66, 69, 77, 78, 80, 81, 83, 84, 86, 89, 95-97]. The perception of the safety [40, 47, 49, 50, 83, 85], efficacy [40, 83, 85, 90] and usefulness [46, 47, 53, 85] of the vaccine, as well as the experience of negative consequences of the disease among family members, friends and acquaintances [43, 56, 94, 96] were associated with vaccination acceptance. Vaccination hesitancy was associated with the perception of insufficient information about the vaccine [39, 56, 69]. Eventually, other factors associated with vaccination acceptance were the concern about emergency [40, 43, 78, 79] and economic situation [66, 96].

Vaccine- and vaccination-specific influences: among these influences short time needed to develop COVID-19 vaccines was reported as a cause of concern and therefore for vaccination hesitancy [85].

DISCUSSION

It has been estimated that in Italy, from January 2021 to January 2022, about 8 million cases, over 500,000 hospitalizations, over 55,000 hospitalizations in intensive care units and about 150,000 deaths were directly prevented by COVID-19 vaccination [98]. However, the phenomenon of vaccine hesitancy, both against COVID-19 vaccines and vaccination in general, skyrocketed since the beginning of the pandemic, with differences related to several aspects [99]. For this reason, every effort to understand the phenomenon is of great value to guide counteracting actions.

Our review addressed the determinants of COVID-19 vaccination acceptance and hesitancy in the Italian population, being the first one, to the best of our knowledge, to provide a broad and overall overview of the topic. The findings of our review showed that, as expected, the major reasons behind COVID-19 vaccination hesitancy were individual and group factors, such as perceived safety, efficacy and usefulness of the vaccine. In addition, the lack of awareness and information was often reported to negatively impact on vaccination attitudes too.

The reasons for COVID-19 vaccination acceptance or hesitancy have been investigated worldwide by a huge

amount of literature, addressing not only the overall population but also specific groups, such as healthcare professionals and students [100-103], or subgroups with expected lower vaccine uptake, such as pregnant women [104, 105], ethnic minority [106-108], adolescents/young adults [109] and parents in respect to their children [110, 111]. Also, all this evidence highlighted that the main reasons for vaccine hesitancy belonged to individual and group influences, including lack of information or misinformation [100, 102, 104, 108],

Table 2
Matrix of factors associated with COVID-19 vaccination acceptance or hesitancy, with bibliographical references

Macroareas of factors	Factors associated with:	Hesitancy [references]	Acceptance [references]
Contextual influences	**Socio-demographic factors, religion, culture, gender**		
	Age		
	Young	[71, 72, 79, 80]	[48, 59]
	Intermediate	[42, 76, 81, 95]	[93]
	Advanced	[74, 82, 88, 89]	[41, 52, 55, 56, 60, 64, 66, 84, 86, 91, 92, 96]
	Higher in children		[53, 69, 71, 94]
	Gender (female)	[41-44, 47, 50, 55, 60, 61, 66, 71-73, 77, 80, 82, 84, 86, 88-90, 92, 96]	[40, 49]
	Citizenship/birth abroad	[41, 82]	
	Marital status (married)	[86]	[49]
	High household size		[53]
	Educational level		
	Low	[41-43, 71, 72, 74, 80, 81]	
	Medium-high	[51]	[73]
	High		[40, 44, 55, 58, 61, 64-66, 69, 84, 86, 88, 89, 96, 97]
	Low income	[74, 80, 81, 89]	
	Occupation		
	Unemployed	[65, 69, 74]	[47, 92]
	In contact with the public	[42]	[60]
	Entrepreneurs	[97]	
	Administrative staff	[49]	
	Health workers and in particular doctors compared to other health professionals		[40, 48, 50, 61, 77, 96]
	Deprivation (high)	[41, 82]	
	Residence		
	North	[70, 74]	
	Central	[43]	
	South		
	High population density areas	[43]	
	Religious affiliation	[88]	
	Information		
	Media	[48, 71, 75, 81, 96]	[58]
	Institutional and scientific information sources		[50, 55, 56, 81, 96]
	Belief in misinformation		[66, 86]
	Policy		
	Political ideology	[40, 66]	
	Trust in government and institutions		[47, 61, 74, 79, 86, 97]
	Support for public health policies (e.g., compulsory vaccination)		[66, 71, 96]
	Lockdown phase, during the emergency		[95]

