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Psychological factors associated with reporting side effects following COVID-19 vaccination: A prospective cohort study (CoVAccS – Wave 3)

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ABSTRACT

Objective: To investigate symptom reporting following the first and second COVID-19 vaccine doses, attribution of symptoms to the vaccine, and factors associated with symptom reporting.
Methods: Prospective cohort study (T1: 13–15 January 2021, T2: 4–15 October 2021). Participants were aged 18 years or older, living in the UK. Personal, clinical, and psychological factors were investigated at T1. Symptoms were reported at T2. We used logistic regression analyses to investigate associations.
Results: After the first COVID-19 vaccine dose, 74.1% (95% CI 71.4% to 76.7%, $n = 762/1028$) of participants reported at least one injection-site symptom, while 65.0% (95% CI 62.0% to 67.9%, $n = 669/1029$) reported at least one other (non-injection-site) symptom. Symptom reporting was associated with being a woman and younger. After the second dose, 52.9% (95% CI 49.8% to 56.0%, $n = 532/1005$) of participants reported at least one injection-site symptom and 43.7% (95% CI 40.7% to 46.8%, $n = 440/1006$) reported at least one other (non-injection-site) symptom. Symptom reporting was associated with having reported symptoms after the first dose, having an illness that put one at higher risk of COVID-19 (non-injection-site symptoms only), and not believing that one had enough information about COVID-19 to make an informed decision about vaccination (injection-site symptoms only).
Conclusions: Women and younger people were more likely to report symptoms from vaccination. People who had reported symptoms from previous doses were also more likely to report symptoms subsequently, although symptom reporting following the second vaccine was lower than following the first vaccine. Few psychological factors were associated with symptom reporting.

1. Introduction

Side effects can occur after taking a medication, including being vaccinated. While some side effects may be due to the pharmacological action of the drug, others may arise from the so-called 'nocebo effect', a phenomenon whereby the expectation that symptoms will develop becomes self-fulfilling. [1] The role of expectation in later perception of side effects has been well-documented for medications [2,3] and vaccinations. [4] Psychosocial factors may contribute to the nocebo effect; for example, seeing or hearing that a vaccine causes side effects, [5] or holding more negative beliefs about medications. [6,7]

Clinical trial data for UK approved COVID-19 vaccines (AstraZeneca, Pfizer-BioNTech, Moderna) indicate that side-effect reporting is lower in older adults. [8–10] However, the association with vaccine dose is less clear cut, with different patterns emerging for the different vaccines. For the AstraZeneca vaccine, side-effect reporting was lower after the second dose than after the first. [8] For the Pfizer-BioNTech vaccine, there was no difference in the percentage of people experiencing local reactions following the first and second dose. [9,11] One UK study investigating symptom reporting on an app (over 627,000 vaccinated

app users) found that people who had the Pfizer-BioNTech vaccine reported more systemic effects (e.g. fatigue and headache) after the second dose, compared to the first. [12] The pattern for reporting systemic reactions differed by previous SARS-CoV-2 infection, with those with evidence of previous infection reporting more systemic reactions after the first dose and those with no evidence of previous infection reporting more systemic reactions after the second dose. [11] Reported adverse effects for the Moderna vaccine were more severe following the second than following the first dose. [10]

Research investigating symptom reporting following vaccination for COVID-19 has focused on the sociodemographic factors associated with symptom reporting. One US survey (over 19,000 respondents) found that reporting adverse effects was associated with being younger, female, Asian ethnicity (compared to white), having had SARS-CoV-2 before, and it being the second vaccine dose (Moderna and Pfizer-BioNTech). [13] A study of UK app users (over 627,000 respondents) found that women, younger people, and those with previous SARS-CoV-2 infection were more likely to report symptoms (local and systemic, both AstraZeneca and Pfizer-BioNTech), but found no clear trend with vaccine type, dose or comorbidity. [12]

Fewer studies have investigated the association between psychological factors and COVID-19 vaccine side-effect reporting. Where they have, studies have focused on the influence of seeing or hearing about symptom reporting in others. For example, one study found that seeing more social media posts about COVID-19 vaccine side effects and severity of impressions from news stories and personal contacts were associated with later experiencing side effects. [14] Another study found that following the reporting of severe adverse events in the media, reporting to the national Centre for Adverse Reactions Monitoring (New Zealand) for effects mentioned in the media increased, whereas there was no change in the reporting of adverse events that were not specifically mentioned. [15] One study, investigating other psychological variables, found evidence for an association between COVID-19 vaccine side-effect reports and higher side-effect expectations, greater worry about COVID-19, and depressive symptoms. [16]

At the start of the COVID-19 vaccine rollout in the UK (January 2021), we conducted an online cross-sectional survey investigating perceptions about COVID-19 and vaccination, vaccination intention and side-effect expectations. [17] We found that only 9% of participants thought that side effects were likely (58% judged them uncertain, 33% judged them unlikely), while clinical trial data indicated that rates experienced were substantially higher (injection-site symptoms up to 89%, non-injection-site symptoms up to 70%). Higher expectations that one would experience side effects from a COVID-19 vaccine were associated with older age, being clinically extremely vulnerable to COVID-19, being afraid of needles, perceiving lower social norms for COVID-19 vaccination, lower perceived necessity and safety of COVID-19 vaccination, and not thinking that one had enough information about COVID-19 vaccination or illness.

