Norwegian Medicines Agency

Weekly report on suspected adverse drug reactions to coronavirus vaccines

Background for the reported cases:

- In Norway, the vaccination campaign (handled by the National Institute of Public Health) have prioritized the elderly in nursing homes and long-term care facilities. So far, this is the only group of patients for whom vaccination has taken place (until 15/01/2021 only with Comirnaty. Vaccination with Moderna starts /15/01/2021).
- Patients in nursing homes represents a very frail group of elderly, and most of the patients have severe underlying diseases.
- In Norway we have a "reporting culture" for vaccines ADRs where the normal procedure is to report all suspected adverse reactions for new vaccines. Healthcare professionals have a low threshold for reporting possible adverse reactions, even when the causal relationships appears very unclear.
- The preferred and most used route of reporting is directly to the health authorities, not via the Marketing Authorisation Holders.
- The Norwegian ADR registry is a national health registry, obliged to report statistics to the public.
- At the highest political level the public has been promised full transparency of the reported ADRs of the covid-19 vaccines. The Norwegian Medicines Agency will publish weekly reports.
- The Norwegian Medicines agency, in close cooperation with the National Institute for Public Health will continuously follow the reporting of suspected ADRs and update national advice accordingly.

About the statistics:

The Norwegian Medicines Agency is transparent about reports of suspected adverse reactions during covid-19 vaccination and publishes weekly updates. These updates provide an overview of reported suspected adverse reactions after vaccination in Norway.

All reports of suspected adverse drug reactions, regardless of whether they are reported by healthcare professionals or patients or received from vaccine manufacturers, end up in the Norwegian ADR Registry.

The weekly updates summarize all suspected adverse reactions that have been assessed and processed.

The adverse reaction reports are assessed on a continuous basis. Reports of suspected serious adverse reactions are prioritized for assessment. The weekly updates will therefore give a skewed picture of the distribution between serious and nonserious reports.

The adverse reaction statistics for the different covid-19 vaccines are not directly comparable because they have not been used in the covid vaccination program for the same length of time, and because the vaccines are administered to different numbers of people and to different age groups.

Adverse reactions are reported on suspicion and the reports describe events that have occurred after vaccination. Even though an event has been reported, this does not necessarily imply that a causal relationship has been established between the event and the vaccines. The known adverse reactions of the vaccines are listed in the product information.

Gender breakdown

Gender	Female	Male
Number	21	8

Table 1: Gender breakdown among patients who have experienced adverse reactions following coronavirus vaccination

Age breakdown

Age group				
18-69	70-79	80-89	90+	Unknown age
4	4	14	7	0

Table 2: Age breakdown among patients who have experienced adverse reactions following coronavirus vaccination

Severity

Total number of reports	Number of reports with fatal outcome	Serious reports excluding death	Non-serious reports
29	13	9	7

Table 3: Breakdown between reports with death, serious and non-serious reports

Adverse reactions broken down according to category

A single adverse reaction report can include a number of suspected adverse reactions or symptoms.

Category	**Number of reported adverse reactions**
General symptoms and reactions at the vaccine administration site E.g. Pain around the injection site, discomfort, fever, fatigue	24
Gastrointestinal symptoms E.g. Stomach pain, nausea, vomiting, diarrhoea	11
Respiratory tract symptoms E.g. Difficulty breathing, shortness of breath, hyperventilation, cough, irritation of the respiratory tract	10
Examinations E.g. Abnormal pulse, reduced blood pressure	7
Neurological symptoms E.g. Headache, dizziness, loss of consciousness, numbness, cramp	6
Psychiatric symptoms	5

E.g. Sleep abnormalities, restlessness, lethargy, anxiety	
Musculoskeletal symptoms E.g. Muscle pain, joint pain, muscle stiffness	4
Vascular symptoms E.g. Flushes, pallor	3
Infections E.g. Pneumonia	2
Kidney and urinary tract symptoms E.g. Urinary tract infection	2
Immune system symptoms E.g. Allergic reaction	1
Skin symptoms E.g. Rash, itching, redness	1
Metabolic and nutrition-related symptoms E.g. Loss of appetite	1
Cardiac symptoms E.g. Abnormal heart rate	1

Table 4: Reported adverse reactions broken down according to category for Comirnaty
The most common reported adverse reactions are general symptoms, such as impaired general condition, fever and general malaise, along with injection site reactions. Gastrointestinal symptoms such as diarrhoea, nausea and vomiting, as well as respiratory tract symptoms such as shortness of breath and cough, are also among the most common reported adverse reactions.