#### **RESEARCH ARTICLE**

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# Bivalent second booster dose of the COVID-19 vaccine: Eligible populations' reasons for receiving in Italy

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#### ABSTRACT

The Italian Ministry of Health recommended the administration of the bivalent second booster dose of the new available mRNA COVID-19 vaccine for subjects aged 60 y and over, aged 12 y and over with high frailty motivated by concomitant/preexisting conditions, and health-care workers. The purposes of this cross-sectional survey were to investigate the reasons for receiving the bivalent second booster dose of the COVID-19 vaccine and associated influencing factors among the eligible population attending two immunization centers randomly selected in the city of Naples, Italy. A total of 535 subjects participated. Only 17.5% revealed high concern about the possibility of acquiring the COVID-19 disease. Those younger, those who had at least one chronic medical condition, and those who had a higher perceived seriousness of the COVID-19 disease were more likely to be very concerned. Having a higher belief of the vaccine's safety and usefulness were significant positive predictors of the respondents' belief of the efficacy of the bivalent second booster dose. The two most common reasons reported for receiving the bivalent second booster dose included the protection for themselves and for their cohabitants. Those younger and those who had a higher perception of the vaccine's usefulness in preventing SARS-CoV-2 infection were more likely to receive the bivalent second booster dose for the protection of their cohabitants. Health-care organizations and health-care professionals can use these findings in their efforts to design educational and communication interventions to accelerate the uptake of this vaccine for reducing the frequency of this disease.

## Introduction

The COVID-19 pandemic still poses a severe threat to global health also because the SARS-CoV-2 virus evolved in different lineages. These mutations have been classified into different variants with increased transmissibility, severity or immune escape.<sup>1-3</sup> In particular, the omicron SARS-CoV-2 variants of concern (VOC) spread rapidly around the world<sup>4</sup> causing higher infection rates.<sup>5-7</sup> It is well established that several measures including social distancing, wearing of face masks, and hand hygiene are important tools to mitigate the impact of COVID-19 and the vaccines are the most effective and secure way for protecting healthy individuals against severe disease, hospitalization with pressure on healthcare infrastructure, and death also caused by variants of the SARS-CoV-2 virus.

Italy, as many other countries worldwide, has started free inoculation of the COVID-19 vaccine since December 2020. On September 23, 2022, the Ministry of Health recommended the administration of bivalent second booster dose of the new available mRNA COVID-19 vaccines, to adults aged 60 and over, individuals aged 12 and over with high frailty motivated by concomitant/preexisting conditions, health-care workers (HCWs), and pregnant women.<sup>8</sup> However, as of February 9, 2023, in Italy only 37.2% of these target populations have undergone SARS-CoV-2 vaccination with the bivalent second

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booster dose,<sup>9</sup> and in the United States, the adherence is even lower with an uptake of 15.7%,<sup>10</sup> despite several studies have confirmed its safety and effectiveness.<sup>11–14</sup> To the best of our knowledge, at the time of the study relatively very few studies have investigated specifically eligible populations' reasons for receiving the bivalent second booster dose.<sup>15,16</sup> Such knowledge is important and can provide a basis for the development of potential strategies and targeted messaging for increasing vaccine uptake. Therefore, this study aims to fill these knowledge gaps by investigating the reasons for receiving the bivalent second booster dose of the COVID-19 vaccine as well as associated influencing factors among a sample of those who were eligible to be vaccinated in Italy.

#### **Materials and methods**

#### Study setting, participants, and recruitment

This survey is a part of larger research activities that investigated perceptions and behaviors toward COVID-19 vaccination among different populations in Southern Italy.<sup>17–27</sup> The survey with a cross-sectional design was conducted between October 3 and 25, 2022, from Monday to Friday, in two immunization centers selected by simple random sampling from the list of all centers in the city of Naples, Southern

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part of Italy. To be eligible, subjects were required to be aged 60 y and over, aged 12 y and over with high frailty motivated by concomitant/preexisting conditions, and HCWs waiting to receive the bivalent second booster dose of the COVID-19 vaccine.