In this study we used results from a follow-up survey, conducted in October 2021, after all UK adults had been offered two doses of the vaccine, [18] to investigate prevalence of injection- and non-injection-site symptoms following COVID-19 vaccination and their attribution to the vaccine. We investigated associations between symptom reporting (injection- and non-injection-site) and personal, clinical, psychological, and contextual factors following the first and second COVID-19 vaccine doses separately.

2. Methods

2.1. Design

Prospective cohort study conducted at two timepoints, with participants who completed the first survey (T1, 13–15 January 2021, $n = 1500$) also completing the second survey (T2, 4–15 October 2021, $n = 1148$, response rate 76.5%). For more details on the study design, see

Smith et al. [18] Results of analyses investigating factors associated with side-effect expectations (measured at T1) have been published elsewhere. [17]

2.2. Participants

People were eligible for the study if they lived in the UK, were aged 18 years or older, and had not completed our previous survey (conducted in July 2020) due to similarities in questionnaire materials. [19] Participants were recruited to the study from Prolific's online research panel (people who have signed up to take part in online surveys). Quota sampling was used, based on age, sex, and ethnicity, so that participant characteristics in these respects were similar to those of the UK population. Consent was provided before starting the survey. Participants were paid £2 per survey upon completion.

For this study, we excluded people who reported having been vaccinated for COVID-19 at T1 ($n = 30$). As the outcome measures are symptom reporting following vaccination, only participants who reported that they had been vaccinated for COVID-19 (one or two doses) were selected (first vaccine dose, $n = 1034$; second vaccine dose, $n = 1009$).

2.3. Measures

Survey materials are available online. [20,21]

2.3.1. Outcome measures

We measured symptom reporting and attribution to the vaccine at T2 using items based on the Side Effect Attribution Scale. [22] Participants were asked if they experienced any symptoms (from a list of thirteen: seven injection-site symptoms, six non-injection-site symptoms; symptoms based on Menni et al. [12]) in the seven days after they received a COVID-19 vaccine. We asked participants about each symptom on a six-point scale ("no", "yes, but definitely not a side effect", "yes, but probably not a side effect", "yes, but unsure whether a side effect", "yes, and probably a side effect" and "yes, and definitely a side effect"). Participants were categorized as having injection-site symptoms if they reported experiencing any of the seven injection-site symptoms after vaccination. Participants were categorized as having non-injection-site symptoms if they reported experiencing any of the six non-injection-site symptoms after vaccination. We asked about participants' first and second dose of the vaccine separately.

2.3.2. Personal and clinical factors

Participants were asked for their age, gender, and ethnicity at T1. Participants were also asked whether they thought they had previously had COVID-19 or currently had it at T1. Answers were recoded into a binary variable ("definitely" and "probably" had it or have it now vs "definitely" and "probably" not had it and do not have it now; we coded "don't know" and "prefer not to say" as missing). At T2, participants were asked whether they had a chronic illness. We recoded this into a binary variable indicating whether or not the participant was at high risk for COVID-19.

2.3.3. Psychological and contextual factors

At T1, participants were asked about their COVID-19 vaccination beliefs and attitudes using a series of seventeen items rated on an eleven-point (0–10) scale anchored at 'strongly disagree' (0) and 'strongly agree' (10). In previous analyses, these items were subjected to a principal components analysis, resulting in five components relating to COVID-19 vaccination beliefs. [23] Participants were also asked whether they were afraid of needles on the same 0–10 scale.

Side-effect expectations were measured at T1 with a single item asking how likely participants thought they were to get side effects from a COVID-19 vaccine on a 0–10 scale anchored at 'extremely unlikely' (0) and 'extremely likely' (10).

2.4. Ethics

Ethical approval for this study was granted by Keele University's Research Ethics Committee (reference: PS-200129).

2.5. Sample size

Our achieved sample size of 1005 for the logistic regression analysis was sufficient to avoid overfitting of a model with 14 estimated parameters and an assumed outcome prevalence of 70%, using a conservative event-to-predictor ratio of 20:1. [24]

2.6. Analysis

Responses to side-effect questions were not forced; there was, therefore, a small amount of missing data for individual symptoms (first vaccine dose, up to 0.6%, $n = 6/1034$; second vaccine dose, up to 0.4%, $n = 4/1009$).

Reporting and attribution of symptoms was investigated following the first and second COVID-19 vaccine doses separately.

We recoded symptom reporting into a binary variable (symptom not reported, vs one or more symptom reported). For reported symptoms, we also recoded symptom attribution into three categories (definitely not, probably not; unsure; probably, definitely). We categorized symptoms into two categories: i) injection-site symptoms (pain or tenderness where the injection was, redness where the injection was, swelling where the injection was, itch where the injection was, warmth where the injection was, bruising where the injection was, other symptom[s] where the injection was), and ii) non-injection-site symptoms (diarrhoea, headache, joint or muscle pain, high temperature/fever, nausea, fatigue). For each vaccine dose, we then created two further variables indicating whether the participant had experienced any injection-site symptoms (no injection-site symptoms reported, vs injection-site symptom reported) or any non-injection-site symptoms (no non-injection-site symptom reported, vs non-injection-site symptom reported) respectively. We did the same for attribution (of symptoms to vaccine).

Symptom reporting and attribution of individual symptoms, and injection- and non-injection-site symptoms, are reported descriptively. A chi-squared test was used to investigate whether there was an association between reporting injection-site symptoms and non-injection-site symptoms.

