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Intention to participate in a COVID-19 vaccine clinical trial and to get vaccinated against COVID-19 in France during the pandemic

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2 **Highlights:**

- 3       • Nearly 75 % of the survey respondents indicated that they were likely to accept  
4       COVID-19 vaccine.
- 5       • 48 % of the survey respondents were likely to accept to participate in a vaccine  
6       clinical trial if asked against SARS-CoV-2 infections.
- 7       • Healthcare workers were more prone to get vaccinated against COVID-19 than non  
8       HCWs.

9   In December 2019, China reported the first cases of Coronavirus Disease (COVID-19) due to a new  
10   Coronavirus: the Severe Acute Respiratory Syndrome-Coronavirus 2 (SARS-CoV 2). The world is  
11   now facing a pandemic, more than 27 millions of people have become infected worldwide, cases are  
12   described in more than 200 hundred countries, and more than 800,000 people died [1].

13   In 2019, the World Health Organization identified ten threats to global health [2]. Among these threats,  
14   vaccine hesitancy, the risk of a global influenza pandemic, and the risk of emergence of high-threat  
15   pathogens such as Middle-East Respiratory Syndrome and/or Severe Acute Respiratory Syndrome  
16   were identified. Since this statement, COVID-19 had emerged. Developing COVID-19 vaccines is a  
17   crucial challenge, and several candidates are currently under basic development [3]. Some of them will  
18   be tested in Phase I trials in the weeks to come [4]. The time it takes to develop a vaccine is estimated  
19   to be 1 or 1.5 years as different steps are necessary during the clinical development of a vaccine [5].  
20   Recruitment of volunteers in a vaccine clinical trial is a real challenge [6], and some trials are stopped  
21   due to difficulties in recruitment. Vaccine hesitancy may also have an impact on recruitment in  
22   COVID-19 vaccine clinical trial [7]. After its clinical development, a COVID-19 vaccine will also face  
23   the challenge of acceptance by the general population in a post-crisis context. .

The impact of the current pandemic on the intention to participate in a COVID-19 vaccine clinical trial and on the intention to get vaccinated against COVID-19 vaccine is not obvious. This is a particular concern in France, which has been shown to be the leader-country of vaccine hesitancy [8]. The aim of this study was to evaluate the intention to get vaccinated against COVID-19 among the general population and healthcare personnel, in the context of the current pandemic.

## **Methods**

We conducted an anonymous online survey (Lime Survey®) from the 26<sup>th</sup> of March to the 20<sup>th</sup> of April 2020 among adult general population and adult patients. The survey was proposed to individuals via social networks (Facebook, Twitter), shared by e-mail, on the website of the University Hospital of Saint-Etienne (France), and in centers for COVID-19 diagnosis and in medical centers. We developed a standardized questionnaire based on a literature review.

The questionnaire addressed: (1) demographical characteristics (age, chronic medical conditions), (2) fears about COVID-19, (3) history of vaccination against pandemic H1N1 influenza and seasonal influenza, (4) intention to get vaccinated if a COVID-19 vaccine was available, (5) vaccine hesitancy. According to the WHO Strategic Advisory Group of Experts on Immunization, vaccine hesitancy refers to delay in acceptance or refusal of vaccines despite availability of vaccination services. Vaccine hesitancy is complex and context specific, varying across time, place and vaccines. It is influenced by factors such as complacency, convenience and confidence [9]. We evaluated participants' self-reported vaccine hesitancy according to the WHO definition using three previously adapted questions: "Have you ever refused a vaccine for yourself or a child because you considered it as useless or dangerous?" "Have you ever postponed a vaccine recommended by a physician because of doubts about it?" "Have you ever had a vaccine for a child or yourself despite doubts about its efficacy"[10]. If a participant answered yes to one of these proposals, he or she was considered to be "vaccine hesitant".

The questionnaire included items to be answered on a 5-level Likert scale including a “don’t know” option to evaluate intention to participate in a clinical trial and to get vaccinated if a vaccine was available. We combined survey responses into two categories (strongly agree/agree, don’t know/disagree/strongly disagree) and ran ordinal regression models to examine demographic and attitudinal factors predictive of respondents' willingness to get vaccinated against COVID-19. To identify suitable candidate variables for regression models, we first conducted univariate analysis using a chi-squared test. Candidates that were significant at  $p < 0.1$  in univariate analyses were then included in a multivariable regression model. Data were analyzed using SPSS version 24.0.

