**The risk of reactogenicity following COVID-19 vaccination is associated with gender, age, history of COVID-19, and similar reactions after a previous dose.**

**The risk of menstrual events is associated with age, history of COVID-19, and similar reactions after a previous dose.**


## ABSTRACT

### BACKGROUND

In the context of the safety monitoring of COVID-19 Vaccines, the European Medicines Agency requested and promoted a prospective cohort event monitoring study in multi-European countries. This abstract presents the results from France.

### OBJECTIVES

- To estimate incidence rates of patient-reported adverse events (AEs) following COVID-19 vaccination
- To identify possible associated risk factors in France.

### METHODS

- Through web applications, vaccine recipients self-enrolled within two days of receiving either the first dose (FD) or a booster dose (BD) of the COVID-19 vaccine.
- Follow-up was conducted via online standardized forms at 1, 2, 6, 8 weeks and 3 months for both FD and BD recipients, and at 6 months for FD recipients only.
- Descriptive analysis was completed by a multivariable logistic regression model to identify associated risk factors to reactogenicity and menstrual cycle perturbations.
- Results present odds ratios with 95% confidence intervals (OR [CI95%]).

### RESULTS

- From June 2021 to August 2022, 1,549 (FD cohort) and 5,317 (BD cohort) vaccine recipients were self-enrolled in the study (median age 32 / 47 years, women 66% / 59%, respectively).
- At least one AE was reported by 61% / 60% of vaccine recipients with ≥1 filled follow-up form, of which 5 / 7 were serious AEs.
- More than 72% / 75% of AEs concerned reactogenicity and 1.7% / 1.1% concerned menstrual cycle perturbations.
- The factors most strongly associated with reactogenicity were in FD cohort: sex (women OR=2.19 [1.68-2.84]), older age (1.50 [1.02-2.22], 1.91 [1.27-2.88], for [30-40[, [40-50[ years old vs <18), previous confirmed Covid-19 infection (2.17 [1.47-3.21]), respiratory system treatment at inclusion (2.02 [1.09-3.73]); and in BD cohort: sex (women OR=1.27 [1.10-1.46]), older age (1.52 [1.12-2.06] for [30-40[ years old, vs <25), reactogenicity after a previous dose injection (4.02 [3.51-4.61]), allergy to insect bites (2.16 [1.14-4.09]) or medication (1.55 [1.12-2.14]), and gastrointestinal and metabolic treatment at inclusion (1.41 [1.05-1.88]). Receipt of ≥1 other vaccine in the 2 weeks before BD was a protective factor for reactogenicity (0.59 [0.42-0.84]).
- Factors most strongly associated with menstrual cycle perturbations were in FD cohort a previous probable Covid-19 infection (4.63 [1.81-11.89]), and in BD cohort, menstrual cycle perturbations after a previous dose injection (7.39 [4.02-13.60]) and younger age (2.23, 3.24 for <30, [30-40[ years old vs ≥40).

### CONCLUSION

French results suggest that the risk of reactogenicity following initial or booster vaccination against COVID-19 is associated with the sex and age of vaccine recipients, and with previous infection with COVID-19 or a previous dose injection, which also impacts the risk of menstrual events in women.



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# *Active Safety Monitoring of COVID-19 Vaccines in France using Patient-Reported Outcomes*


C. Dureau-Pournin[1], E. Guiard[1], M-A. Bernard[1], E. Bignon[1], S. Lamarque[1], R. Lassalle[1], C. Droz-Perroteau[1], NH. Thurin[1]

[1] *Univ. Bordeaux, INSERM CIC-P 1401, Bordeaux PharmacoEpi, Bordeaux, France*


## Baseline characteristics of vaccine recipients

| | First dose cohort | Booster dose cohort |
|---|---|---|
| | 1 549 vaccine recipients | 5 317 vaccine recipients |
| | 66% of women | 59% of women |
| | 33 years old (±14) in mean | 47 years old (±15) in mean |
| | 95% with BioNTech/Pfizer vaccine<br>4% with Moderna vaccine | 44% with BioNTech/Pfizer vaccine<br>55% with Moderna vaccine |
| | 17% with comorbidity (mainly lung)<br>16% with allergy (mainly pollen) | 24% with comorbidity (mainly high blood pressure)<br>11% with allergy (mainly pollen) |
| | 81% without history of COVID-19 infection | 91% without history of COVID-19 infection |

