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Original Article

The outcome of a recent online survey carried out in India on self-reported adverse events following COVID-19 vaccination

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Abstract

The last two years have been mainly in the grip of the coronavirus pandemic. In record time, the healthcare sector has worked tirelessly to introduce the COVID-19 vaccines. As the pandemic continues to rage, the pace of vaccination is being increased to reduce the aftermath of the destruction caused by the virus. Information about the adverse events experienced post-vaccination will help further improve vaccines. The objective of this study was to collect data on adverse events experienced following COVID-19 vaccination in India to assess these vaccines' tolerability and apparent safety. In order to analyse adverse effects post-vaccination, a questionnaire was developed for an online survey. A pilot was carried out and posted online. Responses from 722 respondents were collected between May 2021 to December 2021 and analysed with the help of excel analytics and statistics in a scientific manner. The survey revealed that less than 50% of the vaccinated respondents experienced adverse effects after the first dose of COVID vaccines. Perceived side effects included pain, redness, swelling, headache, body ache, muscle pain, joint pain, tiredness, lethargy, chills, fever, nausea, giddiness, and diarrhoea. Less than 1% of the respondents were reportedly hospitalized for alleviation of their symptoms post-vaccination (first and second doses). The rest recovered from the side effects with none to minimal treatment on an outpatient basis. The vaccines under study elicited side effects in less than 50% of the respondents and were well-tolerated overall.

Keywords: coronavirus, vaccine, online survey, side-effects, adverse reactions, fever

Introduction

The world is in the grip of the COVID-19 pandemic, which originated as a severe outbreak in Wuhan, China, in December 2019. WHO declared the corona outbreak a public health emergency of international concern on January 30, 2020, and a pandemic on March 11, 2020 [1]. Initially, the novel coronavirus was named 2019-nCOV by WHO and was identified from the throat swab sample of a patient on January 7, 2020 [2]. It was later renamed Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) [3]. Coronaviruses range from 60 nm to 140 nm in diameter and are positive-stranded RNA viruses with a crown-like appearance due to spikes on their surface [4]. Coronavirus belongs to the family "Coronaviridae", having the subgroups alpha, beta, gamma, and delta. This SARS-CoV-2 is a beta variant found in bats, palm civets, livestock, and other animals. The virus is responsible for causing respiratory problems such as colds, breathing problems, and enteric problems such as indigestion and decreased liver function [5,6]. Common symptoms include fever, cough, sore throat, headache, fatigue, myalgia, and breathlessness. The range of symptoms varies from asymptomatic cases to acute respiratory distress syndrome, multi-organ failure, and septic shock. Hypoxaemia, acute respiratory distress syndrome, arrhythmia, shock, acute cardiac injury, and acute kidney injury have also been reported in severely infected patients [7,8]. Currently, vaccination is the world-wide strategy for building immunity against coronavirus infections. Having completed their clinical studies, several vaccines are currently being administered to protect against the coronavirus. Thorough investigations

into minor side effects, serious complications, and neurological implications of various vaccines have been conducted and reported in peer-reviewed journals [9-18]. However, there is negligible data on self-reported adverse events post-vaccination. This prompted the authors to undertake a detailed study of self-perceived effects post-vaccination in the Indian population via an online survey. A detailed questionnaire covering vital adverse events that can be self-diagnosed was designed, and the study was undertaken from May 2021 to December 2021. As per the author's knowledge, this is the first-ever systematically planned study of the adverse effects reported post-vaccination and will help shed light on undesirable events experienced by the vaccinated population. Scientists, as well as regulators, can utilise this data to gain a better understanding of the vaccines currently employed in the battle against COVID-19 in India.

In India, the vaccine co-developed by University of Oxford and AstraZeneca PLC and manufactured by Serum Institute of India, Covishield™, indigenously developed Covaxin® and Sputnik V of Russian origin have been approved by DCGI for immunization.

Covishield™ is a replication-deficient chimp adenovirus vector that encodes the SARS-CoV-2 Spike (S) glycoprotein. It is produced in genetically modified human embryonic kidney (HEK) 293 cells [19]. It is administered as an intramuscular injection in two doses of 0.5 ml each; the second dose is administered between 12 and 16 weeks after the first dose. Some commonly reported side effects include pain, tenderness, warmth at the site of injection, fatigue, chills, headache, muscle pain, nausea, joint pain, and feverishness [20].