Sample size was calculated by assuming that 50% of respondents had received the bivalent second booster dose because they want to protect their cohabitant members from infection, a margin of error of 5%, a confidence interval of 95%, and an expected response rate of 90%. So, a minimum sample size of 427 participants was determined.

#### **Data collection**

The research team randomly approached the attenders to identify those meeting the eligibility criteria. After eligibility assessment, the team illustrated the purpose and procedures of the survey, the voluntary participation, that no subject-specific identifiers were recorded, that information was confidential, and the possibility to withdraw participation at any time without justification. Consent to participate in the survey was assumed by the fact that participants accepted to answer the questionnaire. Participants completed the questionnaire in about 10 min after the vaccine uptake and return it to the research team. Those who had writing or reading difficulties had the opportunity to be interviewed face-to-face by the research team. No compensation or incentive was given to those completing the questionnaire.

The study protocol has been reviewed and approved by the Institutional Ethical Committee of the Teaching Hospital of the University of Campania "Luigi Vanvitelli".

#### Questionnaire

The self-reported questionnaire was developed based on those used by the research team in similar previous research carried out among different populations.<sup>17–27</sup> A pilot study has been conducted among 20 non-selected individuals prior the administration of the questionnaire to evaluate and improve the questions and ensure clarity, wording, and comprehension. The results were not included in the final sample.

The questionnaire collects information in three sections. The first section contains socio-demographic and anamnesis characteristics (i.e., gender, age, relationship status, employment status, presence of chronic medical condition, having been infected by SARS-CoV-2, family member/friend having been infected by SARS-CoV-2). The second section investigated the attitudes toward the COVID-19 infection (concern of being infected by SARS-CoV-2, concern about the severity of COVID-19) and the bivalent second booster dose (perceived efficacy, safety, usefulness). Responses were graded on a tenpoint Likert type scale, with responses ranging from 1 representing not at all to 10 representing very much. Participants were also asked in a multiple-choice question to indicate the reason(s) that were most influential in their decision to take the bivalent second booster dose, with 12 options of response and all could be selected. The third section was about their sources of information on the bivalent second booster dose

with the possibility of multiple-choice answer and whether they need further information on this topic.

#### Statistical analysis

Data entry and statistical analysis were performed using the Stata software program, version 15. Descriptive analysis was performed by using relative frequencies, mean, and standard deviation. Student's *t*-test,  $\chi^2$  test, and ANOVA test were conducted to determine the associations between the outcomes of interest and the different explanatory variables. Independent variables with a *p*-value equal to or less than 0.25 in the univariate analysis, were included in multivariate linear and logistic regression analysis performed to identify the associated factors with the following outcomes of interest: concern about the possibility of acquiring the COVID-19 disease (continuous) (Model 1); belief of the efficacy of the bivalent second booster dose of the COVID-19 vaccine (continuous) (Model 2); and having received the bivalent second booster dose of the COVID-19 vaccine to protect their cohabitants (no = 0; yes = 1) (Model 3). For Models 1 and 2, the outcome variables, measured on a ten-point Likert type scale, were treated as continuous. The following independent variables have been included in all models: gender (male = 0; female = 1), age (continuous), partnership status (unmarried = 0; married/cohabited with a partner = 1), being HCWs (no = 0; yes = 1), having at least one chronic medical condition (no = 0; yes = 1), having been infected by SARS-CoV-2 (no = 0; yes = 1), perceived seriousness of the COVID-19 disease (continuous), belief that the bivalent second booster dose of the COVID-19 vaccine is safe (continuous), belief that the bivalent second booster dose of the COVID-19 vaccine is useful (continuous), belief that the COVID-19 vaccination should be mandatory (continuous), having received information on the bivalent second booster dose of the COVID-19 vaccine from physicians (no = 0; yes = 1), and need of additional information on the bivalent second booster dose of the COVID-19 vaccine (no = 0; yes = 1). The variables regarding the perception of efficacy of the bivalent second booster dose of the COVID-19 vaccine (continuous) and the concern about the possibility of acquiring the COVID-19 disease (continuous) were included in Model 3. Odds ratios (OR) with 95% confidence interval (CI) and standardized regression coefficients (ß) for potential determinants associated with the study outcomes were respectively estimated in the multivariate logistic and linear regression models. The tests for significance were two-sided and p-values equal to or less than 0.05 were considered statistically significant.

