Title page

TITLE

Suspected adverse events following immunization against SARS-CoV2 in a university hospital in 2021

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Author contributions

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Funding

This is an Investigator Initiative study which has not received any specific grant. This study will be carried out with the research team's own funds.

Declaration of Interests

The authors declare no conflict of interests.

Availability of data

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Abstract

Aim: Vaccination against SARS-CoV2 has been proposed as a fundamental element for the control of the pandemic. The aim of this study is to describe the suspected adverse reactions (ADRs) reported among vaccinated hospital workers.

Methods: Descriptive study of suspected ADRs identified between January and March 2021. The suspected ADRs were identified by specifically designed electronic form and by spontaneous reporting. Data was also collected regarding the characteristics of the professionals, vaccine administered, severity, and outcome of the ADR.

Results: 8,169 professionals received the two doses of SARS-CoV2 vaccine (6,672 Comirnaty® and 1,497 Spikevax®) and 894 reports of suspected ADR were reported (762 for Comirnaty® and 132 for Spikevax®), so a cumulative AEFIs incidence of 10.94% (95%CI: 10.27-11.62). The majority of ADRs were reported only after the second dose, 497(56.2%) while 211 (23.6%) was reported only after the first dose and a 186 (21%) after both doses. Symptoms were mostly mild, did not require medical assistance and disappeared in about 3 days. One hundred and seventeen professionals had a history of COVID-19. These reported, statistically significant, more suspected ADRs after the first dose (42.7%) than professionals with no history of COVID-19 (20.7%). Among the professionals, more ADRs occurred after the first dose with the Spikevax® vaccine (41.6%) than with the Comirnaty® vaccine (20.5%).

Conclusion: The majority of the suspected ADRs reported were those described in the summary of product characteristics (SmPC). Professionals with history of COVID-19 reported more suspected ADRs after the first dose than professionals without history.

Keywords:

COVID-19 Vaccine, SARS-CoV-2 Vaccine, SARS-CoV-2, COVID-19, pharmacovigilance, viral vaccines

Abbreviations

AEMPS	Spanish Agency for Medicines and Health Products
US	United States of America
EMA	European Medicines Agency
FDA	Food and drug administration
EMR	Electronic medical records
HUB	Bellvitge University Hospital
MedDRA	Medical Dictionary for Regulatory Activities
PhFV	Pharmacovigilance Program
ADR	Adverse drug reaction
SEFV	Spanish Pharmacovigilance System
SmPC	Summary of product characteristics
SPSS	Statistical Package of Social Sciences
VAERS	Vaccine Adverse Event Reporting System

What this study adds?

What is already known about this subject: The available information on the safety of the COVID-19 Vaccine in humans in clinical trials has shown a favorable risk/benefit ratio. The adverse effects described as frequent in humans in clinical trials was pain at the injection site, fatigue or feeling tired headache, myalgia, chills, arthralgia, fever and lymphadenopathies. There is a need for additional information on vaccine use in the general population outside the context of clinical trials.
What this study adds: Most of the suspected ADRs that appear after the administration of the vaccine against COVID-19 are those described in the summary of product characteristics. Spontaneous reports of adverse reactions have confirmed that the COVID-19 Vaccine in humans has a favorable risk / benefit ratio. Professionals with a history of COVID-19 disease filed a greater number of reports after the first dose.

Manuscript

INTRODUCTION

Despite the improvement in treatment for COVID-19 over the months, no curative treatment is available to date. For this reason, vaccination plays a key role in the control of the pandemic. (1)

Vaccination campaigns began in Catalonia in December 2020, following the indications of the vaccination strategy defined in the document: *COVID-19 Vaccination strategy in Spain*. Priority was given to populations considered essential, including healthcare/nursing home personnel, as well as residents and dependent elderly people. The strategy was updated according to the epidemiological situation, the availability of vaccines, and the emergence of new information. (2)

Authorization for the COVID-19 vaccines was granted as the results of the clinical trials emerged. The European Medicines Agency (EMA) first authorized the Comirnaty® vaccine developed by BioNTech/Pfizer (3) on December 21st, 2020, then Spikevax® developed by Moderna/Lonza (4) on January 6th, 2021, the Vaxzevria® vaccine of AstraZeneca (5) on January 29th, 2021, and the Janssen® COVID-19 Vaccine (6) on March 15th, 2021. All have received conditional authorization and are subject to additional follow-up with intensive monitoring.

