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Side-effect expectations from COVID-19 vaccination: Findings from a nationally representative cross-sectional survey (CoVAccS – wave 2)

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ABSTRACT

Objectives: Concern about side effects is one of the most common reasons for refusing vaccination. Side-effect expectations are known to predict perception of side effects. We aimed to investigate the percentage of people who thought side effects from COVID-19 vaccination were likely and investigate factors associated with side-effect expectation.

Methods: Online cross-sectional survey of 1470 UK adults who had not been vaccinated for COVID-19 (conducted 13 to 15 January 2021). We asked participants how likely they thought side effects from COVID-19 vaccination were. Linear regression analyses were used to investigate associations with side-effect expectations.

Results: Most participants were uncertain whether they would experience side effects from a COVID-19 vaccine; only a minority reported that side effects were very likely (9.4%, 95% CI 7.9% to 10.9%, $n = 138/1470$). Personal and clinical characteristics, general, and COVID-19 vaccination beliefs and attitudes explained 29.7% of the variance in side-effect expectation, with COVID-19 vaccination beliefs alone accounting for 17.2%. Side-effect expectations were associated with: older age, being clinically extremely vulnerable to COVID-19, being afraid of needles, lower perceived social norms for COVID-19 vaccination, lower perceived necessity and safety of COVID-19 vaccination, and perceived lack of information about COVID-19 and vaccination.

Conclusions: Side-effect expectation was associated with believing that COVID-19 vaccination was unsafe, ineffective and that others would be less likely to approve of you having a COVID-19 vaccination. Communications should emphasise the safety, effectiveness, and widespread uptake of vaccination, while promoting accurate perceptions of the incidence of vaccination side effects.

1. Introduction

Fears about vaccine side effects are among the most common reasons for refusal of vaccinations, including during the H1N1 influenza pandemic. [1–3] At the time of writing, three COVID-19 vaccines had been approved for use in the UK: the Pfizer/BioNTech (approved 2 December 2020), AstraZeneca (30 December 2020), and Moderna (8 January 2021) vaccines. [4–6] Clinical trial data indicate that injection site adverse events are very common (up to 83% Pfizer/BioNTech, 67% AstraZeneca, 89% Moderna). [7–9] Common systemic adverse effects include fatigue (Pfizer/BioNTech up to 59%, AstraZeneca 70%), headache (Pfizer/BioNTech up to 52%, AstraZeneca 68%), and fever (Pfizer/BioNTech up to 16%, AstraZeneca 18%). [7,8,10] Older people experience fewer adverse effects. [8,9] There is some evidence that side effects may be more common (Pfizer/BioNTech) and severe (Moderna) following the second dose of the vaccine. [8–10]

The cause of adverse effects from vaccination is not always clear. While some may be caused by biological mechanisms of the vaccine, psychological factors also play a part. Side-effect expectations are important, fuelling the 'nocebo effect', a phenomenon whereby the expectation of symptoms is self-fulfilling. The association between side-effect expectations and subsequent reporting of side effects has been

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found for a range of medications, including cancer treatments, rheumatoid arthritis medication, and child vaccination. [11–13] A systematic review of factors associated with expectations of side effects from medical interventions found some evidence that negative beliefs about medications was associated with greater side-effect expectations. [14]

The aim of this study was to estimate the percentage of the UK population who expected side effects from the COVID-19 vaccine, and to investigate associations between side-effect expectations and personal and clinical characteristics, general vaccine beliefs and attitudes, and COVID-19 vaccination beliefs and attitudes.

2. Methods

This study reports data from the second wave of the COVID-19 vaccination acceptability study (CoVAccS). Full methods of the study have been reported elsewhere. [15]

2.1. Design

Cross-sectional online survey hosted on Qualtrics. Data were collected from 13 to 15 January 2021.

2.2. Participants

1500 participants were recruited through Prolific's UK online research panel. Participants were eligible for the study if they were aged eighteen years or over, lived in the UK, and had not completed our previous survey ($n > 31{,}000$ eligible participants). [16] We used quota sampling based on age, sex, and ethnicity so that participant characteristics were broadly reflective of those in the UK population. Participants provided informed consent to take part in the study before being able to commence the survey. Upon completion of the survey, participants were paid £2.

For this study, we included participants if they indicated that they had not yet received a COVID-19 vaccine ($n = 1470$).

2.2.1. Measures

Full survey materials are available online. [17]

Side-effect expectation was measured by a single item asking participants how likely they thought it was that they "would get side effects from a coronavirus vaccine" on an 11-point scale, from "extremely unlikely" (0) to "extremely likely" (10).