We investigated factors associated with reporting of injection-site and non-injection-site symptoms separately, using binary logistic regression. Explanatory variables (except for at risk for COVID-19) were measured at T1, while the outcomes (symptom reporting) were reported at T2. Explanatory variables were entered into the logistic regression model in two blocks, selected a priori based on previous analyses. [18,23] We entered personal and clinical characteristics into the first block: age, gender, ethnicity, at risk for COVID-19, think or had COVID-19 previously or currently, and vaccine brand. Psychological and contextual factors were entered into the second block: fear of needles, four principal vaccine components (social norms relating to vaccination, perceived necessity of vaccination, perceived safety of the vaccine, adequacy of information about the vaccine; associated with side-effect expectations in previous analyses [17]) and side-effect expectations. In analyses investigating symptom reporting following the second vaccine dose we also included a single item in a third block: symptom reporting following the first vaccine. The Nagelkerke (pseudo-) R^2 was used to investigate the predictive strength of the regression models; this statistic can take values between 0 and 1.

Statistical significance was set at $p \leq .05$.

We did not conduct analyses of associations with symptom attribution owing to the very small number of symptoms that were not attributed to vaccination, in relation to both the first and the second vaccine.

3. Results

3.1. Participant characteristics

After excluding those who had been vaccinated at T1, and those who had not been vaccinated, preferred not to say, or did not know if they had been vaccinated at T2, 1034 participants were included in analyses of symptom reporting. Just over half (52.1%) were female, most (86.9%) were white, and the mean age was 48.7 years (Table 1). The most commonly reported vaccine received was AstraZeneca, followed by Pfizer-BioNTech and Moderna.

3.2. Symptom reporting and attribution to COVID-19 vaccination

The most common injection-site symptom reported following the first and second doses of a COVID-19 vaccine was pain or tenderness where the injection was (Table 2). The most common non-injection-site symptoms were fatigue, joint or muscle pain, and headache.

Following the first dose of the vaccine, 74.1% (95% CI 71.4% to 76.7%, $n = 762/1028$) of participants reported experiencing at least one injection-site symptom. Of these, 88.1% (95% CI 85.6% to 90.2%, $n = 671/762$) attributed at least one symptom experienced to the vaccine. 65.0% (95% CI 62.0% to 67.9%, $n = 669/1029$) reported experiencing at least one other (non-injection-site) symptom. Of these, 79.8% (95% CI 76.6% to 82.7%, $n = 534/669$) attributed at least one symptom experienced to the vaccine.

Following the second dose of the vaccine, 52.9% (95% CI 49.8% to 56.0%, $n = 532/1005$) of participants reported experiencing at least one injection-site symptom. Of these, 88.3% (95% CI 85.3% to 90.8%, $n = 470/532$) attributed at least one symptom experienced to the vaccine. 43.7% (95% CI 40.7% to 46.8%, $n = 440/1006$) reported experiencing at least one other (non-injection-site) symptom. Of these, 78.9% (95% CI 74.8% to 82.4%, $n = 347/440$) attributed at least one symptom experienced to the vaccine.

There was a significant difference in reporting of injection-site and non-injection-site symptoms for both vaccines, with 354/1028 (34.4%) of participants reporting one type of symptom but not the other for the first vaccine ($\chi^2_1 = 40.9$, $p < .001$) and a corresponding figure of 367/

Table 1
Participant characteristics.

	n (%)
Vaccinated at T2	
Two doses	1009 (89.8)
One dose	25 (2.2)
Not vaccinated [a]	85 (7.6)
Prefer not to say [a]	4 (0.4)
Don't know [a]	1 (0.1)
Total included in analyses	1034 (100.0)
Gender	
Female	539 (52.1)
Male	492 (47.6)
Non-binary	2 (0.2)
Prefer to self-describe	1 (0.1)
Ethnicity	
White	899 (86.9)
Other ethnic groups	131 (12.7)
Prefer not to say	4 (0.4)
Age	
Range 18 to 80 years	M = 48.7, SD = 15.1
Vaccine received	
AstraZeneca	597 (57.7)
Pfizer-BioNTech	395 (38.2)
Moderna	36 (3.5)
Janssen	1 (0.1)
Vaccine not listed	3 (0.3)
Don't know	2 (0.2)

[a] Not included in analyses of symptom reporting as participants had to be vaccinated by definition.

Table 2

Symptom reporting and attribution to COVID-19 vaccination for the first and second vaccine dose separately.