The available information on the safety of the vaccines in humans was evaluated by the regulatory agencies, which permitted the authorization of these vaccines for presenting a favorable risk/benefit ratio. The adverse effects described as frequent in the summary of product characteristics (SmPC) are pain at the injection site, fatigue or feeling tired, headache, myalgia, chills, arthralgia, fever and lymphadenopathies. However, there is a need for additional information on vaccine use in the general population outside the context of clinical trials. (7) An analysis has been published on the reports received by the Vaccine Adverse Event Reporting System (VAERS), a US vaccine safety surveillance program run by the Centers for Disease Control and Prevention and the Food and Drug Administration (FDA), regarding COVID-19 mRNA vaccines. This report analyzed 3,908 adverse reactions gathered during December 2020, in a population with an average age of 42 years, where 80% were women and 95% referred to the vaccine developed by BioNTech/Pfizer. The most frequently described adverse reactions were fatigue, pain, chills, headache, dizziness, and paresthesia (8).

Europe has established a Pharmacovigilance Plan Network with different strategies to evaluate the safety of post-market COVID-19 vaccines, which includes, among others, encouraging the spontaneous reporting of suspected adverse reactions to vaccines through the options offered by the Spanish Pharmacovigilance System (SEFV) (7). The main objective of the Pharmacovigilance Plan is to identify signals of adverse events that may not have been detected in clinical trials (9,10). On the other hand, the regulatory agencies provide updated and aggregated information regarding the suspected adverse drug reaction (ADR) reports received. The Spanish Agency of Medicines and Health Products (AEMPS) provides regular information in its Pharmacovigilance Reports on the COVID-19 vaccine (11).

The Pharmacovigilance Program (PhFV) carried out by the Clinical Pharmacology Department of Bellvitge University Hospital (HUB), in collaboration with other departments of the hospital, has intensified efforts aimed at identifying the appearance of these suspected ADRs among professionals who received the vaccine at HUB, along with facilitating the delivery of these reports to the Spanish Pharmacovigilance System. The objective of this study is to describe the suspected ADRs collected from vaccinated hospital workers between January and March, 2021.

METHODOLOGY

Study design and population

This is an observational, retrospective, and descriptive study of suspected ADRs identified among healthcare and non-healthcare professionals included in the HUB vaccination campaign during the period from January 5 to March 31, 2021.

Inclusion and exclusion criteria

Included were healthcare and non-healthcare professionals from the HUB and from external collaborating companies such as the blood bank, logistic services, emergency medical services, ambulances, and others that received one of the COVID-19 vaccines at the hospital and that reported a suspected ADR to the PhFV of the HUB during the study period, either after the first and/or second dose between January and March 2021.

Vaccine Administration Strategy and Pharmacovigilance Program

On January 5th, 2021, vaccines began to be administered among the healthcare and no-healthcare professionals of the HUB. The first doses administered corresponded to the first vaccine available, which was Comirnaty® of BioNTech/Pfizer, and, as of February, Spikevax® of Moderna/Lonza was also administered, jointly, according to the availability of the vaccines.

The vaccination strategy criteria followed the guidelines defined by the Spanish National Health System included in the COVID-19 Vaccination Strategy document. This document underwent several modifications, five of which appeared during the study period. One of the relevant changes in version 4 of the aforementioned document dated February 26th (2) was to administer a single dose of vaccine to those under the ages 55 with a history of COVID-19.

HUB is a 770-bed tertiary care public hospital for adults in Barcelona (Catalonia, Spain). Since 2007, HUB has a PhFV that, among other activities, carries out intensive monitoring of suspected ADRs as the cause of emergency department patients to be admitted for in-hospital care and, also, collects the suspected ADR reports from HUB professionals. This Program facilitates the reporting of ADRs to the SEFV (12). With the rollout of COVID-19 vaccination, the HUB's PhFV has redirected its activities, on the one hand, to the close monitoring of the safety issues regarding the vaccination of hospital workers and, on the other hand, to the identification of possible unknown ADRs. To this end, efforts were intensified to encourage spontaneous reporting among vaccinated professionals. Emails were sent to all

professionals containing the email address and telephone number of the Clinical Pharmacology Department. An online ADR report form was created with access for the personnel cited for vaccination so they could file a report if they deemed it necessary, and which was specifically designed to facilitate the identification of signals regarding vaccine toxicity. This form included a list of the ADRs described in the SmPC and an open section for other undescribed ADRs.