Continues

Table 2
Continued

Macroareas of factors	Factors associated with:	Hesitancy [references]	Acceptance [references]
Individual and group influences	**Knowledge, beliefs, attitudes, experiences about health and prevention**		
	Confidence in science, medicine, health institutions, health professionals		[39, 61, 66, 69, 71, 76, 84, 86, 88, 96, 97]
	Positive attitude to alternative medicine	[44]	
	Attitude towards for preventive behaviour (e.g., use of masks, flu vaccination, screening, adherence to possible therapies)		[40, 42, 43, 45-48, 51, 53, 57, 59, 60, 62, 64, 66, 67, 70, 72, 73, 76, 78, 82, 83, 86, 90, 91, 95, 97]
	Confidence vaccines (in general)		[44-47, 57, 59, 63, 74, 80, 81, 83, 89, 92, 95-97]
	Health literacy (highlevel)		[68]
	Health engagement		[63, 68]
	Underlying chronic diseases	[39, 70, 87]	[41, 43, 54, 80-82, 96]
	Perceived health status (good)	[39]	[55, 61]
	Living with fragile subjects	[70, 85] (viral vector vaccines)	[48, 85] (mRNA vaccines)
	Previous reactions after vaccination	[67, 70, 93]	
	Vaccine and disease perception		
	Vaccine perception		
	Safety		[40, 47, 49, 50, 83, 85]
	Efficacy		[40, 83, 85, 90]
	Usefulness/Utility		[46, 47, 53, 85]
	Insufficient information	[39, 56, 69]	
	Desire to choose the type of vaccine	[85]	
	Disease perception		
	Risks related to COVID-19 (due to severity of illness, high exposure, susceptibility to infection)	[51]	[40, 43, 44, 46, 49, 50, 52, 53, 61, 63, 66, 69, 77, 78, 80, 81, 83, 84, 86, 89, 95-97]
	Previous infection (confirmed or presumed)	[50, 62, 69, 70, 74]	[82, 85]
	Experience of the disease and its consequences (e.g., hospitalisation, death) among relatives/friends/ acquaintances		[43, 56, 94, 96]
	Human-psychological factors		
	Negative affective state		[96]
	External health locus of control	[52, 61]	
	Conspiracy mentality	[51, 66, 74, 79, 85, 88, 96]	
	Calculation	[51]	
	Low perception of social support from family and friends	[74]	
	Desire to protect		[48, 67, 96]
	Desire to return to normality		[78]
	Economic concerns		[66, 96]
	Concern about the emergency situation		[40, 43, 78, 79]
	Attachment to the home country		[74]
	Social life (extremely active or very inactive)	[42]	
	Relatives/friends opposed to the vaccine	[67]	
Vaccine and vaccination-specific influences	**New vaccines**		
	Speed of new vaccine development	[85]	
	Role of health professionals		
	Recommendation by the doctor		[69, 71]

together with concerns about vaccine safety [100, 102-104, 106], efficacy [102-103, 106], and adverse events [100-102, 104]. Social and institution trust/mistrust was also identified as a relevant determinant [102, 103, 108, 109]. These factors were found to be significant determinants of COVID-19 vaccine acceptance or hesitancy in our review as well as in other reviews addressing the same topic at worldwide level [112-115] or in respect to other pandemics [116].

According to our review, contextual influences were the most studied factors after individual and group influences. In particular, socio-demographic factors, such as female gender, younger age, low income, and low educational level were found to be associated with COVID-19 vaccine hesitancy in Italy. These factors were found to be relevant determinants of COVID-19 vaccine hesitancy also by other reviews addressing the worldwide population [114, 115, 117, 118]. It is worthwhile to observe that influences of this kind are particularly relevant also in respect to children vaccination, according to our review as well as other ones [110]. Prevalent women's role as children's caregivers should particularly call for tailored programs addressing their concerns about vaccines to increase their compliance with vaccination for themselves and their children too.