#### Results

Of the 569 subjects approached, 535 agreed to participate for an overall response rate of 94.1%. Table 1 shows the principal characteristics of the sample. More than half were male (53.9%), the average age was 63.6 y, 16.6% were HCWs, more than half had at least one chronic medical condition, 65.7% reported to have never been infected by SARS-CoV-2, and 92.6% had at least one family member/colleague/friend who have been infected by SARS-CoV-2. Table 1. Main socio-demographic and general characteristics of the sample.

Characteristics	N	%
Age, y	$63.6 \pm 13.5 \ (19-94)^{a}$	
Gender		
Male	283	53.9
Female	242	46.1
Partnership status		
Married/cohabited with a partner	373	72.1
Unmarried/separated/divorced/widowed	144	27.9
Employment status		
HCWs	81	16.6
Other	407	83.4
Having at least one chronic medical condition		
No	250	47.1
Yes	281	51.9
Having been infected by SARS-CoV-2		
No	351	65.7
Yes	183	34.3
At least one relative/colleague/friend who have been infected by SARS-CoV-2		
No	36	7.4
Yes	449	92.6

<sup>a</sup>Mean ± Standard deviation (range).

Number for each item may not add up to total number of study population due to missing value.

The participants' beliefs and attitudes toward COVID-19 and its vaccination, measured on a 10-point Likert-type scale, indicated that 33.8% had a higher perceived seriousness of the COVID-19 disease, with an overall average value of 8.2. The concern about the possibility of acquiring the COVID-19 disease resulted with mean value of 6.9 and 17.5% revealed high concern. The results of the multivariate linear and logistic regression models predicting the different outcomes of interest are summarized in Table 2. The multivariate linear regression analysis showed that those younger, those who had at least one chronic medical condition, and those who had a higher perceived seriousness of the COVID-19 disease were more likely to be very concerned about the possibility of acquiring the COVID-19 disease (Model 1). Regarding the statements of the beliefs of the bivalent second booster dose of the COVID-19 vaccine, the mean total values about its efficacy, safety, and usefulness were respectively 8.5, 8.4, and 9.1 which indicate a high perceived level of the vaccine's characteristics. Only 8.5% of the sample displayed a high trust in the information received on the bivalent second booster dose of the COVID-19 vaccine and only 1% did not trust it at all, with an overall mean value of 7. The multivariate linear regression analysis revealed that having a higher belief of the vaccine's safety and usefulness were significant positive predictors of the respondents' belief of the efficacy of the bivalent second booster dose of the COVID-19 vaccine (Model 2 in Table 2).

The two most common reasons that the respondents had reported for receiving the bivalent second booster dose of the COVID-19 vaccine included the protection for themselves (78.4%) and for their cohabitants (34.5%). The multivariate logistic regression analysis revealed that those who were more likely to receive the bivalent second booster dose of the

Table 2. Results of the multivariate linear and logistic regression analysis showing determinants of the different outcomes of interest.