Selection process

The sources of identification of the suspected ADRs were:

1. An electronic ADR report form, specifically designed, to which the staff member summoned for vaccination had access in order to file a report that could be related to the administration of the vaccine. There was a list of known ADRs (pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, fever, lymphadenopathies, urticarial rash, and digestive symptoms) and a free report section.
2. Spontaneous report to the Clinical Pharmacology Department staff through other means (telephone, email, in-person) already provided for by the HUB's PhFV.

Study variables

Data were collected regarding the characteristics of the professionals: demographic data, pathological history, and history of COVID-19. From the data on suspected ADRs, the descriptor term of the suspected ADRs reported was collected. The date of ADR onset, the number of general symptoms, ADR duration, severity, outcome, and the causality algorithm were also collected. The data gathered regarding the vaccine were the name, site (arm) of administration, batch number, and date of vaccination.

The definition of ADR employed was the one established on the Royal Decree 577/2013, which regulates pharmacovigilance in Spain (13). The MedDRA (*Medical Dictionary for Regulatory Activities)* version 24.0 was used for the coding and classification of the descriptor terms for reactions. For the construction of the causality algorithm, the imputation methods of the SEFV were followed (14).

Follow-up

The professionals were followed-up via electronic medical records (EMR) to know if they had required medical assistance to treat the symptoms, to assess severity, and the outcome. In case of doubt or lack of information in the EMR, the information was collected via a phone call to the professional in itself.

Statistical analysis

A descriptive analysis of the variables studied was performed. Results were expressed as absolute and relative frequencies for qualitative variables, and by mean, standard deviation or median and interquartile range when appropriate for quantitative variables. A Chi-squared test was performed for the comparison of percentages and t-student for the comparison of means if a normal distribution appeared. Statistical significance was determined at a p-value <0.05 with a 95% confidence interval. The statistical analysis

was carried out with the programs: Microsoft Office Excel 2007 and Statistical Package of Social Sciences (SPSS) version 25.

No calculation of the sample size was performed as all suspected ADRs reported by the professionals who met the inclusion criteria during the study period were collected.

Ethical aspects

The study protocol obtained approval from the HUB Drug Research Ethics Committee. All suspected ADRs considered of special interest were reported to the Catalan Pharmacovigilance Centre of the SEFV (15).

RESULTS

From January 5th to March 31st, 2021, 9,549 first doses of vaccine were administered (6,906 of Comirnaty® and 2,643 of Spikevax®) and 8,169 second doses (6,672 of Comirnaty® and 1,497 of Spikevax®). Among those vaccinated during this same time period, 894 professionals reported a suspected vaccine-associated ADR. Only one dose was administered in nine cases as they had had the disease and, according to the state recommendations of February 26, 2021, a second dose was not necessary if the professional was under 55 years of age. Of the 894 cases, 211 (23.6%) reported a suspected ADR only after the first dose. Of the 885 cases receiving the two doses, 497 (56.2%) presented a suspected ADR with only the second dose and 186 (21%) with both doses. Regarding the 8,169 professionals who received the two doses of vaccine (full vaccination), the percentage of cases that reported a suspected ADR to the vaccine in one of the two doses (894 cases) was 11%.

Baseline Characteristics

The mean age of the population reporting a suspected ADR was 39 years-old (range 18 to 69 years) and 696 (78%) were women. Regarding the professional category, 317 (35.5%) were nursing professionals, 294 (33%) corresponded to other healthcare professionals (nursing assistants, laboratory and radiology technicians), 146 (16.3%) were non-healthcare professionals, and 137 (15.3%) were physicians. There was a history of chronic disease in 148 (16.6%) cases, where hypertension, present in 26 cases (3%), and thyroid alterations, present in 24 cases (2.7%), stand out.

A history of having had COVID-19, confirmed by a positive diagnostic test in the clinical history, was present in 117 cases (13%).

Description of suspected adverse reactions

Table 1 presents the most common adverse effects differentiated according to whether they appeared regarding the first or second dose.

Among the other suspected ADRs (**Table 1)**, episodes of herpes simplex (6 cases) and herpes zoster (5 cases) reported after the first dose stand out; as well as an episode of thrombophlebitis of the

thoraccoepigastric vein after the first dose and another of phlebitis at the same location after the second dose. These two venous episodes were related to the Comirnaty® vaccine and recovered favorably.

The median duration of symptoms was 2 days (IQR 1-3 days) for de first dose, with a mean of 3,7 days and a range of 1 to 36 days. The median duration of symptoms at the second dose was 2 days (IQR 1-2 days), with a mean of 2,8 days and a range of 1 to 60 days.

