CONFERENCE PAPER

J Health Inequal 2023; 9 (2): 148–148

Submitted: 12.11.2023; accepted: 13.12.2023

DOI: https://doi.org/10.5114/jhi.2023.133871

JOURNAL
of Health Inequalities

A study of the incidence of adverse post-vaccination reactions and adverse medical events after COVID-19 vaccinations in Poland

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Contribution presented at the 3rd Calisia Conference on Family Health, Kalisz, Poland, 18-20 June 2023

In classifying the types of SUS after COVID-19 vaccines, criteria were used in accordance with the Regulation of the Minister of Health of 21 December 2010 on undesirable postvaccinal reactions and the criteria for their diagnosis (Journal of Laws 2010, No. 254, item 1711, as amended), according to which SUS are divided into severe, serious, and mild. When classifying NOPs, the definition set out in the Act of 6 September 2001 was adopted (i.e. Journal of Laws 2001, No. 126, item 1381, as amended).

In Poland, the NOP monitoring system was introduced in 1996, based on WHO recommendations, and the applied surveillance is passive in nature, i.e. it is the doctor who decides on the legitimacy of reporting an NOP. The obligation to report an adverse vaccination reaction stems from Article 21 of the Act of 5 December 2008 on preventing and combating infections and infectious diseases in humans, and failure to do so is punishable by a fine, as stipulated in Article 52 of the Act.

A doctor who recognises or suspects the occurrence of NOP is obliged to report this fact within 24 hours to the territorially competent State District Sanitary Inspector (PPIS) via the gabinet.gov.pl application using an e-form integrated into the State Sanitary Inspection Registration System (SEPIS). Each registered notification is forwarded to the National Institute of Public Health – National Institute of Hygiene (NIZP-PZH).

The analysis of the incidence of adverse vaccine reactions and adverse medical events in Poland was performed using reports obtained from the collections maintained by the NIZP-PZH in the period from 27.12.2020 to 31.12.2022 concerning the number of registered cases of NOP and NZM, taking into account their classification and characteristics. The analysis included registered NOPs and NZMs after COVID-19 vaccines authorised in European Union countries, i.e. Comirnaty (Pfizer-BioNTech), Spikevax (Moderna), Vaxzevria (AstraZeneca), and COVID-19 Vaccine (Janssen). The analysis of the data in the NIZP-PZH reports shows that the benefits of COVID-19 Vaccine still outweigh the risk of adverse reactions, including the rare life-threatening symptoms that occur with all 4 vaccines.

Detailed data on the number of NOPs and NZMs reported to NIZP PZH-PIB and their qualification in the period from 27.12.2020 to 31.12.2022 will be presented in the next issue of the journal. I will present data on the following: the percentage of NOP and NZM according to the severity of the reaction, depending on the type of vaccine administered, in relation to the number of doses of each preparation administered, the number of deaths temporally associated with vaccination, and the type of vaccine against COVID-19m taking into account the age and sex of vaccinated persons.

DISCLOSURE

The author reports no conflict of interest.