To measure general vaccination beliefs and attitudes, we asked participants to what extent they agreed that vaccination is a good thing in general and that they were afraid of needles, on an 11-point scale from "strongly disagree" (0) to "strongly agree" (10).

We measured COVID-19 vaccination beliefs and attitudes using 21 statements investigating: perceived effectiveness and safety of COVID-19 vaccination; barriers and facilitators to vaccination; perceived information sufficiency about COVID-19 and the vaccine; social norms about vaccination; beliefs about profiteering; and beliefs concerning the impact of vaccination on restrictions. Participants were asked to what extent they agreed with the statements from "strongly disagree" (0) to "strongly agree" (10). Sixteen of these items were included in a principal components analysis, which identified five components accounting for 68% of the variance in the original items: social norms regarding vaccination, necessity of vaccination, safety of the vaccine, adequacy of information about the vaccine, and freedom from restrictions through the vaccine. [15]

We asked participants for their age, sex, ethnicity, religion, highest level of qualification, and employment status. Participants were asked whether they, or someone they lived with, had a medical condition that made them extremely clinically vulnerable to COVID-19. [18] We also asked participants if they worked or volunteered in roles critical to COVID-19 ("key worker"). [19]

2.2.2. Ethics

We obtained ethical approval for this study from Keele University's Research Ethics Committee (reference: PS-200129).

2.2.3. Power

A sample size of 1500 was chosen to allow a sufficiently high ratio of cases to estimated parameters, avoiding overfitting and loss of generalizability in the regression model. [21]

2.2.4. Analysis

We categorised respondents as expecting side effects from COVID-19 vaccination using *a priori* cut offs on the likelihood scale (zero to two = very unlikely, three to seven = uncertain, eight to ten = very likely). [15,16]

To investigate factors associated with side-effect expectations we used a linear regression model, using the original 0 to 10 scale as the outcome measure. Variables were entered into the model in blocks: personal and clinical characteristics (block 1); general beliefs and attitudes relating to vaccination (block 2); and beliefs and attitudes relating to COVID-19 vaccination (block 3).

To control the rate of Type 1 errors, we set statistical significance at $p \leq .01$ and therefore calculated 99% confidence intervals (CIs) for regression coefficients.

3. Results

The 1470 participants included in analyses were broadly representative of the UK population (50.8%, $n = 746$ female; 85.2%, $n = 1246$ white ethnicity; mean age 45.5 years, SD = 15.5, range 18 to 80 years).

Most participants were uncertain about the likelihood of side effects from COVID-19 vaccination, with the midpoint of the scale being the most selected (modal) response. When using our *a priori* cut-offs, a minority of participants reported that side effects from a COVID-19 vaccine were very likely (9.4%, 95% CI 7.9% to 10.9%, $n = 138/1470$; Fig. 1). One-third of participants thought that side effects were very unlikely (33.1%, 95% CI 30.7% to 35.5%, $n = 486/1470$), while 57.6% (95% CI 55.0% to 60.1%, $n = 846/1470$) were uncertain.

1427 participants had complete data and were included in regression analyses. The overall regression model explained 29.7% of the variance, with COVID-19 vaccination beliefs and attitudes alone explaining 17.2% of the variance. Side-effect expectation was associated with: older age; being clinically extremely vulnerable to COVID-19 oneself; being afraid of needles; lower perceived social norms regarding COVID-19 vaccination; perceiving COVID-19 vaccination to be less necessary; poorer perceived safety of COVID-19 vaccination; and perceived inadequacy of information about vaccination (Table 1).

4. Discussion

Despite clinical trial data indicating that most people will go on to develop local or systemic adverse effects of COVID-19 vaccination, [7–9] participants were uncertain about the likelihood of side effects from COVID-19 vaccination and only a minority thought side effects were very likely. Under-estimation of the likelihood of side effects is unusual for medications. [20] In this instance, low levels of expectation may increase uptake of the first dose of the vaccination. [1–3] How the unexpected occurrence of side effects might affect uptake of the second dose is less clear. Since data collection, evidence indicating that the AstraZeneca vaccine may be linked to unusual blood clots with low blood platelets (published 7 April 2021) has been the focus of much media attention. [21] Research has shown that coverage of medication side effects in the news media increases symptom reporting. [22] Preliminary evidence suggests that coverage of a possible link between the AstraZeneca vaccine and blood clots may have affected side-effect expectations. [23] However, these data remain important by virtue of quantifying the prevalence of side-effect expectations and associated