A specific analysis was carried out for the six most common general symptoms (fatigue, headache, myalgia, arthralgia, chills, and fever). After the first dose, 225 (25.2%) professionals reported one of these general symptoms and 619 (70%) reported them after the second dose. Since some professionals reported the occurrence of several of these symptoms at the same time, **Figure 1** shows the distribution of professionals by the number of general symptoms reported simultaneously according to whether they were reported after the first or second dose.

Healthcare demand, outcome, severity, and causality of suspected ADRs

Among the 397 professionals who presented a suspected ADR after the first dose, 36 (9%) required medical assistance (20 consulted in a primary care center and 16 in the hospital's emergency room), 373 cases (94%) had recovered at the time of terminating the study. Only one case was considered serious, being a thrombophlebitis of the thoracoepigastric vein. In 369 (93%) cases, the association between the vaccine and the ADR was considered probable, in 25 (6.3%) cases possible, in two cases defined, and in one case conditional.

Among the 683 professionals who presented a suspected ADR after the second dose, 57 (8.3%) requested medical assistance (one case required hospital admission for pneumonia, 41 consulted in a primary care center, and 15 in the hospital's emergency room). Six hundred and fifty-five cases (97.3%) had recovered at the time of terminating the study, two cases were considered severe (pneumonia and phlebitis of the thoracoepigastric vein in a patient different to the one presented regarding the first dose). In 664 (97.2%) cases, the association between the vaccine and the ADR was considered probable, in 17 (2.5%) cases possible, and in two cases definite.

Professionals with a history of COVID-19

Among professionals who reported a suspected vaccine-associated ADR, 117 (13%) had a history of SARS-CorV-2 infection. The mean age was 39 years, the same as for the whole group under study, regardless of SARS-CorV-2 infection. There was a higher percentage of men in the cases with a history of COVID-19 than without, 39 (33.3%) vs. 159 (20.5%). This difference is statistically significant (p-value: 0.002). Only seven (6%) cases had been admitted to hospital for COVID-19, two of them in intensive care. The mean time from COVID-19 diagnosis (positive PCR) to vaccine administration was 6.74 months, with a median of eight. In 45 (38.5%) cases the vaccine was administered less than 6 months after contracting the disease, and after less than 3 months in 25 (21.4%) cases **(see Figure 2).**

Among the professionals with a history of COVID-19, the Comirnaty® vaccine was employed in 88 (75.2%) cases and the Spikevax® vaccine in 29 (24.8%). Among professionals without a history of COVID-19, 674 (86.7%) received the Comirnaty® vaccine and 103 (13.3%) Spikevax®. The proportion of cases that received the Moderna vaccine was higher than Pfizer/Biontech among those who had contracted COVID-19, this difference being statistically significant (p-value 0.001).

Table 2 describes the number of reports received according to dose in the two groups (with or without a history of COVID-19). More ADRs were reported after the first dose than after the second by the professionals who had had SARS-Cov2 infection when compared to those who had not had the disease (p<0,05). **Figure 3** describes the suspected ADRs reported according to whether they appeared after the first or second dose.

With respect to the number of general symptoms (fatigue, headache, myalgia, arthralgia, chills and fever), the mean was 1.73 symptoms for professionals with a history of COVID-19 after the first dose and 0.45 for those without [p-value <0.001; 95%CI: (-0.5,-1.01)]; while the mean of general symptoms for professionals with a history of COVID-19 after the second dose was 2.11 and 2.51 for those without [p-value: 0.137; 95%CI: (-0.2, +0.8)]. **Figure 4** shows the distribution by number of general symptoms per group.

The mean duration of symptoms was 3.24 days for the first dose among professionals with a history of COVID-19, and 3.79 for those without [p-value: 0.068; 95%CI: (-0.8, +1.9)]. As for the second dose, the mean duration was 2.09 for professionals with a history of COVID-19 and 2.91 for those without [p-value: 0.024; 95%CI: (-0.4, +2)].

Regarding the demand for care, outcome, severity, and causality criteria of the suspected ADRs, there were no differences between the two groups, either with the first or second dose.

Professionals vaccinated with Comirnaty® or Spikevax®

Among professionals who reported a suspected vaccine-associated ADR, 762 (85.2%) cases had received the Comirnaty® vaccine and 132 (14.8%) the Spikevax® vaccine.