The protocol complied with the data privacy laws of the National Commission for Informatics and Civil Liberties and was approved by the institutional review board with the number IRBN422020/CHUSTE. Full dataset (complete answers to the survey) and codebook are available on: [https://osf.io/jp6cx/?view\\_only=41a48461846448c4843d08567d881a2e](https://osf.io/jp6cx/?view_only=41a48461846448c4843d08567d881a2e).

## **Results**

During the study period, 3,656 people opened the web links for the online survey, 3,259 (89.1 %) people answered the online questionnaire. Demographic characteristics are displayed in table 1. Women accounted for 67.4 % of the respondents. Seven hundred and eighty-seven (24.1%) respondents reported a chronic medical condition. Vaccine hesitancy was observed in 1,150 respondents (35.3% 95% CI 33.6-36.9%). Two thousand four hundred-thirty four (74.7% 95 % CI 73.2-76.2%) respondents had fears about COVID-19; 2,124 (65.2% 95% CI 63.6-66.8%) respondents considered themselves at risk for COVID-19.

### *Willingness to get vaccinated against COVID-19*

According to their statements, 2,512 participants (77.6%, 95 % CI 76.2-79.0 %) will certainly or probably be willing to get vaccinated against COVID-19. Among the 1,063 men, 883 (83.1% 95% CI 80.8-85.3%) are COVID-19 vaccine acceptors, 1,629 women among the 2,196 respondents (74.2 % 95 % CI 72.3-76.0%) are COVID-19 vaccine acceptors ( $p < 0.005$ ). The proportion of vaccine hesitant respondents who would probably be willing to get vaccinated against COVID-19 vaccine was 61.9 %

(95 % CI 59.1-64.7 %) during the current pandemics. The proportion of healthcare workers willing to get vaccinated was 81.5 %, and this proportion was 73.7 % in non-healthcare workers ( $p<0.005$ ). Factors associated with COVID-19 vaccine acceptance are displayed in Table 2. In multivariable analysis, older age, male gender, fear about COVID-19, be healthcare workers and individual perceived risk remained associated with COVID-19 vaccine acceptance. Vaccine hesitancy was associated with lower acceptance of a COVID-19 vaccine.

#### *Willingness to participate in a COVID-19 vaccine clinical trial*

One thousand and five hundred and fifty two respondents (47.6 % 95 % CI 45.9-49.3 %) will certainly or probably be willing to participate in a COVID-19 vaccine clinical trial. Among the 1,063 men, 634 (59.6 % 95 % CI 56.7-62.5 %) will probably accept to participate in a COVID-19 vaccine clinical trial, this proportion is significantly greater than women (41.8 % 95 % CI 39.7-43.9 %,  $p<0.005$ ). The percentage of potential participants in a COVID-19 vaccine clinical trial was 56.8 % (53.4-60.2 %) in the 50-64 years age group, and 58.7 % ( 95 % CI 52.8-64.6 %) in the 65-80 years age group. Healthcare workers are more prone to participate in a vaccine clinical trial than non-healthcare workers (50.5 % vs 45.4 %,  $p<0.005$ ). Factors associated with COVID-19 vaccine clinical trial acceptance are displayed in Table 3.

## **Discussion**

In this online survey, we observed that nearly three quarters of the respondents would accept a vaccine against COVID-19 although 35 % of the respondents were qualified as “vaccine hesitant”. Moreover, around a half of the respondents would accept to participate in a clinical trial for a COVID-19 vaccine. Concerning the intention to get vaccinated, our results are similar to the results of the longitudinal Coconel study conducted by the Observatoire Régional de Santé Provence Alpes Côte d’Azur [11] and to results of investigations conducted in the USA [12,13]. Similar to coconel, we observed that men were more prone to get vaccinated than women. Women accounted for the vast majority of our study respondents, suggesting that in real-life settings, COVID-19 vaccine acceptance could be greater. In addition, older individuals are more prone to get vaccinated in both studies, this is probably due to a

greater perceived risk of getting infected and developing a severe disease in older people. We analyzed factors associated with perceived risk of SARS-CoV-2 infections, and with fear about COVID-19. Male gender and older age were not associated with perceived individual risk but were associated with fear about COVID-19 (data not shown). In the same vein, healthcare workers were more prone to get vaccinated or to participate in a vaccine clinical trial than the others. We hypothesized that healthcare workers perceived a greater risk to get infected. Healthcare workers are particularly vulnerable and accounted for 10 % of the infected people in Italy, and in Greece [14,15]. On the contrary, expecting a low infection risk is associated with a lower willingness to get vaccinated [16]. Seventy-eight percent of healthcare workers considered themselves at-risk to get infected, however after adjustment on age, gender, and comorbidities, being a healthcare worker was not associated with perceived risk to get infected, but with fear about COVID-19 (data not shown).