	ß Coeff.	SE	t	р
Model 1. Perceived concern about the possibility of acquiring the COVID-19 disease				
$F(5, 440) = 13.69, p < .0001, R^2 = 13.4\%$ , adjusted $R^2 = 12.4\%$				
Younger	-0.05	0.01	-5.86	<.001
Having at least one chronic medical condition	0.89	0.24	3.75	<.001
Concern about the severity of COVID-19	0.24	0.06	3.97	<.001
HCWs	0.41	0.32	1.27	.205
Having received information on the bivalent second booster dose from physicians	0.2	0.22	0.9	.37
<b>Model 2.</b> Having a higher belief of the efficacy of the bivalent second booster dose of $F$ (5, 454) = 29.78, $p < .0001$ , $R^2 = 35.9\%$ , adjusted $R^2 = 35.2\%$	the COVID-19 vaccir	ne		
Having a higher perception of the vaccine's safety	0.31	0.04	7.66	<.001
Having a higher perception of the vaccine's usefulness	0.32	0.05	6.18	<.001
Concern about the severity of COVID-19	0.06	0.03	1.92	.055
Belief that the COVID-19 vaccination should be mandatory	0.04	0.02	1.87	.061
Not concern of being infected by SARS-CoV-2	-0.04	0.02	-1.77	.77
	OR	SE	95% CI	р
<b>Model 3</b> . Having received the bivalent second booster dose of the COVID-19 vaccine to Log likelihood = $-259.07$ , $\chi^2 = 37.51$ (5 df), $p < .0001$	protect their cohal	bitants		
Younger	0.97	0.01	0.95-0.98	<.001
Having a higher perception of the vaccine's usefulness	1.24	0.11	1.04-1.49	.019
Having been infected by SARS-CoV-2	1.41	0.31	0.91-2.17	.126
Female	1.37	0.29	0.91-2.01	.133
HCWs	1.51	0.43	0.86-2.66	.153

COVID-19 vaccine for the protection of their cohabitants were those younger (OR = 0.97; 95% CI = 0.95-0.98) and those who believed that the vaccine was useful in preventing the SARS-CoV-2 infection (OR = 1.24; 95% CI = 1.04-1.49) (Model 3 in Table 2).

Almost all participants (98.3%) had received information about the bivalent second booster dose of the COVID-19 vaccine and half of them indicated physicians (51.3%) followed by mass media (47.2%) and institutional sources (28.8%). Moreover, less than one-third (29.6%) were interested in acquiring more information.

### Discussion

This cross-sectional survey aimed to provide new insights into the motivations to receive the bivalent second booster dose of the COVID-19 vaccine among eligible category at risk of people with chronic medical conditions and elderly in Italy and to understand the factors that influenced subjects' attitudes and decision to receive this dose.

In the present survey, diverse attitudes and beliefs to the disease and to the bivalent second booster dose of the COVID-19 vaccine have been investigated. The respondents' concern about the possibility of acquiring the COVID-19 disease, measured on a ten-point Likert type scale, resulted with a mean value of 6.9 and roughly two in ten individuals revealed a high concern. The results of the multivariate results of the linear regression analysis suggest that several characteristics were important determinants of the respondent's concern about the possibility of acquiring the COVID-19 disease. These include respondents' age, health status, and perception of the seriousness of the COVID-19 disease. Indeed, those of younger age, those with at least one chronic medical condition, and those with a higher level of perceived seriousness of the COVID-19 disease were more likely to be very concerned. Regarding age, one potential explanation has to do with the widespread impression that those younger are more likely to be engaged in social activities and, therefore, they feel to be at higher risk of being infected by SARS-CoV-2. Moreover, the finding that those with preexisting health conditions were more likely to be concerned about the possibility of acquiring this disease may be explained by the fact that it has been recognized that there are many non-communicable conditions that increase the risk of acquiring the COVID-19 and of developing adverse outcomes related to the disease, such as, for example, longer duration of hospitalization and higher mortality.<sup>28-31</sup> This suggests that for frail individuals the booster vaccine is held as more important than in healthy individuals. This finding is consistent with several previous studies detecting that these groups have experienced a higher willingness and uptake of COVID-19 vaccine.<sup>19,32</sup> The result that having a higher level of perceived seriousness of the COVID-19 disease and, as already indicated, that having at least one chronic medical condition were significant predictors of the respondent's higher concern about the possibility of acquiring the disease may determine an active desire to vaccinate and, therefore, also support the notion that this perception is likely to increase vaccine receipt.<sup>33–37</sup> Another important point to note in the present survey is that the multivariate logistic

regression analysis, which also examined the impact of different variables on the belief of the effectiveness of the bivalent second booster dose of the COVID-19 vaccine in preventing SARS-CoV-2 infection, showed that, as hypothesized, having a higher belief that the vaccine is safety and usefulness were associated with a significantly higher likelihood of having a higher belief. This is accordance with several previous studies showing that the perception of vaccine's safety has been observed to have a significant positive influence regarding willingness and uptake of COVID-19 vaccine.<sup>17,38,39</sup>