With respect to the 6,672 professionals who received the two doses of the Comirnaty® vaccine (full vaccination), the percentage of cases that reported a suspected vaccine-associated ADR with one of the two doses was 11.42% (95%CI: 10,72-12,13; 762 cases). For the 1,497 professionals who received the two doses of the Spikevax® vaccine (full vaccination), 8.82% (95%CI: 7,38-10,25; 132 cases) reported suspected vaccine-associated ADRs with one of the two doses, so statistically lower than with Comirnaty exposure.

The mean age was 38 years for those receiving Comirnaty® and 42.5 years-old for those receiving Spikevax® [p 0.58; CI(-4.9, -0.6)]. The gender distribution was similar between the two vaccine groups

with 594 (78%) women receiving Comirnaty® and 102 (77.3%) receiving Spikevax®.

Among the cases that received Comirnaty®, 88 (11.5%) had had COVID-19 compared with 29 cases (22%) for Spikevax®. This difference is statistically significant (p 0.001).

Of the 762 cases vaccinated with Comirnaty®, 301 (39.5%) reported a suspected ADR after the first dose. One case did not receive the second dose as they had had the disease and were under 55 years of age. Of the 761 cases who received the second dose, 606 (79.6%) had a suspected ADR after the second dose. Of the 132 cases vaccinated with Spikevax®, 96 cases (73%) reported a suspected adverse reaction after the first dose. In eight cases the second dose was not administered as they had had the disease and were under 55 years of age. Of the 124 cases who received the second dose, 77 (62%) had a suspected ADR after the second dose. **Table 3** describes the number of reports received according to dose in the two groups. The professionals who received Spikevax® reported more ADRs after the first dose than the second.

Figure 5 shows the suspected ADRs reported according to whether they appeared after the first or second dose.

With respect to the number of general symptoms (fatigue, headache, myalgia, arthralgia, chills and fever), mean symptoms were 0.49 for professionals receiving the first dose of Comirnaty® and 1.32 for Spikevax® [p-value <0.001; 95%CI: (-1.06,-0.6)], while the mean symptoms for professionals receiving the second dose was 2.5 for Comirnaty® and 2.2 for Spikevax® [p-value: 0.09; 95%CI: (-0.96, +0.8)]. **Figure 6** shows the distribution by number of general symptoms per group.

The mean duration of symptoms was 3.80 days for the first dose among professionals receiving Comirnaty®, and 3.32 for Spikevax® [p-value: 0.27; 95%CI:(-0.8, +1.55)]. At the second dose, the mean was 2.86 for Comirnaty® and 2.59 for Spikevax® [p-value: 0.4; 95%CI: (-0.9, +1.4)].

Regarding to the demand for care, outcome, severity, and causality criteria of suspected ADRs there were no differences between the two groups, either with the first or second dose.

***Post hoc* analysis: differences in suspected ADRs between the first dose of Comirnaty® and the first dose of Spikevax®.**

The fact that a higher percentage of professionals with a history of COVID-19 received the Spikevax® vaccine could justify the higher frequency of ADRs reported after the first dose of Spikevax® than with Comirnaty®. To corroborate this possible explanation, a *post hoc* analysis was carried out for the suspected ADRs after the first dose of the two vaccines, separating the professionals into groups with or without a history of COVID-19 **(see table 4).** As regards general (fatigue, headache, myalgia, arthralgia, chills and fever) and gastrointestinal symptoms, the differences were greater among professionals with a history of COVID-19, but there was still a higher number of reports relating to the first dose among

professionals who received the Moderna/Lonza vaccine and had not had COVID-19. However, regarding to pain at the injection site, there was a greater difference for professionals with no history of COVID-19.

DISCUSSION

The main results of this study show that, in three months, 9,549 professionals were vaccinated with one dose and 8,169 with two doses. Suspected ADRs were reported by 894 professionals, representing 11% of those vaccinated in that time period. There was a higher percentage of reports associated with the second dose (77.2%) than with the first (44.4%). The majority of suspected ADRs reported are those included in the SmPC. As seen in clinical trials (16,17), pain at the injection site and general symptoms (fatigue, headache, myalgia) are the most reported ADRs. These symptoms, as also detected in the clinical trials conducted, appear more frequently after the second dose. In most cases, they were mild symptoms that did not require medical assistance and recovery was achieved in about 3 days.