## Description of adverse events following the first or a booster dose of COVID-19 vaccines

| | First dose cohort n = 1180[a] | | Booster dose cohort n = 4415[a] | |
|---|---|---|---|---|
| **≥1 adverse event following injection, n (%)** | 719 | (60.9) | 2629 | (59.5) |
| **Description of adverse events (frequency ≥ 3%), n (%)** | | | | |
| Injection site reaction | 497 | (42.1) | 1697 | (38.4) |
| Fatigue | 363 | (30.8) | 1468 | (33.3) |
| Myalgia | 299 | (25.3) | 1015 | (23.0) |
| Headache | 236 | (20.0) | 994 | (22.5) |
| Malaise | 140 | (11.9) | 829 | (18.8) |
| Nausea | 100 | (8.5) | 309 | (7.0) |
| Shivering | 82 | (6.9) | 749 | (17.0) |
| Fever | 80 | (6.8) | 696 | (15.8) |
| Arthralgia | 75 | (6.3) | 416 | (9.4) |
| Reactogenicity | 693 | (58.7) | 2477 | (56.1) |
| Menstrual disorders[b] | 36 | (4.5) | 88 | (3.3) |

[a] Among vaccine recipients with at least one follow-up questionnaire completed; [b] Among women

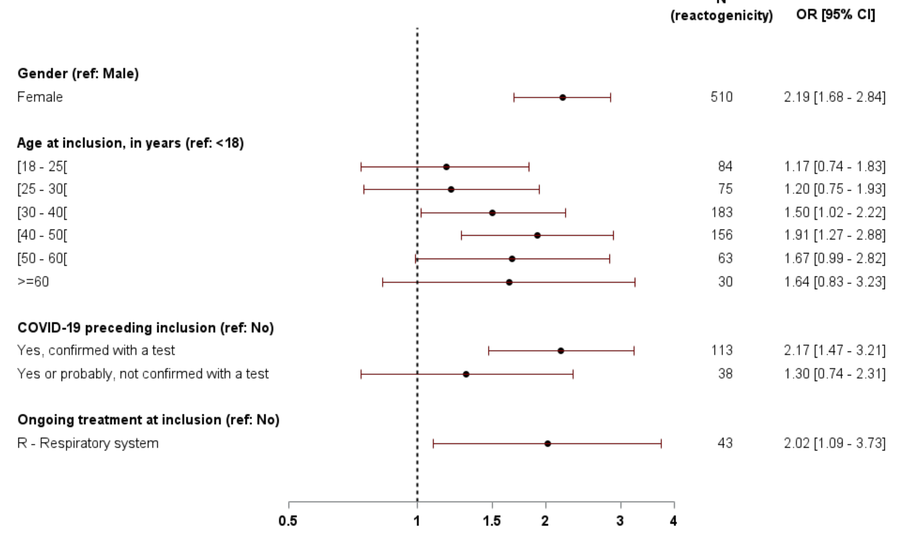
| | First dose cohort n = 1180[a] | | Booster dose cohort n = 4415[a] | |
|---|---|---|---|---|
| **≥1 serious adverse event following injection, n (%)** | 5 | (0.4) | 7 | (0.2) |
| **Description of serious adverse events, n (%)** | | | | |
| Fatigue | 2 | (0.2) | - | |
| Headache | 2 | (0.2) | - | |
| Nausea | 2 | (0.2) | - | |
| Fever | 1 | (0.1) | - | |
| Shivering | 1 | (0.1) | - | |
| Arthralgia | - | | 1 | (< 0.1) |
| Paresthesia | 1 | (0.1) | - | |
| Aggravated condition | 1 | (0.1) | - | |
| Depression | 1 | (0.1) | - | |
| Facial swelling | 1 | (0.1) | - | |
| Respiratory distress | 1 | (0.1) | - | |
| Other (frequency < 0.1)[b] | - | | 6 | (< 0.1) |
| Reactogenicity | 4 | (0.3) | 1 | (0.1) |
| Menstrual disorders[c] | 0 | (0.0) | 0 | (0.0) |

[a] Among vaccine recipients with at least one follow-up questionnaire completed; [b] Tachycardia: n=2; Breast cancer, Pulmonary embolism, Transient ischemic attack, VI nerve paralysis: n=1; [c] Among women