Covaxin® is developed by Bharat Biotech in collaboration with ICMR-National Institute of Virology and includes whole-virion inactivated SARS-CoV-2 antigen (strain: NIV-2020-770). It is administered as an injection into the deltoid muscle of the upper arm and is given in two doses, four weeks apart [21]. Common adverse effects include fever, headache, irritability, pain, swelling or both at the site of injection, fatigue, body aches, nausea, vomiting, and chills [22].

The Sputnik V vaccine was developed by the Gamaleya National Research Centre in Russia and is manufactured by Dr. Reddy's Laboratories in India. The Sputnik V (Gam-COVID-Vac) uses two distinct adenoviral vectors to produce the SARS-CoV-2 spike protein gene: Adenovirus 26 (Ad26) in vaccine 1 and Adenovirus 5 (Ad5) in vaccine 2. The vaccine should be administered intramuscularly in two doses, twenty-one days apart. Flu-like illness, local reaction, asthenia, injection site reaction, malaise, pyrexia, fever sensation, hypertension, headache, tonsillitis, cough, rhinorrhoea, nasal congestion, contact dermatitis, diarrhoea, nausea, dyspepsia, abdominal discomfort, myalgia, and arthralgia are the most common side effects reported [23].

Methodology

A quantitative survey-based approach was used to design a 49-item questionnaire based on the side-effects mentioned in peer-reviewed publications. The questions were mandatory and in English only. The questionnaire was in multiple-choice format, with the option of selecting one out of the four options given. All respondents' identities have been kept private. The survey was hosted on a Google-based platform, i.e., Google Form. The survey was promoted via telecalls and social media platforms, namely WhatsApp, Facebook, and Instagram. The collected data was cleaned and analysed in Microsoft® Excel using Pivot table analytics. For some questions, if the number of respondents was too small to be statistically significant, the dataset was decided to be dropped and was not included in the study. The remaining data was assimilated, analysed, and the findings were presented graphically or in table form. The questions in the online questionnaire are incorporated after the Conclusion section for the reader's benefit.

Results

The online survey was conducted on 722 respondents who were vaccinated with their first dose. Among those, 54.8% were females, while 45.2% were males. While 60.1% of the respondents were in the age group of 18 to 30, 19% were in the age group of 46 to 60 years. This indicates the enthusiastic participation of the youth in the vaccination program. Only 8.7% of the respondents were older than 60

years (Figure 1). This could be a cause for concern as studies indicate that mortality is overwhelming in this age group [24,25]. However, this may be associated with online surveys, which the elderly are unfamiliar with. A physical survey can be adopted in the future to include more older adults.

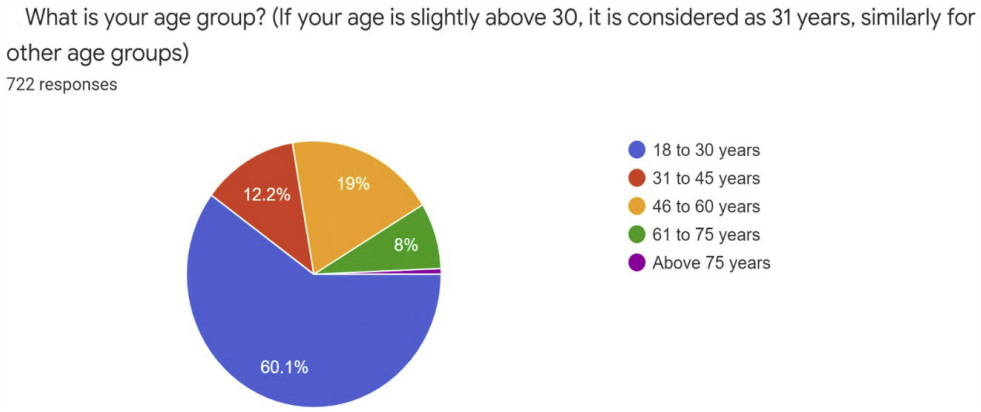

Figure 1. Age wise distribution of respondents of Covid-19 vaccination survey.

A glimpse at the data revealed that the treatment option Covishield™ was administered to 84.9% of the study group, whereas Covaxin® was administered to 13.9%, and Sputnik V was administered to 1.2%. Because of the limited number of persons who received the Sputnik V vaccination, all findings should be interpreted with a healthy dose of scepticism. It was found to be an intriguing fact that 63.8% of the respondents had had their vaccinations at government facilities, while the remaining respondents had received their vaccinations at private centres (Figure 2). This leads one to believe that most individuals were offered Covishield™ and choose to receive their vaccinations in government facilities.