Among the undescribed ADRs, herpes simplex and herpes zoster were the most frequent notifications, as well as dizziness and paresthesia. Post-marketing safety monitoring and reporting of undescribed suspected ADRs is the most appropriate strategy for assessing less frequent adverse reactions associated with medicinal products and also with vaccines (18). Hence, the pharmacovigilance programs of different health centers play a fundamental role in the generation of new signals. In recent months we have seen important changes in the SmPC of some vaccines, as well as recommendations affecting specific population groups (19).

Among professionals who had had COVID-19, more suspected ADRs were reported after the first dose when compared with those who had not had the disease. The number of general symptoms was also higher among professionals with a history of COVID-19. However, the ADR profile and prognosis were similar in both groups. This information may be useful for adjusting vaccination strategies among different population groups (20).

In the fourth Pharmacovigilance report on COVID-19 vaccines published on April 9th, 2021, by the AEMPS, the 10 most frequently reported suspected ADRs for both Comirnaty® and Spikevax® vaccines were: pyrexia, headache, myalgia, pain at the injection site, discomfort, nauseas, chills, arthralgia, fatigue, and lymphadenopathy. Although the percentages are different from those in our study, the ADR profile is very similar. Regarding unknown ADRs, the gastrointestinal ADRs (diarrhea and vomiting) were the ones also detected in our study. However, other less common adverse events listed in the report, such as immune thrombocytopenia, were not reported in our study. (21)

In the publication of the reports analyses received by the Vaccine Adverse Event Reporting System (VAERS), 3,908 ADRs were collected during December 2020. The population included was similar to that included in our study: average age of 42 years-old, 80% women, and 95% referred to the vaccine developed by Pfizer. The most frequently described ADRs in the publication were fatigue, pain, chills, headache, dizziness and paresthesia. This ADR profile is very similar to that of our study, where dizziness

and paresthesia were, in addition to the symptoms described in clinical trials, frequent suspected ADRs (8).

The Spikevax® vaccine rollout happened later. Maybe for this reason fewer professionals were referred to this vaccine, although the number of vaccines available in the hospital could also justify this difference. Among those that received Spikevax®, there was a higher proportion of professionals with a history of COVID-19. This could be justified due to the later introduction of the Spikevax® vaccine and that some professionals were waiting for the recommended time to elapse between disease and vaccine administration. On the other hand, the fact that the percentage of professionals with a history of COVID-19 is higher in the Spikevax® group could explain why the ADR reports were more frequent after the first dose with Spikevax® than with Comirnaty®. However, the post hoc analysis performed showed that the differences were greater for those with a history of COVID-19, when considering only general and gastrointestinal symptoms. Additionally, a greater number of reports after the first dose was maintained among professionals who received the Moderna vaccine, including those who had not had COVID-19. A review published by Meo *et al*., on the comparison between the Comirnaty® and Spikevax® vaccines, also suggests that the latter presents a greater number of ADRs, although the same authors affirm that these results could be accounted for by the heterogeneity of the studies since no direct comparisons were available (22).

Among the limitations of this study, it should be noted that these were suspected ADR reports made by professionals who received the vaccine. Therefore, we cannot calculate the incidence or prevalence of adverse effects across the population, nor compare subgroups.

One limitation is that the reports were not totally spontaneous since, on the one hand, those vaccinated were invited to fill out a form in case of ADR at the time of administering the vaccine and, in addition, in the collection via the form there was a list with the known reactions and a free report section. This limitation may have been increased for two reasons: one being the great impact that the vaccination process has had in the media, which might induce the reporting of an already known suspected ADR profile; the other reason is that the suspected ADRs were reported by professionals that work together, so we cannot rule out a contamination phenomenon.

Another limitation is that the population that participated in the study were active professionals. This conditioned the age of the population studied. No data are available for people over 69 years of age and only two professionals were over 65 years of age.

The design of the study does not allow us to know whether the differences found between the vaccines are due to confounding factors.

CONCLUSIONS

Most of the suspected ADRs that appear after the administration of the vaccine against COVID-19 are

those described in the SmPC. These were mild symptoms that did not require medical assistance and that recovered in about 3 days.

Professionals with a history of COVID-19 disease filed a greater number of reports after the first dose.

The Spikevax® vaccine is associated with a higher number of suspected ADRs after the first dose, but we cannot rule out that this difference between the two vaccines may be due to confounding factors.

Funding

This is an Investigator Initiative study which has not received any specific grant. This study will be carried out with the research team's own funds.

Declaration of Interests

The authors declare no conflict of interests.

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