		Did you experience this symptom and if so, do you think it was a side effect of the COVID-19 vaccine? [a]										
		First vaccine, *n* (%) [b]					Second vaccine, *n* (%) [b]					
		n	No	Yes; definitely or probably not a side effect	Yes; unsure whether a side effect	Yes; probably or definitely a side effect	*n*	No	Yes; definitely or probably not a side effect	Yes; unsure whether a side effect	Yes; probably or definitely a side effect	
Injection-site symptoms	Pain or tenderness where the injection was	1032	323 (31.3)	48 (4.7)	28 (2.7)	633 (61.3)	1009	519 (51.4)	35 (3.5)	19 (1.9)	422 (43.2)	
	Redness where the injection was	1030	811 (78.7)	19 (1.8)	12 (1.2)	188 (18.3)	1007	873 (86.7)	13 (1.3)	6 (0.6)	115 (11.4)	
	Swelling where the injection was	1030	854 (82.9)	11 (1.1)	9 (0.9)	156 (15.1)	1006	892 (88.7)	8 (0.8)	7 (0.7)	99 (9.8)	
	Itch where the injection was	1029	907 (88.1)	18 (1.7)	7 (0.7)	97 (9.4)	1006	936 (93.0)	8 (0.8)	8 (0.8)	54 (5.4)	
	Warmth where the injection was	1030	822 (79.8)	17 (1.7)	17 (1.7)	174 (16.9)	1006	892 (88.7)	8 (0.8)	6 (0.6)	100 (9.9)	
	Bruising where the injection was	1029	909 (88.3)	11 (1.1)	6 (0.6)	103 (10.0)	1006	936 (93.0)	4 (0.4)	4 (0.4)	62 (6.2)	
	Other symptom (s) where the injection was	1028	1007 (98.0)	5 (0.5)	3 (0.3)	13 (1.3)	1005	995 (99.0)	3 (0.3)	2 (0.2)	5 (0.5)	
	Any injection-site symptom	1028	266 (25.9)	59 (5.7)	32 (3.1)	671 (65.3)	1005	473 (47.1)	42 (4.2)	20 (2.0)	470 (46.8)	
Non-injection-site symptoms	Diarrhoea	1029	999 (97.1)	10 (1.0)	8 (0.8)	12 (1.2)	1006	987 (98.1)	9 (0.9)	3 (0.3)	7 (0.7)	
	Headache	1030	651 (63.2)	42 (4.1)	74 (7.2)	263 (25.5)	1006	789 (78.4)	27 (2.7)	42 (4.2)	148 (14.7)	
	Joint or muscle pain	1033	585 (56.6)	33 (3.2)	57 (5.5)	358 (34.7)	1007	737 (73.2)	26 (2.6)	30 (3.0)	214 (21.3)	
	High temperature/ fever	1030	830 (80.6)	6 (0.6)	20 (1.9)	174 (16.9)	1006	918 (91.3)	5 (0.5)	10 (1.0)	73 (7.3)	
	Nausea	1030	910 (88.3)	12 (1.2)	18 (1.7)	90 (8.7)	1006	943 (93.7)	15 (1.5)	7 (0.7)	41 (4.1)	
	Fatigue	1031	542 (52.6)	50 (4.8)	83 (8.1)	356 (34.5)	1009	693 (68.7)	44 (4.4)	48 (4.8)	224 (22.2)	
	Any non-injection-site symptom	1029	360 (35.0)	52 (5.1)	83 (8.1)	534 (51.9)	1006	566 (56.3)	48 (4.8)	45 (4.5)	347 (34.5)	

[a] Responses to these items were not forced, therefore *n* values for individual symptoms reported vary slightly.

[b] Where percentages do not add to 100, this is due to rounding.

1005 (36.5%) for the second vaccine dose ($\chi_1^2 = 78.7$, $p < .001$; Table 3).

3.3. Associations between symptom reporting and personal, clinical, psychological, and contextual factors

Results reported are from the full regression model. Results from block 1 alone are presented in Appendix A. Descriptive statistics relating to variables in the regression models are presented in Table 4. Missing data in the regression models are due to missing values for individual variables.

Table 3

Number of people reporting injection-site and non-injection-site symptoms after the first and second vaccine dose.

		First vaccine, *n* = 1028		Second vaccine, *n* = 1005	
		Non-injection-site symptoms, *n* (%)		Non-injection-site symptoms, *n* (%)	
		Not reported	Reported	Not reported	Reported
Injection-site symptoms	Not reported	136 (37.8)	130 (19.5)	336 (59.4)	137 (31.2)
	Reported	224 (62.2)	538 (80.5)	230 (40.6)	302 (68.8)
	Total	360 (100.0)	668 (100.0)	566 (100.0)	439 (100.0)

3.3.1. First vaccine dose

After the first vaccine dose, reporting of injection-site and of non-injection-site symptoms was in each case associated with being female and younger (Table 5). Reporting symptoms at either site was also associated with vaccine brand. Examination of Table 4 reveals that reporting was highest for the Moderna vaccine, at 92.0% and 72.0% for vaccine-site and non-vaccine-site symptoms respectively, though these estimates are imprecise in view of the small number of cases in this category. Reporting was somewhat higher for the Pfizer-BioNTech vaccine than for the AstraZeneca vaccine for injection-site symptoms, but the reverse was the case for non-injection-site symptoms.

The regression model for injection-site symptoms had greater predictive power (Nagelkerke $R^2 = 0.140$) than that for non-injection-site-symptoms (Nagelkerke $R^2 = 0.099$). In both cases, the addition of psychological and contextual factors in the second block produced only a small increase in the R^2 value over that derived from the personal and clinical variables in the first block.

3.3.2. Second vaccine dose

In respect of both injection-site and non-injection-site symptoms, those having reported symptoms after the first dose were much more likely to do so after the second dose (Table 6). Reporting injection-site and non-injection-site symptoms after the second vaccine dose was associated with vaccine brand, in relation to both types of symptoms. As in the case of first-dose symptoms, the highest rate reported was for the Moderna vaccine (82.6% and 87.0% for injection-site and non-injection-

Table 4

Participant characteristics, in subgroups according to dose and symptom reporting. Data are *n* (%) except where indicated otherwise.