Further studies should surely better disentangle the interrelationship between determinants of vaccine hesitancy and vaccination uptake and assess the effectiveness of context-specific interventions to counteract vaccine hesitancy. However, the available huge body of evidence on the topic suggests that interventions to counteract COVID-19 vaccine hesitancy should address information and health literacy to offer people the possibility of making evidence-based choices. Furthermore, these interventions should be primarily targeted to some population groups that are shown to be more hesitant, namely women, young people, and with low income.

As the Italian population mostly identifies the health scientific community as a reliable source of information [119], it is essential to seize the enormous opportunity offered by this position to counter vaccine hesitancy, both with structured continuous intervention programs and with targeted interventions aimed at specific population subgroups. On the other hand, especially to reach also those pockets among population that do not rely on science and on scientific community, innovative real effective communication strategies are needed to be applied; indeed, the point is not only giving more detailed information, but rather offering it in a more effective and reliable way. To reach this goal, healthcare professionals are especially called to face their main competitor as source of information, namely social media. Vaccine hesitancy seems to be strictly related to erosion of public trust on scientific and social institutions that is strongly amplified by misinformation widely spread and sustained on social media. In contrast to traditional media, social media are characterized by its potential to rapidly spread a huge amount of information in a disintermediate environment and easily produce infodemics.

The intersection between social media-supported infodemics and epidemics certainly represents one of the most critical areas for future studies and interventions. Indeed, as social media radically changed the mechanism of accessing information and forming opinions, we need to better understand how individuals do acquire or avoid information and how their decisions can affect their behaviour. Including the complexity of human behaviour in the management of an epidemic is of critical importance to address its many facets through a scientifically based approach, in order to support the design of effective communication strategies and develop tools to correctly manage both the infodemics and the epidemics. To achieve this goal and capture the overall dimensions of epidemic/infodemic management, health professionals cannot work alone relying on medical competences only, but a multidisciplinary approach is essentially needed [120]. As recognized and underlined also in the National Prevention Plan 2020-2025 [121], a such effort should not be limited to the pandemic context alone, but should be transformed into a structured and continuous program targeted to the population, and in particular to the new generations, to improve health literacy increase and provide people with the necessary tools to make conscious choices for their own health.

This review has some limitations that should be considered when interpreting results. One of the major limitations is the PubMed search approach. However, our objective was to conduct a rapid synthesis of the evidence on factors associated to COVID-19 vaccine hesitancy in Italy and PubMed is a standalone, reliable platform to effectively retrieve most relevant publications. Evidence summarized from PubMed-based articles could indeed provide an initial but yet informative guidance for informing interventions to reach out hesitant people. Another limitation is that the protocol of this systematic review was not registered and that a potential bias in the selection of studies cannot be completely ruled out, even though selection was performed independently by two researchers. Eventually, the heterogeneity of studies' methodology prevented us making a quantitative analysis and issuing more conclusive finding. In this respect, it should be said that the whole literature on vaccine hesitancy and its determinants is still undermined by the lack of standardization of definitions (i.e., confidence, acceptance and uptake are generally used interchangeably), data collection, and analysis. Nonetheless, to the best of our knowledge, this is the first systematic review giving an overview of determinants of COVID-19 vaccine hesitancy in the Italian population. Furthermore, as further strengths, most of the included studies were judged of moderate to good quality and the Vaccine Hesitancy Determinants Matrix was used to summarize the evidence.

CONCLUSION

Vaccine hesitancy represents a challenge for the successful implementation of COVID-19 vaccination in Italy. Our review demonstrated that various factors, particularly belonging to individual and group influences such as misinformation and perceived vaccine safety, efficacy, and usefulness, influence acceptance or

hesitancy towards COVID-19 vaccination. Real effective interventions to increase vaccine uptake in Italy are needed and should rely on a multidisciplinary approach to address individuals' concerns over vaccines, vaccine-related misinformation, social media-related infodemic dynamics and health literacy in order to support individuals in making conscious choices for individual and collective health.

Conflict of interest statement

There are no potential conflicts of interest or any financial or personal relationships with other people or organizations that could inappropriately bias conduct and findings of this study.

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