Intention to protect themselves and their cohabitants were two of the top reasons that affected the respondents for having received the bivalent second booster dose of the COVID-19 vaccine. These main reasons for COVID-19 vaccination were consistent with previous studies that surveyed the willingness or uptake among diverse groups of individuals.<sup>22-26,40-44</sup> Younger interviewees were more likely to receive the dose for the protection of cohabitants than those with older age, which is largely congruent with the existing literature conducted to date examining the reasons about COVID-19 vaccination among other populations.<sup>38,45,46</sup> One potential explanation has to do with the widespread impression that those of younger age may be at higher risk of acquiring COVID-19 because they may have more opportunities of being exposed to several behavioral and lifestyle habits with social contacts and, therefore, they are also most likely to be a potential source of disease transmission. Furthermore, belief significantly impacted cohabitants protection, since this reason was also more likely to be observed among the respondents with a higher level of perceived second booster dose of the COVID-19 vaccine effectiveness in preventing SARS-CoV-2 infection. This association makes sense because having positive attitude toward the dose of the vaccine increases the objective likelihood of getting the vaccine and, for this reason, to protect the cohabitants.

The most commonly used source of information for the respondents about the bivalent second booster dose of the COVID-19 vaccine were physicians although the proportion of those who reported to have received information from this source was low since it has been indicated only about half of the sample. This is of concern, although using this source was not associated with the outcomes of interest, since receiving information from a trusted source is of central importance to achieve the full benefit of the immunization efforts. Therefore, more HCWs, mainly physicians, must adopt appropriate strategies that target and reach high-risk persons, particularly those with chronic medical conditions and elderly, for information and communication campaigns to improve people awareness and knowledge of vaccination and to help them to get conscious decision regarding this vaccination. Physicians are the best way to disseminate accurate and reliable vaccine information, and this is also supported by solid data in the literature that they represent the most affordable source of information on vaccinations and having a recommendation from a health-care provider is one of the most significant determinants of vaccine acceptance and uptake.<sup>20,23,25,47-50</sup> However, it is interesting to observe that almost half of respondents reported they sourced information on COVID-19 from mass-media, and this is of concern due to the widespread misinformation, especially on social media platforms, and

anti-vaccine campaigns.<sup>51–54</sup> Furthermore, it is notable that less than one-third were interested in acquiring more information and this reinforces the notion that health promotion communication strategies should be promoted.

As with all similar research, a few methodological limitations of this survey should be taken into account when synthesizing and interpreting the findings. First, the crosssectional study design has its own limitations and, consequently, it might be difficult to draw definitive causative links between the independent variables and the outcomes of interest. Second, the sample was limited to one geographic area and, therefore, the results may not be generalizable to the whole country. Third, the survey is vulnerable to social desirability bias, thus it is possible that respondents may not report truthfully, and they tend to answer questions in a manner that will be favorably viewed by others. However, potential bias may have been partially minimized because all participants were assured that their answers were anonymous and confidential. Despite these limitations, the current findings provide valuable insights for public health messaging.

In summary, this survey highlights some important aspects and contributes to elucidate the motivations to receive the bivalent second booster dose of the COVID-19 vaccine in people at risk and to assess the relationships with several characteristics. One of the main decision to vaccinate was the protection for themselves and it was influenced by vaccine effectiveness perception. Healthcare organizations and health-care professionals can use these findings in their future efforts to design educational and communication interventions to accelerate the uptake of this vaccine for reducing the frequency of this disease.

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### Author contributions

G.D.P. and G.M.d.G participated in the design of the study. G.D.P., G.M.d. G., and C.P.P. contributed to the data collection, data analysis, and interpretation; I.F.A., the principal investigator, designed the study, was responsible for the statistical analysis and interpretation, and wrote the article. All authors have read and agreed to the published version of the manuscript.

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