		First vaccine, *n* (%)				Second vaccine, *n* (%)			
		Injection-site symptoms		Non-injection-site symptoms		Injection-site symptoms		Non-injection-site symptoms	
		Not reported *n* = 234	Reported *n* = 666	Not reported *n* = 234	Reported *n* = 666	Not reported *n* = 419	Reported *n* = 463	Not reported *n* = 501	Reported *n* = 382
Age (years); mean (SD)		53.4 (14.4)	47.1 (15.2)	52.7 (14.9)	46.6 (15.0)	52.0 (14.4)	46.3 (15.3)	51.6 (14.1)	45.5 (15.7)
Gender	Female	82 (17.5)	386 (82.5)	143 (30.5)	326 (69.5)	192 (41.6)	269 (58.4)	242 (52.4)	220 (47.6)
	Male	152 (35.2)	280 (64.8)	170 (39.4)	262 (60.6)	227 (53.9)	194 (46.1)	259 (61.5)	162 (38.5)
Ethnicity	White	209 (26.4)	582 (73.6)	284 (35.9)	508 (64.1)	377 (48.7)	397 (51.3)	451 (58.2)	324 (41.8)
	Other ethnic groups	25 (22.9)	84 (77.1)	29 (26.6)	80 (73.4)	42 (38.9)	66 (61.1)	50 (46.3)	58 (53.7)
At risk for COVID-19	No	187 (25.4)	548 (74.6)	244 (33.2)	491 (66.8)	341 (47.4)	379 (52.6)	412 (57.2)	308 (42.8)
	Yes	47 (28.5)	118 (71.5)	69 (41.6)	97 (58.4)	78 (48.1)	84 (51.9)	89 (54.6)	74 (45.4)
Think previously or currently had COVID-19	No	205 (26.8)	559 (73.2)	277 (36.3)	487 (63.7)	369 (49.1)	383 (50.9)	444 (59.0)	308 (41.0)
	Yes	29 (21.3)	107 (78.7)	36 (26.3)	101 (73.7)	50 (38.5)	80 (61.5)	57 (43.5)	74 (56.5)
Vaccine brand	Pfizer-BioNTech	64 (17.9)	293 (82.1)	142 (39.8)	215 (60.2)	128 (36.9)	219 (63.1)	176 (50.7)	171 (49.3)
	AstraZeneca	168 (32.4)	350 (67.6)	164 (31.6)	355 (68.4)	287 (56.1)	225 (43.9)	322 (62.8)	191 (37.2)
	Moderna	2 (8.0)	23 (92.0)	7 (28.0)	18 (72.0)	4 (17.4)	19 (82.6)	3 (13.0)	20 (87.0)
I am afraid of needles (0–10, strongly disagree to strongly agree); mean (SD)		2.2 (3.1)	2.8 (3.3)	2.3 (3.2)	2.8 (3.3)	2.4 (3.2)	2.8 (3.4)	2.5 (3.3)	2.8 (3.3)
How likely to get side effects from vaccine? (0–10, strongly disagree to strongly agree); mean (SD)		3.6 (2.4)	3.7 (2.3)	3.6 (2.4)	3.7 (2.3)	3.5 (2.3)	3.8 (2.3)	3.5 (2.3)	3.8 (2.3)
Symptoms reported after first vaccine dose	No	–	–	–	–	207 (89.2)	25 (10.8)	266 (86.6)	41 (13.4)
	Yes	–	–	–	–	212 (32.6)	438 (67.4)	235 (40.8)	341 (59.2)

SD = standard deviation.

site symptoms, respectively; Table 4). The rate was higher for the Pfizer-BioNTech than for the AstraZeneca vaccine in both cases. Reporting non-injection-site symptoms was associated with having an illness that put one at higher risk of COVID-19. Reporting injection-site symptoms was associated with not believing that one had enough information about COVID-19 (illness and vaccination) to make an informed decision about vaccination.

The predictive power of the regression models for injection-site and non-injection-site symptoms was similar (Nagelkerke R^2 of 0.361 and 0.338, respectively). The higher R^2 values than in the regression models for the first dose is largely due to the marked effect of reporting of symptoms related to the first dose; before this predictor was added in the third block, the R^2 values (0.115 and 0.105) were not markedly different from those in the regression models for first-dose symptom reporting.

4. Discussion

We found that 74% of people included in this study reported injection-site symptoms and 65% reported non-injection-site symptoms following their first COVID-19 vaccine dose. Following the second vaccine dose, 53% reported injection-site and 44% reported non-injection-site symptoms. Clinical trial data indicate that side-effect reporting is lower for the second dose of the AstraZeneca vaccine, [8] which most of our participants (58%) reported receiving. Rates of commonly reported injection-site and non-injection-site symptoms (fatigue, headache, fever) were within the range of those seen in clinical trial data. [9,12,25] Most people attributed at least one of the symptoms reported after vaccination to the vaccine.

In line with previous research, we found that younger people were more likely to report vaccine side effects. [8–10] Women were also more likely to report symptoms, as in other studies investigating symptom reporting following COVID-19 vaccination. [12,13] Higher rates of symptoms are consistently perceived by females than by males in studies investigating symptom reporting. [26,27] Though most research points to an association between female sex and symptom perception, a recent comprehensive systematic review of factors associated with the nocebo

response found little evidence for a gender effect. [3] We found no evidence for an association between previous or current SARS-CoV-2 infection and symptom reporting, contrary to previous research. [12,13] This may have been due to smaller sample sizes and wording of the item used to include current infection. Personal and clinical characteristics contributed little to the predictive strength of the regression models in this study.