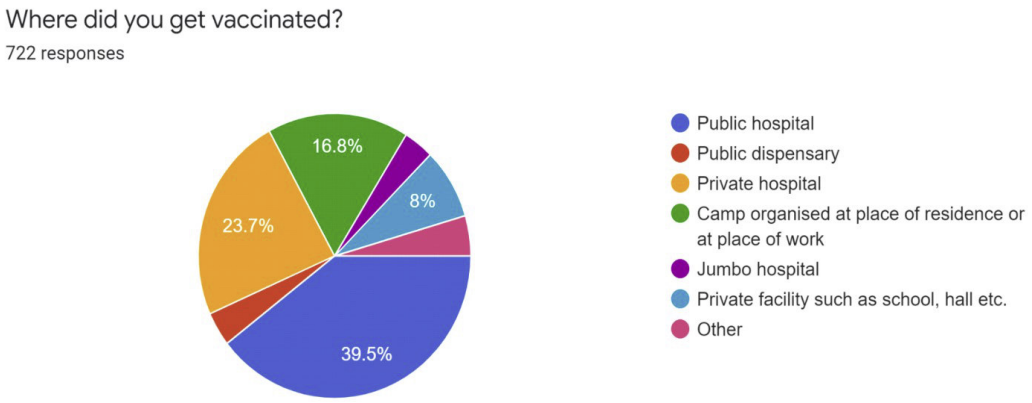

Figure 2. Place of vaccination.

In response to the query on whether adverse effects were experienced after the first dose, 46.5% answered in the affirmative. This implies that the vaccines were well tolerated by more than 50% of the respondents. The adverse effects were elicited within six hours in 31% of the vaccinated (9.7% of the overall) respondents and between 6 and 24 hours in 43.5% of the vaccinated (20.2% of the overall) respondents. The remaining respondents experienced the symptoms more than 24 hours after being vaccinated. Only 2.7% of vaccinated respondents (1.2% of total respondents) reported the onset of a severe immediate allergic reaction, with 0.4% hospitalized. This number is statistically insignificant but needs to be substantiated with bigger sample size.

Investigation of the data revealed that nine out of 613 (less than 1.5%) respondents injected with Covishield™ experienced an immediate allergic response. Of these, three respondents were hospitalised for treatment and discharged after that. One in nine respondents (11.1%) vaccinated with Sputnik V reported an immediate adverse effect but did not require hospitalisation, while none of the 100 injected

with Covaxin® reported an immediate allergic response. Overall, symptoms subsided in 20.5% of vaccinated respondents within 12 hours, 38.5% of vaccinated respondents within 12 to 24 hours, and 41.0% of survey respondents within 48 hours.

Pain, redness, or swelling at the site of the injection was reported by 72.3% of the vaccinated respondents (33.6% of total respondents). This is a commonly reported drawback of vaccines and, therefore, not a cause for concern [26]. Amongst the other side effects reported were fever (34.6% of the overall respondents), headache (27.1% of the overall respondents), body ache (33.3% of the overall respondents), muscle pain (31% of the overall respondents), joint pain (14.5% of the overall respondents), tiredness and lethargy (34.6% of the overall respondents), chills (20.2% of the overall respondents), nausea (10.5% of the overall respondents), giddiness (10.0% of the overall respondents) and diarrhoea (2.9% of the overall respondents). A drug allowed by the government protocol was given to 51.4% of the respondents to counteract the adverse effects. The percentage of people experiencing individual side effects after the first and second doses is summarised in Table 1.

Table 1. Individual adverse effects experienced by vaccinated respondents after the first and second doses of Covid-19 vaccines expressed in percentage.

Sr no	Adverse effect	Percentage after first dose *	Percentage after second dose**
1	Overall	46.5	21.2
2	Immediate allergic reaction	2.7	0.47
3	Pain/redness/swelling	33.6	13.2
4	Headache	27.1	9
5	Body ache	33.3	14.1
6	Muscle pain	31	11.3
7	Joint pain	14.5	7.5
8	Tiredness & lethargy	34.6	13.7
9	Chills	20.2	6.6
10	Fever	34.6	9.4
11	Nausea	10.5	1.4
12	Giddiness	10	3.7
13	Diarrhoea	2.9	0.9

* Percentage is calculated based on the total number of respondents who were vaccinated with the first dose i.e., 722 respondents.
** Percentage is calculated based on number of fully vaccinated respondents i.e., 212 respondents.

