Spontaneous adverse event reporting by COVID-19 vaccinated healthcare professionals through an electronic form implemented by the hospital pharmacy

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Abstract

Aim Implementation of a web-form based pharmacovigilance plan for the spontaneous notification of adverse events to the Comirnaty® COVID-19 vaccine during its administration to hospital healthcare professionals. **Methods** An electronic pharmacovigilance form was developed containing 8 pre-defined event options, an open answer option for the description of other events and/or symptoms, and a question about the overall intensity of symptoms. The adverse events reports were standardised according to physiological and pathological condition. **Results** A total of 4119 adverse events notifications were obtained with a 45% rate of electronic notification. The most clinically relevant events reported were: tachycardia (n=19), dyspnoea (n=7), chest pain (n=6), facial/labial oedema (n=6), lipothymia (n=5), bronchospasm (n=2), herpetic infection (n=2), vasculitis (n=2), arrhythmia (n=1), difficult to control arterial hypertension (n=1), gastritis (n=1) and spontaneous abortion (n=1). Regarding the intensity of symptoms (n=2928), 70.0% were reported as mild, 25.8% as moderate and 4.27% as severe, with higher intensity in the 2nd dose compared to 1st dose. The highest frequency of severe events were reported in the groups from 40 to 59 years in both vaccination periods. During the vaccination process, no hospitalisations and no deaths were notified and/or recorded. **Conclusion** In this real world study, comparing with Comirnaty clinical trials program, it was observed a higher frequency of adenomegaly and gastrointestinal disorders. Noteworthy, the notification of a case of miscarriage. The use of hospital pharmacy pharmacovigilance electronic forms, seemed to be relevant to notification adherence and to obtain a greater and faster knowledge of COVID-19 vaccine safety profile.

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<p>Pharmacovigilance Vaccine SARS-CoV-2</p> <p>*Mandatory</p> <p>1. Indicate the vaccine that was administered: *</p> <p>☐ Comirnaty - (BioNTech / Pfizer)</p> <p>☐ COVID-19 Vaccine AstraZeneca - (AstraZeneca)</p> <p>2. Administration dose: *</p> <p>☐ 1st</p> <p>☐ 2nd</p> <p>3. Enter your initials *</p> <p>4. Indicate your gender *</p> <p>☐ Male</p> <p>☐ Feminine</p> <p>5. Enter your date of birth *</p> <p>6. Have you experienced any of these symptoms since the vaccination? *</p> <p>☐ Injection site (pain, redness, swelling, itching)</p> <p>☐ Chills</p> <p>☐ Fatigue, drowsiness</p> <p>☐ Head, joint, muscle, body pain</p> <p>☐ Febrile</p> <p>☐ Nausea, vomiting, diarrhoea, abdominal pain</p> <p>☐ Rash</p> <p>☐ No symptoms</p> <p>☐ Other: _____</p> <p>7. Overall, rate the intensity of your symptoms: *</p> <p>☐ Mild (Feels symptoms, but they are not disabling)</p> <p>☐ Moderate (May cause limitations to daily activities)</p> <p>☐ Severe (Symptoms that make daily activities difficult or impossible)</p> <p>8. Authorizes contact by phone for subsequent submission of data to the <i>INFARMED- Portal RAM</i></p> <p>☐ Yes</p> <p>☐ No</p> <p>9. Provide a phone contact</p> <p>10. Enter your email</p>