Few psychological and contextual factors were significantly associated with symptom reporting following COVID-19 vaccination, except for prior symptom experience. This variable likely drove the additional predictive power (increase in Nagelkerke R^2 from 0.116 to 0.361 for injection-site symptoms and from 0.106 to 0.338 for non-injection-site symptoms) when added to personal and clinical characteristics in the regression models of symptom reporting following the second vaccine dose. An important implication for policy, however, is that high uptake of the second COVID-19 vaccine dose suggests that previously experiencing symptoms from the first vaccine did not influence uptake of the second vaccine dose. This contrasts with review findings that fear of side effects is one of the most common reasons for vaccine refusal. [28,29] However, one study suggests that perceived severity of, and worry about, side effects, rather than mere perception of side effects, may affect future uptake. [30] Other possible reasons that uptake of the second COVID-19 vaccine dose was high include the emphasis on vaccination in the media and public discourse about the pandemic. Alternatively, people may have perceived side effects as evidence that the vaccine is "working", increasing motivation to have a second dose. [31] One mechanism through which previous symptom experience may feed into later symptom perception is expectation. Symptom expectation is strongly associated with the nocebo effect and later symptom perception. [3,4,32] However, in this study, we did not find a statistically significant association between side-effect expectations at the start of the vaccine rollout in the UK and later symptom reporting. One reason for this may be that most participants were unsure whether they would experience symptoms from a COVID-19 vaccine at T1. [17]

We investigated factors associated with side-effect expectations in our T1 survey, [17] as well as others theoretically associated with

Table 5

Results of the full logistic regression models analysing associations with symptom reporting following the first dose of a COVID-19 vaccination. Parameter estimates relate to the full model containing all explanatory variables (injection-site symptoms, $n = 900$, 13.0% missing data; non-injection-site symptoms, $n = 901$, 12.9% missing data). For continuous variables, the adjusted odds ratios represent the change in likelihood of side effects for a one-unit increase in the predictor variable, apart from age, where an increase of one-unit represents an increase by decade.

	Predictor variable	Level	Injection-site symptoms, $n = 900$		Non-injection-site symptoms, $n = 901$	
			Adjusted odds ratio (95% CI) for reporting symptoms [a]	p value	Adjusted odds ratio (95% CI) for reporting symptoms [a]	p value
Block 1 – personal and clinical characteristics	Age	Decade	0.785 (0.691 to 0.893)	<0.001*	0.722 (0.644 to 0.810)	<0.001*
	Gender	Female	Reference	–	Reference	–
		Male	0.356 (0.257 to 0.492)	<0.001*	0.656 (0.492 to 0.875)	0.004*
	Ethnicity	White	Reference	–	Reference	–
		Other ethnic groups	0.954 (0.566 to 1.608)	0.860	1.129 (0.699 to 1.822)	0.620
	At risk for COVID-19	No	Reference	–	Reference	–
		Yes	0.965 (0.643 to 1.446)	0.861	0.854 (0.589 to 1.240)	0.408
	Think previously or currently had COVID-19	No	Reference	–	Reference	–
		Yes	0.874 (0.542 to 1.410)	0.582	1.251 (0.811 to 1.929)	0.311
	Vaccine brand			0.002*		<0.001*
		Pfizer-BioNTech	Reference		Reference	
		AstraZeneca	0.514 (0.361 to 0.732)		2.066 (1.506 to 2.835)	
		Moderna	2.029 (0.454 to 9.075)		1.132 (0.448 to 2.858)	
Block 2 – psychological and contextual factors	I am afraid of needles	0 (strongly disagree) to 10 (strongly agree)	1.043 (0.991 to 1.098)	0.108	1.020 (0.974 to 1.067)	0.407
	COVID-19 vaccination beliefs component 1: social norms regarding COVID-19 vaccination	–	1.070 (0.874 to 1.309)	0.514	0.966 (0.806 to 1.158)	0.706
	COVID-19 vaccination beliefs component 2: the necessity of vaccination	–	1.083 (0.906 to 1.294)	0.383	1.059 (0.900 to 1.246)	0.491
	COVID-19 vaccination beliefs component 3: safety of the vaccine	–	0.983 (0.801 to 1.206)	0.869	1.065 (0.885 to 1.282)	0.502
	COVID-19 vaccination beliefs component 4: adequacy of information about vaccination	–	0.973 (0.813 to 1.166)	0.770	0.960 (0.814 to 1.133)	0.632
	How likely do you think it is that you would get side effects from a coronavirus vaccine?	0 (extremely unlikely) to 10 (extremely likely)	1.003 (0.929 to 1.084)	0.936	1.000 (0.931 to 1.075)	0.991
Nagelkerke R^2			For 1st block = 0.134 For full model = 0.140		For 1st block = 0.096 For full model = 0.099	

CI = confidence interval

[a] Adjusting for all other variables.