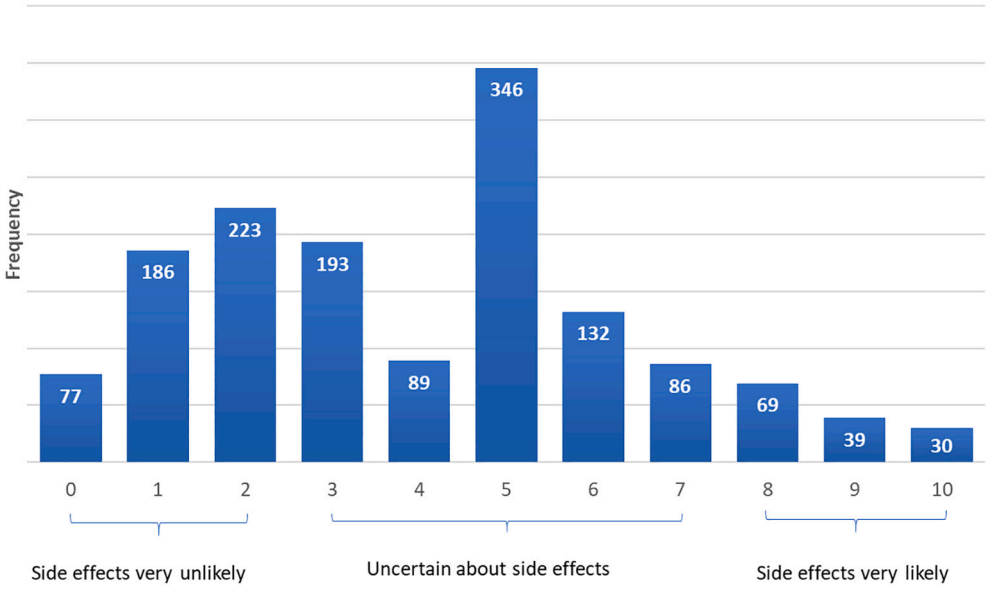

Fig. 1. Frequency distribution of side-effect expectations (0 = "extremely unlikely" to 10 = "extremely likely").

Table 1
Results of the full linear regression model analysing associations with side-effect expectation (adjusted $R^2 = 0.297$). Parameter estimates relate to the full model containing all predictors. The unstandardized regression coefficients represent the change in likelihood of side effects for a one-unit increase in the predictor variable (or, for dummy variables, a shift from the reference category to the category concerned). The model was based on 1427 participants with complete data.

Predictor variable	Level	Standardized coefficient	Unstandardized coefficient	99% confidence interval	*p* value
Block 1 – personal and clinical characteristics [a]					
Age (years)		0.107	0.017	0.006 to 0.028	<0.001*
Sex (reference: female)	Male	−0.039	−0.185	−0.471 to 0.102	0.096
Ethnicity (reference: black and minority ethnic)	White	−0.029	−0.198	−0.653 to 0.257	0.262
Religion (reference: none)					0.307
	Christian	−0.026	−0.128	−0.440 to 0.184	
	Other	0.021	0.193	−0.409 to 0.796	
Qualifications (reference: other)	Degree equivalent or higher	−0.008	−0.038	−0.332 to 0.255	0.736
Employment status (reference: not working/other)					0.125
	Part-time	0.053	0.341	−0.091 to 0.773	0.042
	Full-time	0.028	0.136	−0.214 to 0.486	0.317
Key worker (reference: not key worker)	Key worker	0.005	0.025	−0.307 to 0.357	0.845
Extremely clinically vulnerable – self (reference: no)	Yes	0.061	0.354	0.007 to 0.702	0.009*
Extremely clinically vulnerable – household member (reference: no)	Yes	0.004	0.025	−0.356 to 0.405	0.868
Block 2 – general vaccination beliefs and attitudes [b]					
Vaccination is generally good (0–10) [d]		0.018	0.026	−0.096 to 0.148	0.577
I am afraid of needles (0–10) [d]		0.068	0.050	0.006 to 0.094	0.003*
Block 3 – beliefs and attitudes about COVID-19 vaccination [c]					
Component: social norms regarding COVID-19 vaccination (−4.71 to 2.82)		−0.209	−0.517	−0.703 to −0.330	<0.001*
Component: the necessity of vaccination (−3.80 to 3.67)		−0.144	−0.349	−0.527 to −0.171	<0.001*
Component: safety of the vaccine (−3.91 to 2.56)		−0.454	−1.104	−1.285 to −0.923	<0.001*
Component: adequacy of information about vaccination (−3.77 to 3.41)		−0.076	−0.187	−0.338 to −0.035	0.002*
Component: freedom from restrictions through the vaccine (−2.41 to 3.26)		−0.017	−0.041	−0.188 to 0.107	0.478
The way the coronavirus vaccines are being given in the UK goes against the manufacturers' recommendations (0–10) [d]		0.014	0.011	−0.037 to 0.060	0.550
Only people who are at risk of serious illness from coronavirus need to be vaccinated (0–10) [d]		0.005	0.004	−0.052 to 0.061	0.841
Widespread coronavirus vaccination is just a way to make money for vaccine manufacturers (0–10) [d]		0.026	0.024	−0.051 to 0.100	0.409

* $p \leq .01$.
[a] variables in this block explained 1.3% of the variance.
[b] variables in this block explained 0.3% of the variance.
[c] variables in this block explained 17.2% of the variance.
[d] 0 = strongly disagree, 10 = strongly agree.

factors in the absence of much information at the start of the vaccine rollout in the UK.