It is evident that the prevalence of side effects after the second dose is significantly lower, indicating a higher level of tolerability and apparent safety (Figure 3).

Reflecting on this, more than 30% of the respondents of this survey who were vaccinated with the first dose of the COVID vaccine reported pain/redness/swelling, fever, body aches, muscle pain, tiredness, and lethargy. In contrast, a smaller percentage of respondents affirmed the other side effects, including headache, joint pain, chills, nausea, giddiness, and diarrhoea. None of the above side effects is severe and has subsided completely. These findings correlate well with the reported adverse events of COVID vaccines [9-18, 26].

The second half of the survey questionnaire revealed that only 212 out of 722 respondents had completed the second dose per the protocol and were categorised as fully vaccinated. This can be attributed to the interval between two doses being 84 days for Covishield™, the vaccine administered to most of the people who have participated in this study. Also, vaccination of those in the age group of 18 to 44 years commenced in May 2021. After the second dose, only 21.2% of the total respondents (45 out of 212) experienced side effects, as compared to 46.5% after the first dose. This indicates that the tolerability of the second dose is higher than the first dose. Symptoms were elicited within 6 hours in 22% of those who reported adverse effects and within 6 to 24 hours in another 62.2%. The adverse effects subsided for 66% of these respondents within 24 hours. In 0.9% of fully vaccinated respondents, Covishield™ and Covaxin® elicited severe immediate allergic reactions (statistically insignificant but needs to be validated in a larger study population).

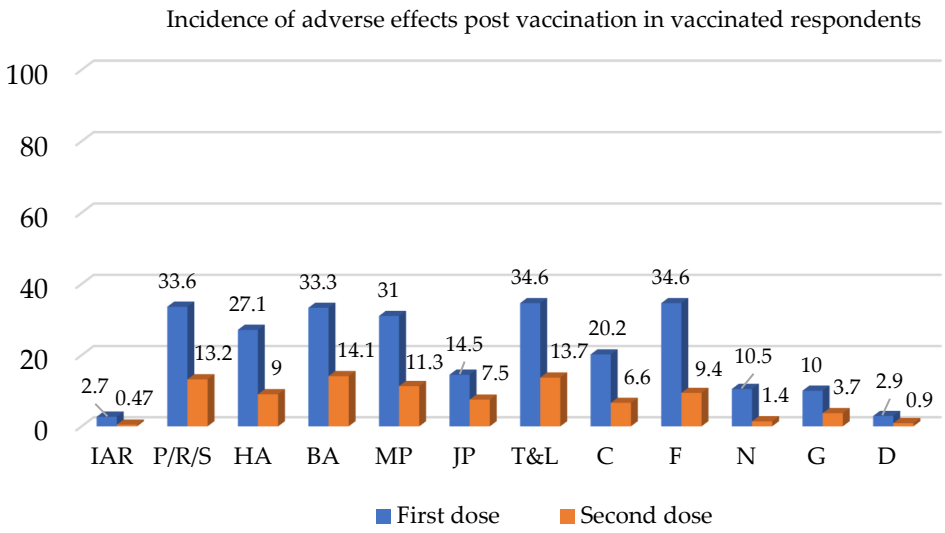

Figure 3. A graph depicting the percentage of respondents who experienced side effects after receiving the first and second doses of vaccine.
Immediate allergic reaction (IAR); Pain/redness/swelling (P/R/S); Headache (HA); Body ache (BA); Muscle pain (MP); Joint pain (JP); Tiredness & lethargy (T&L); Chills (C); Fever (F); Nausea (N); Giddiness (G); Diarrhoea (D).

MS Excel was used to further analyse the gathered data in order to uncover crucial information about these vaccines.

Correlation between age and adverse effects

There is no difference in adverse effects for those between the ages of 18 and 60 (Table 2) after the first dose and after the second dose of the vaccine. However, there is an overall drop in the percentage of respondents experiencing adverse effects after the second dose. Unsurprisingly, in the age group of 61 years and above, adverse effects are reported by 19% after the first dose and 10.4% of those fully vaccinated. This is substantial evidence that an ageing-associated decline in immunity leads to a lower incidence of adverse events.