* $p \leq .05$.

nocebo reporting [3] and side-effect expectations. [33] However, we found few associations with symptom reporting, and in particular few associations with psychological factors. This may be due to the long period of time between measurement of psychological factors (January 2021) and symptom reporting (October 2021) and the fact that each explanatory variable was adjusted for all of the other variables in the statistical model. For example, we found no evidence for an association between perceived vaccine safety and side-effect reporting. In the UK, there was a media flurry around vaccine safety in April 2021, when news broke that the AstraZeneca vaccine may have been linked to unusual blood clots with low platelets. [34] This occurred after we had measured the psychological factors used as predictors in this study, and is likely to have affected perceptions. Studies have found that media reporting is associated with symptom reporting from the COVID-19 vaccine. [14,15] Investigation of possible associations of the influence of media and social media on symptom reporting was outside the scope of the study. Other explanations are also possible. Biological factors may play a stronger role in incidence of symptoms following COVID-19 vaccination than psychological factors. Relevant psychological factors may not have been measured. Alternatively, the influence of psychological factors previously found to be associated with symptom reporting and attribution may have been attenuated in this unique pandemic situation, where emphasis was repeatedly placed on vaccination as a "route out of the pandemic". [35,36]

Strengths of this study include its large sample size and consequent power to detect small effects. Limitations include that our outcomes (symptom reporting after the first and second COVID-19 vaccines) were measured in October 2021. While the second wave of data collection was timed to coincide with when all UK adults had been offered both vaccine doses, thus avoiding systematic biases within the data, some participants may have completed their vaccine schedule some months before. Recall for symptoms can fade quickly. [37] Therefore symptom reporting, especially for the first vaccine dose (generally given 12 weeks before the second vaccine dose) may have been affected by recall bias. We were unable to investigate factors associated with symptom attribution, as very few people did not attribute their symptoms to the vaccine (first and second vaccine dose). We were unable to investigate whether reporting side effects following the first vaccine dose affected uptake of the second dose due to small numbers. As so few people reported only having one dose (2%, $n = 25/1034$), we assume there was no impact. This is supported by other research finding that experiencing side effects from the initial course of the COVID-19 vaccine (two doses) did not affect intention to receive a booster dose. [38] Few people reported receiving a Moderna vaccine and so confidence intervals are wider for these analyses, and no hypothesis tests were performed in respect of comparisons between the three vaccines in view of the disparity in the size of these subgroups. There may be some experience of adverse events from vaccination in those infected with SARS-CoV-2 when vaccinated. [10] Our question measuring previous SARS-CoV-2 infection asked whether participants had previously had, or currently had, COVID-19 and was asked at T1. Therefore, some participants may have been infected with SARS-CoV-2 after having completed the T1 questionnaire, but before receiving their first vaccine, whom we were not able to identify.

Table 6

Results of the full logistic regression models analysing associations with symptom reporting following the second dose of a COVID-19 vaccination. Parameter estimates relate to the full model containing all explanatory variables (injection-site symptoms, $n = 882$, 14.7% missing data; non-injection-site symptoms, $n = 883$, 14.6% missing data). For continuous variables, the adjusted odds ratios represent the change in likelihood of side effects for a one-unit increase in the predictor variable, apart from age, where it an increase of one-unit represents an increase by decade.

	Predictor variable	Level	Injection-site symptoms, $n = 882$		Non-injection-site symptoms, $n = 883$	
			Adjusted odds ratio (95% CI) for reporting symptoms [a]	p value	Adjusted odds ratio (95% CI) for reporting symptoms [a]	p value
Block 1 – personal and clinical characteristics	Age	Decade	0.947 (0.837 to 1.070)	0.383	0.942 (0.833 to 1.066)	0.343
	Gender	Female	Reference	–	Reference	–
		Male	0.845 (0.613 to 1.166)	0.305	0.776 (0.567 to 1.063)	0.114
	Ethnicity	White	Reference	–	Reference	–
		Other ethnic groups	1.232 (0.738 to 2.056)	0.425	1.221 (0.752 to 1.981)	0.420
	At risk for COVID-19	No	Reference	–	Reference	–
		Yes	1.291 (0.851 to 1.960)	0.229	1.737 (1.144 to 2.635)	0.010*
	Think previously or currently had COVID-19	No	Reference	–	Reference	–
		Yes	1.234 (0.781 to 1.950)	0.368	1.341 (0.865 to 2.080)	0.190
	Vaccine brand			0.007*		<0.001*
		Pfizer-BioNTech	Reference		Reference	
		AstraZeneca	0.627 (0.446 to 0.883)		0.483 (0.339 to 0.688)	
		Moderna	2.332 (0.671 to 8.108)		8.593 (2.182 to 33.837)	
Block 2 – psychological and contextual factors	I am afraid of needles (0–10)	0 (strongly disagree) to 10 (strongly agree)	1.005 (0.957 to 1.055)	0.838	0.997 (0.950 to 1.047)	0.920
	COVID-19 vaccination beliefs component 1: social norms regarding COVID-19 vaccination	–	0.895 (0.730 to 1.097)	0.285	0.869 (0.712 to 1.060)	0.167
	COVID-19 vaccination beliefs component 2: the necessity of vaccination	–	0.915 (0.762 to 1.099)	0.344	0.886 (0.739 to 1.063)	0.193
	COVID-19 vaccination beliefs component 3: safety of the vaccine	–	0.943 (0.770 to 1.155)	0.572	0.958 (0.785 to 1.169)	0.670
	COVID-19 vaccination beliefs component 4: adequacy of information about vaccination	–	0.780 (0.648 to 0.939)	0.009*	0.989 (0.828 to 1.181)	0.898
	How likely do you think it is that you would get side effects from a coronavirus vaccine?	0 (extremely unlikely) to 10 (extremely likely)	1.020 (0.943 to 1.103)	0.626	1.051 (0.973 to 1.135)	0.209
Block 3 – previous symptoms	Symptoms reported after first vaccine dose [b]	No	Reference	–	Reference	–
		Yes	15.424 (9.724 to 24.467)	<0.001*	11.243 (7.489 to 16.878)	<0.001*
Nagelkerke R^2			For 1st block = 0.102		For 1st block = 0.100	
			For 1st & 2nd block = 0.116		For 1st & 2nd block = 0.106	
			For full model = 0.361		For full model = 0.338	

CI = confidence interval

[a] Adjusting for all other variables.