Unsurprisingly, poorer perceived safety of COVID-19 vaccination was associated with greater side-effect expectations. [11] In line with research finding that negative beliefs about vaccinations were associated with increased side-effect expectations, [20] we also found that lower perceived necessity of COVID-19 vaccination was associated with greater side-effect expectations. Lower perceived social norms for COVID-19 vaccination (*i.e.* being less likely to think that others would approve of you having a COVID-19 vaccine) were also associated with greater side-effect expectations. This may be an example of the 'horn effect' (opposite of the 'halo effect'), whereby a negative impression of something negatively influences perceptions in a related area.

Perceived lack of information about COVID-19 and COVID-19 vaccination was associated with greater side-effect expectations. As side-effect expectations are lower than suggested by clinical trial data, communications should aim to promote an accurate perception of the incidence of side effects, and the mild and temporary nature of side effects likely to be experienced by most recipients of a COVID-19 vaccine.

Although adverse effects are more likely in younger people, [8–10] we found that older people had greater side-effect expectations. This may be reflective of the stage in the vaccination rollout in the UK at the time of this study (January 2021), with older people being offered the vaccine first. As the rollout progresses, and people learn about others developing side effects following vaccinations, [24,25] side-effect expectations in younger age groups may increase. Being clinically extremely vulnerable to COVID-19 was also associated with greater side-effect expectations. There is evidence that side-effect expectations are associated with currently experiencing symptoms. [14] As people who were clinically extremely vulnerable to COVID-19 reported having an underlying medical condition, they may have been more likely to be experiencing symptoms at the time of data collection.

It is important that people are informed transparently and accurately about the likelihood and severity of side effects from vaccination. While educational interventions may be an attractive option, there is mixed evidence for their effect on vaccine uptake. [26,27] Using simple infographics (*e.g.* pictographs) and improving the clarity and readability of information increase the accuracy of side-effect expectations. [28,29] Our results indicate that side-effect expectations at the start of the COVID-19 vaccine rollout in the UK were low compared to rates described by clinical trial data. Therefore, bringing people's expectations in line with these data may increase the incidence of nocebo-related symptoms. However, side-effect expectations have increased since the MHRA's announcement that the AstraZeneca vaccine may be linked to unusual blood clots related to low blood platelets (published 7 April 2021). [23] Providing reassurance about the typically transitory and non-harmful nature of side-effects may be a useful strategy in increasing initial vaccine uptake and reducing long-term attrition among those offered booster jabs (offered in the UK since October 2021).

As this study is cross-sectional, we cannot infer direction of causality between attitudes and beliefs and side-effect expectations. Further, the survey methodology used cannot rule out self-selection bias affecting the study results. To the best of our knowledge, there is no validated measure of side-effect expectation. We used a single item to measure side-effect expectation, with regard to the established psychometric properties of a 0 to 10 numerical rating scale format. [30] This item was based on previous research conducted by our group. [11] Not all potential variables that could have been associated with side-effect expectations were investigated due to space limitations in the survey.

5. Conclusion

At the start of the COVID-19 vaccine rollout in the UK, most people were unsure whether side effects from vaccination were likely. Media coverage of side effects and seeing people experience side effects as the vaccine rollout continues may heighten side-effect expectations. COVID-19 vaccination beliefs and attitudes were associated with side-effect expectations. In particular, side-effect expectations were associated with poorer perceived safety and effectiveness of the vaccine, thinking that others were less likely to approve if you were to have the vaccine, and a perceived lack of information about COVID-19 and vaccination. Public health communications should emphasise the safety, effectiveness, and widespread uptake of COVID-19 vaccination, while also promoting accurate perceptions of the incidence and nature of side effects from vaccination.

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Declaration of Competing Interest

All authors have completed the Unified Competing Interest form at http://www.icmje.org/coi_disclosure.pdf and declare that data collection was funded by a Keele University Faculty of Natural Sciences Research Development award to SS, JS and NS, and a King's COVID Appeal Fund award granted jointly to LS, GJR, RA, NS, SS and JS.

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