Around the half of the respondents will accept to participate in a COVID-19 vaccine clinical trial. In the context of a clinical trial, men were also more prone to participate. Fears about COVID-19 were not associated with willingness to participate in a clinical trial. However, individuals who considered themselves at-risk for COVID-19 infection were more prone to accept to participate in a clinical trial for a vaccine. Outside the pandemic context, self-perceived risk for a disease was not the main motivation to participate in a vaccine clinical trial [7]. Moreover, older age was associated (except in the group over 80 years) with willingness to participate in a COVID-19 vaccine clinical trial, this observation contrasts with a previous study about willingness to participate in a vaccine clinical trial [7]. This observation suggests that in the pandemics context, individuals are more prone to participate in a clinical trial for a vaccine.

We also observed that a part of respondents who will certainly accept to participate in a vaccine clinical trial will not certainly get the vaccine if available. Further studies are needed to explore in-depth the differences in barriers and motivations to participation in a vaccine clinical trial, and to the acceptance of the vaccine. Next steps will be the construction of multi-component interventions to facilitate recruitment of volunteers in clinical trials, and to increase COVID-19 vaccine acceptance.

Communities should be involved in the development of these interventions. The rush to develop a COVID-19 vaccine may jeopardize public confidence in scientists [17].

The proportion of French People favorable to a COVID-19 vaccine can appear low, but we have to put this in perspective with the fact that the vaccine would be a new vaccine, and that vaccine coverage against 2009 H1N1 pandemic influenza was only 11.1 % in France [18]. However, a greater proportion of respondents to our survey declared they had been vaccinated against 2009 H1N1 pandemic influenza, so this observation may suggest that the respondents are more pro-vaccine than the general population in France, and more often healthcare workers. We observed a similar prevalence of vaccine hesitancy than in a recent study in France, which identified a prevalence of 40 % [10]. One limitation of our work may be the use of social media to recruit study participants. Social media users who use platforms, such as Facebook and Twitter, as health information sources are more prone to get vaccinated against seasonal influenza in the United States of America [19]. Furthermore, a great number of healthcare workers answered the survey and we observed that healthcare workers were more prone to get vaccinated or to participate in a vaccine clinical trial independently of the perceived risk to get contaminated. However, vaccine hesitancy also affects healthcare workers [20–22]. In our study sample, vaccine hesitancy affects around 30 % of the healthcare workers and 40 % of the non-healthcare workers.

Our work suffers from limitations. First, our sample is not completely representative of the French general population, and the great amount of HCWs may overestimate the proportion of individuals with intentions to get vaccinated. In a recent report, in 7 European countries, the proportion of individuals with intention to get vaccinated against COVID-19 was 73.9 %, but in France, it was only 62 % [23]. This survey was also conducted on line but *a priori* in a representative panel of 1.000 individuals per country. Secondly, we did not precise in our survey, the type of clinical trials, and intention to participate may change between early and later phases clinical trials [7].



152 In conclusion, during the pandemics, around 75 % of the French people would agree to get vaccinated.  
153 Due to the burden of the disease, and the potential natural immunity, it may well be possible that this  
154 proportion would be enough to obtain a herd effect [24]. Antecedents of vaccine hesitancy may affect  
155 vaccine acceptance even in a context of a pandemic due to an emerging pathogens. Around fifty  
156 percent will agree to participate in a COVID-19 vaccine clinical trial; we can hope that vaccine trials  
157 would not be stopped because of recruitment difficulties.

158 Co-authors have no conflict of interest to declare for this work.

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	N=3,259 (%)
Gender	
Male	1,063 (32.6)
Female	2,196 (67.4)
Age	
Under 30 years old	670 (20.6)
30-49 years old	1,502 (46.1)
50-64 years old	803 (24.6)
65-80 years old	271 (8.3)
Over 80 years old	13 (0.4)
Health care workers	
Yes	1,421 (43.6)
No	1,838 (56.4)
Chronic medical conditions	627 (19.2)
Hypertension	260 (8.0)
Diabetes	68 (2.1)
Chronic lung disease	139 (4.3)
Chronic cardiac failure	92 (2.8)
Chronic renal insufficiency	2 (0.1)
Immunosuppressive medication	63 (1.9)
Are you afraid of the new coronavirus?	
Yes, a lot	766 (23.5)
Yes, a little	1,668 (51.2)
I don't know	176 (5.4)
Not really	549 (16.8)
No	100 (3.1)