[b] Injection-site symptoms reported after first vaccine dose included in model investigating reporting of injection-site symptoms. Non-injection-site symptoms reported after first vaccine dose included in model investigating reporting of non-injection-site symptoms.

* $p \leq .05$.

In conclusion, in this study, more people reported injection-site symptoms than non-injection-site symptoms. Symptoms were more likely to be reported following the first compared to the second vaccine dose. Approximately 90% of people reporting symptoms attributed them to the vaccine. Women and younger people were more likely to report symptoms, in line with clinical trial data. The factor most strongly associated with symptom reporting following the second vaccine dose was reporting symptoms from the first vaccine. However, few people had only had one vaccine, suggesting that perception of side effects did not deter people from having their second vaccine. Few psychological factors were associated with side-effect reporting, possibly due to the long time period between waves of data collection (January and October 2021).

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.

NS is the director of the London Safety and Training Solutions Ltd., which offers training in patient safety, implementation solutions and human factors to healthcare organizations and the pharmaceutical industry; RA is employed by the UK Health Security Agency. At the time of writing GJR is acting as an expert witness in an unrelated case involving Bayer PLC. LS helped prepare documents for the testimony. The other authors have no conflicts of interest to declare.

Appendix A. Appendix

Table A.1

Results of the logistic regression models for block one (personal and clinical characteristics only) analysing associations with symptom reporting following the first dose of a COVID-19 vaccination. For continuous variables, the adjusted odds ratios (aORs) represent the change in likelihood of side effects for a one-unit increase in the predictor variable, apart from age, where it an increase of one-unit represents an increase by decade.

	Predictor variable	Level	Injection-site symptoms, $n = 900$		Non-injection-site symptoms, $n = 901$	
			Adjusted odds ratio (95% CI) for reporting symptoms [a]	*p* value	Adjusted odds ratio (95% CI) for reporting symptoms [a]	*p* value
Block 1 – personal and clinical characteristics	Age	Decade	0.778 (0.687 to 0.881)	<0.001*	0.714 (0.639 to 0.798)	<0.001*
	Gender	Female	Reference	–	Reference	–
		Male	0.359 (0.260 to 0.495)	<0.001*	0.665 (0.499 to 0.885)	0.005*
	Ethnicity	White	Reference	–	Reference	–
		Other ethnic groups	0.944 (0.563 to 1.583)	0.827	1.129 (0.702 to 1.816)	0.617
	At risk for COVID-19	No	Reference	–	Reference	–
		Yes	0.963 (0.646 to 1.435)	0.852	0.853 (0.591 to 1.232)	0.398
	Think previously or currently had COVID-19	No	Reference	–	Reference	–
		Yes	0.881 (0.548 to 1.418)	0.603	1.242 (0.807 to 1.911)	0.325
	Vaccine brand			0.001*		<0.001*
		Pfizer-BioNTech	Reference		Reference	
		AstraZeneca	0.530 (0.374 to 0.752)		2.073 (1.514 to 2.837)	
		Moderna	2.059 (0.462 to 9.176)		1.135 (0.451 to 2.853)	

[a] Adjusting for age, gender, ethnicity, being at risk for COVID-19, think or had COVID-19 previously or currently, and vaccine brand.
* $p \leq .05$.

Table A.2

Results of the logistic regression models for block one (personal and clinical characteristics only) analysing associations with symptom reporting following the second dose of a COVID-19 vaccination. For continuous variables, the adjusted odds ratios (aORs) represent the change in likelihood of side effects for a one-unit increase in the predictor variable, apart from age, where it an increase of one-unit represents an increase by decade.

	Predictor variable	Level	Injection-site symptoms, $n = 882$		Non-injection-site symptoms, $n = 883$	
			Adjusted odds ratio (95% CI) for reporting symptoms [a]	*p* value	Adjusted odds ratio (95% CI) for reporting symptoms [a]	*p* value
Block 1 – personal and clinical characteristics	Age	Decade	0.844 (0.760 to 0.937)	0.001*	0.813 (0.733 to 0.903)	<0.001*
	Gender	Female	Reference	–	Reference	–
		Male	0.579 (0.439 to 0.764)	<0.001*	0.666 (0.504 to 0.880)	0.004*
	Ethnicity	White	Reference	–	Reference	–
		Black and minority ethnic	1.219 (0.782 to 1.900)	0.382	1.276 (0.826 to 1.969)	0.272
	At risk for COVID-19	No	Reference	–	Reference	–
		Yes	1.138 (0.795 to 1.628)	0.481	1.395 (0.974 to 1.998)	0.069
	Think previously or currently had COVID-19	No	Reference	–	Reference	–
		Yes	1.153 (0.769 to 1.727)	0.492	1.429 (0.962 to 2.121)	0.08 to 0.077
	Vaccine brand			<0.001*		0.002*
		Pfizer-BioNTech	Reference		Reference	
		AstraZeneca	0.534 (0.396 to 0.727)		0.759 (0.563 to 1.025)	
		Moderna	2.471 (0.809 to 7.545)		6.044 (1.739 to 21.006)	

[a] Adjusting for age, gender, ethnicity, being at risk for COVID-19, think or had COVID-19 previously or currently, and vaccine brand.
* $p \leq .05$.

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