Table 2. The age distribution of respondents who experienced adverse effects after receiving their first and second doses of COVID-19 vaccine.

Age group	Percentage of vaccinated respondents who reported adverse effects after first dose *	Percentage of fully vaccinated respondents who reported adverse effects after second dose*
18 to 30 years	49.7**	26.5
31 to 45 years	45.5	26.3
46 to 60 years	49.6	22.6
61 to 75 years	19.0	10.4
Above 75 years	20.0	Not reported

* Percentages are calculated based on the total number of vaccinated respondents of each of the age groups.
** A total of 434 respondents in the age group 18 to 30 received the first dose. Of these, 216 (49.7%) experienced adverse effects. Similar calculations have been done for other sub groups.

Adverse effects in males versus adverse effects in females

As shown in Table 3, the incidence of adverse events following the first and second doses of the vaccination was significantly greater in females compared to males. After the second dose, the adverse effects were less severe in both males and females.

Does post-covid vaccination influence the occurrence of adverse effects?

It would be interesting to find out how many people who were vaccinated soon after turning out to have a positive COVID test reported experiencing adverse effects. In light of this, the data collected were analysed, and the results may be found in Table 4.

As per the data, whether a person has been infected with COVID or not has no bearing on the frequency of occurrence of adverse events after the first and the second dose.

Table 3. Shows the percentages of males and females who experienced side effects after receiving the first and second doses of COVID-19 vaccines.

Sex	Percentage of vaccinated respondents suffering from adverse effects after first dose*	Percentage of fully vaccinated respondents suffering from adverse effects after second dose*
Male	38.0	17
Female	53.0	25.4

*Percentages are calculated based on the total number of vaccinated respondents of each sex.

Percentage of people showing adverse effects after vaccination with each of the vaccines in the study

As compared to Covishield™, Covaxin® and Sputnik V recipients elicited a lower incidence of adverse drug effects after the first dose (Table 4). Nevertheless, after the second dose, Covishield™ has a lower frequency of side effects than the other two vaccines (Table 5). However, because the number of completely vaccinated (both doses) respondents is so small (212), this data may need to be verified further.

Table 4. Correlation between covid positive status and adverse effects.

Covid status in last six months	Percentage of respondents suffering from adverse effects after first shot*	Percentage of respondents suffering from adverse effects after second shot*
Covid positive	47	15.3
Covid negative	46.5	21.6

* Percentages are calculated based on the total number of vaccinated respondents of each sub group.

The study concluded with an opinion poll, revealing that 89% of the vaccinated respondents continued to follow COVID-appropriate behaviour post-vaccination. These COVID warriors diligently followed protocols of social distancing, wearing masks and frequent sanitization of hands. Thus, government policies and awareness campaigns can be concluded to be highly effective.

Table 5. Effect of each of the vaccines on the occurrence of adverse effects.

Vaccine	Percentage of respondents suffering from adverse effects after first shot	Percentage of respondents suffering from adverse effects after second shot
Covishield™	50.4	17.5
Covaxin®	25.0	28.8
Sputnik V	22.2	33.0
Overall	46.5	21.2

Discussion

This study is one of the first comprehensive compilations of self-reported adverse effects of the COVID vaccine in India that is academic in origin and carried out by pharmacy professionals. This study is an independent pharmacovigilance study carried out on the three vaccines currently being used in the fight against COVID in India, namely Covishield™, Covaxin®, and Sputnik V. The authors wish to draw the readers' notice that while the sample size was small (722 respondents), the subjects were heterogeneous. Therefore, the findings of this survey can be used better to understand the nature and severity of self-reported adverse effects. Regulators can also use the data to corroborate the claims made by the vaccine manufacturers.

This study has brought forth several valuable insights into COVID vaccine-related adverse effects. To summarise as:

- The younger generation (18 to 30 years) has participated enthusiastically in the immunisation drive, thereby contributing to its success.
- The incidence and severity of adverse effects due to COVID vaccination decreased with age. Those aged 60 and above were less likely to be inconvenienced by these adverse events.
- Females were more likely to experience adverse effects.
- There is a greater likelihood of people getting vaccinated at government-run centres.