Do you feel at risk of getting infected by the new coronavirus	
Yes, a lot	644 (19.8)
Yes, a little	1,480 (45.4)
I don't know	426 (13.1)
Not really	615 (18.9)
No	94 (2.9)
Vaccine hesitancy	
Have you ever refused a vaccine for yourself or a child because you considered it as useless or dangerous?	395 (12.1)
Have you ever postponed a vaccine recommended by a physician?	341 (10.5)
Have you ever had a vaccine for a child or yourself despite doubts about its efficacy?	570 (17.5)
Global vaccine hesitancy	1,150 (35.3)
If a preventive vaccine clinical trial against the new coronavirus existed, would you agree to participate?	
Yes certainly	923 (28.3)
Yes possibly	629 (19.3)
I don't know	767 (23.5)
No, possibly	604 (18.5)
Definitely no	336 (10.3)
If a vaccine against the new coronavirus was available for next season, would you get vaccinated?	
Yes certainly	776 (23.8)
Yes possibly	1,754 (53.8)
I don't know	394 (12.1)
No, possibly	207 (6.4)

Definitely no	128 (3.9)
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**Table 1: Demographic characteristics of the responders to the on-line survey, data are expressed by n and (%)**

	Univariate analysis	p	Mutivariable analysis	p
Gender				
Female	Ref	<0.001	Ref	<0.001
Male	1.707 (1.417-2.058)		1.878 (1.529-2.306)	
Age				
Under 30 years old	Ref	<0.001	Ref	<0.001
30-49 years old	1.506 (1.231-1.842)		1.532 (1.230-1.909)	
50-64 years old	2.246 (1.758-2.870)		1.445 (1.259-1.658)	
65-80 years old	2.692 (1.854-3.908)		1.395 (1.198-1.624)	
Over 80 years old	5.593 (0.723-43.293)		1.412 (0.827-2.412)	
Healthcare workers				
No	Ref	<0.001	Ref	<0.001
Yes	1.574 (1.329-1.864)		1.533 (1.269-1.851)	
Chronic medical conditions				
No	Ref	0.1		0.22
Yes	1.196 (0.983-1.455)		0.891 (0.713-1.113)	
Fear about COVID-19				
No	Ref	<0.001	Ref	<0.001
Yes	2.095 (1.757-2.499)		2.445 (1.998-2.991)	
Perceived individual risk				
No	Ref	<0.001	Ref	<0.001
Yes	1.831 (1.549-2.163)		1.510 (1.269-1.851)	
Vaccine hesitancy				
No	Ref	<0.001	Ref	<0.001
Yes	0.279 (0.236-0.331)		0.275 (0.230-0.329)	

**Table 2 Factors associated with COVID-19 vaccine acceptance expressed with odds ratio (ref: reference), in multivariable analysis, only variables with a p-value<0.1 in univariate analysis were integrated in the model.**



	Univariate analysis	p	Mutivariable analysis	p
Gender				
Male	2.057 (1.773-2.388)	<0.001	1.881 (1.532-2.309)	<0.001
Female	Ref		Ref	
Age				
Under 30 years old	Ref	<0.001	Ref	<0.001
30-49 years old	1.043 (0.868-1.254)		1.518 (1.220-1.888)	
50-64 years old	1.797 (1.461-2.211)		1.481 ( 1.297-1.690)	
65-80 years old	1.941 (1.458-2.585)		1.408 (1.229-1.612)	
Over 80 years old	0.608 (0.185-1.993)		1.494 (0.881-2.531)	
Healthcare workers				
No	Ref	0.004	Ref	0.007
Yes	1.223 (1.065-1.405)		1.540 (1.275-1.860)**	
Chronic medical conditions				
No	Ref	0.32		
Yes	1.085 (0.924-1.274)			
Fear about COVID-19				
No	Ref	0.17	Ref	0.53
Yes	0.895 (0.764-1.048)		0.928 (0.784-1.099)	
Perceived individual risk				
No	Ref	0.006	Ref	0.03
Yes	1.226 (1.061-1.417)		1.235 (1.061-1.439)	
Vaccine hesitancy				
No	Ref	<0.001	Ref	<0.001
Yes	0.502 (0.433-0.582)		0.512 (0.4411-0.595)	

**Table 3 Factors associated with potential participation in a COVID-19 vaccine trial expressed with odds ratio, in multivariable analysis, only variables with a p-value<0.1 in univariate analysis were integrated in the model. (Ref: reference)**