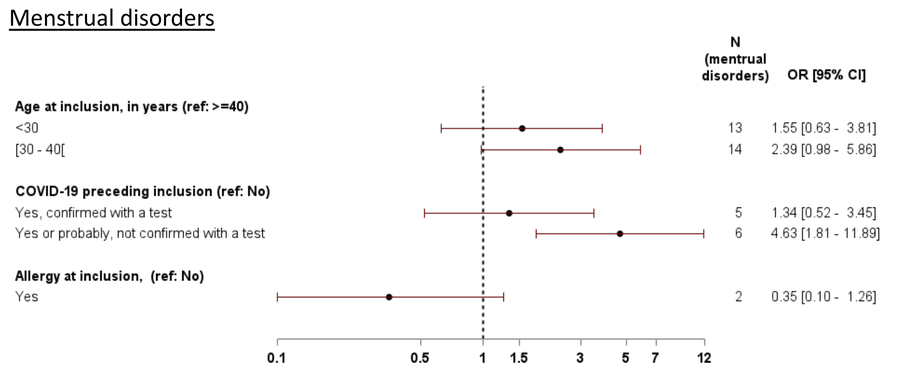
## Risk factors for adverse events following the first or a booster dose of COVID-19 vaccines

### First dose cohort

Reactogenicity

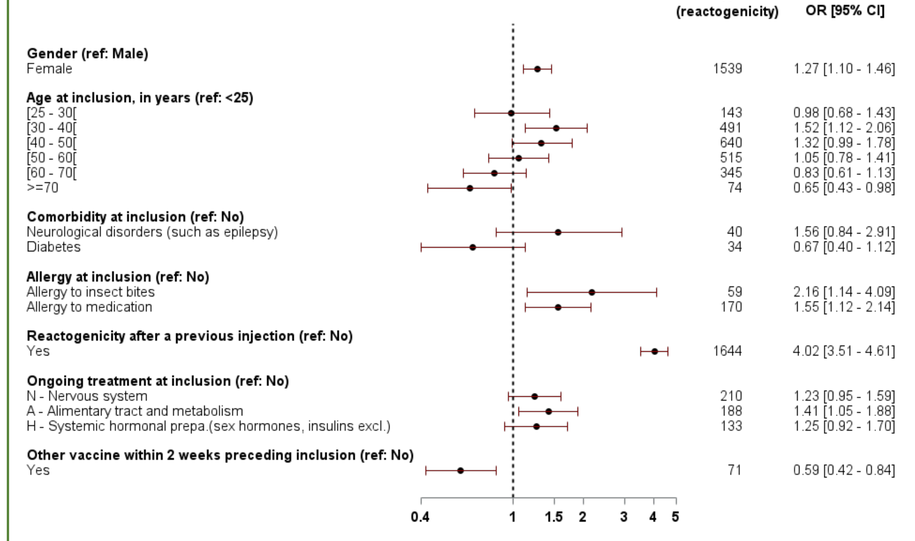



Menstrual disorders

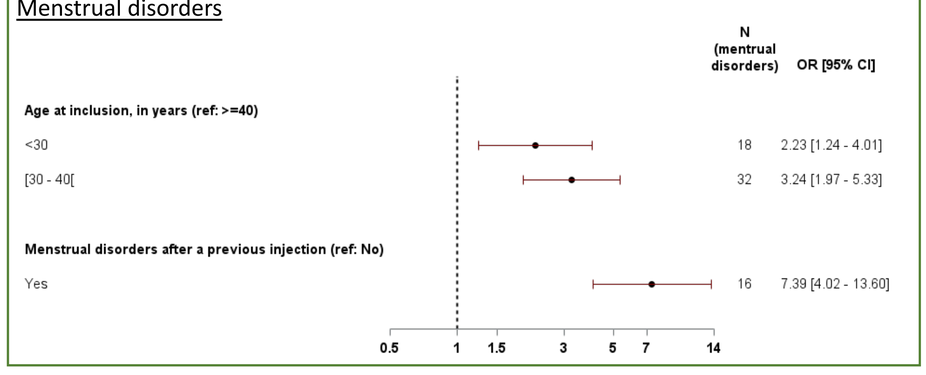



### Booster dose cohort

Reactogenicity




Menstrual disorders





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