- The vast majority of those immunized did not report experiencing any adverse side effects. Most patients could heal without experiencing any severe side effects, whether they took medicine or not. Although hospitalization was necessary for a small proportion of the respondents, full recoveries were achieved.
- The side effects perceived by the respondents included pain, redness, swelling at the site of the injection, fever, headache, body ache, muscle pain, joint pain, tiredness, lethargy, chills, nausea, giddiness, and diarrhoea. These symptoms were reported after the first and second doses of the vaccine.
- Being diagnosed as COVID positive in the immediate past had no bearing on the extent of adverse effects experienced by the respondents.
- Compared to Covaxin® and Sputnik V, more than a dozen respondents experienced adverse effects after the first shot of Covishield™. However, it was better tolerated than the others after the second dose. Overall, there was a significant drop in the number of people reporting adverse events after the second dose compared to the first dose.

Conclusion

The data and the findings presented herewith are based on an independent study using an online survey methodology. The questionnaire collected information about the symptoms that were self-perceived by vaccinated people. The data was analysed and compiled in an easy-to-understand and easy-to-interpret manner. This preliminary evidence can be used as a starting point for better understanding the adverse effects of COVID vaccination. The study can be extended further by carrying out a pan-India survey with a more significant number of subjects vaccinated with both doses and can look into the long-term effects of vaccination. The scope of the study can be broadened further by carrying out a similar survey in the subpopulation that has received the booster dose. On the other hand, the authors would like to emphasise that the possibility of experiencing potential adverse effects is dependent on the prevalence and reporting of other more serious but less visible health problems such as thrombosis, myocarditis, and other conditions that cannot be self-perceived and require the expertise of a trained professional as well as dedicated notification. Regulatory agencies must create dedicated pharmacovigilance centres to collect evidence of adverse occurrences that could have significant repercussions.

Questions included in the online questionnaire

What is your age group? (If your age is slightly above 30, it is considered as 31 years, similarly for other age groups)

What is your sex?

What is your body weight? (If your weight is slightly above 40, it is considered as 41 kg, similarly for other groups)

What is your height?

Do you have diabetes?

Are you suffering from arthritis?

Do you have psoriasis/vitiligo?

Have you been detected as covid positive in the last six months?

Which vaccine did you receive?

Where did you get vaccinated?

Did you experience any side effects/adverse effects after vaccination?

How soon did the symptoms appear after vaccination?

How quickly did the symptoms subside?

Did you experience severe immediate allergic reaction?

Were you hospitalised due to severe allergic reaction?

Did you experience pain/redness/swelling at the site of injection

How quickly did the pain/redness/swelling at the site of injection subside?

Did you experience headache post vaccination?

Did you experience body ache post vaccination?

Did you experience muscle pain post vaccination?
Did you experience joint pain post vaccination?
Did you experience tiredness and lethargy post vaccination?
Did you experience chills post vaccination?
Did you develop fever post vaccination?
Did you feel nauseous post vaccination?
Did you experience giddiness post vaccination?
Did you experience bout of diarrhoea post vaccination?
Did you take any medicines to counter the side effects?
Have you taken the second dose of vaccine?
Where did you get vaccinated?
Did you experience any side effects/adverse effects after vaccination?
How soon did the symptoms appear after vaccination?
How quickly did the symptoms subside?
Did you experience severe immediate allergic reaction?
Were you hospitalised due to severe allergic reaction?
Did you experience pain/redness/swelling at the site of injection
How quickly did the pain/redness/swelling at the site of injection subside?
Did you experience headache post vaccination?
Did you experience body ache post vaccination?
Did you experience muscle pain post vaccination?
Did you experience joint pain post vaccination?
Did you experience tiredness and lethargy post vaccination?
Did you experience chills post vaccination?
Did you develop fever post vaccination?
Did you feel nauseous post vaccination?
Did you experience giddiness post vaccination?
Did you experience bout of diarrhoea post vaccination?
Did you take any medicines to counter the side effects?
Do you wear a mask, maintain social distance and sanitise frequently post second dose of vaccine?

Ethical statement

The authors have conducted an online survey of people post voluntary vaccination and collected data about self-perceived symptoms. No clinical investigation of any kind was performed. Since this is a nationwide online survey and not a clinical study, approval from ethics committee was not considered necessary. Therefore, Helsinki declaration is not needed here.

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Authors contribution

All the authors have contributed equally.

Conflict of interest

The authors declare no conflict of interest.

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