Statens legemiddelverk

Reported suspected adverse drug reactions to coronavirus vaccines

About the report:

- A summary is presented below of all processed reports concerning suspected adverse reactions following coronavirus vaccination from 27 December 2020, the date on which the first vaccine became available.
- The figures are taken from the ADR Registry and include reports from health professionals, the general population and vaccine manufacturers in Norway.
- Only reports, which have undergone quality assurance and have been processed in the ADR Registry are included in the report. At any time, there will be reports that are being processed – these reports are not included in this summary.
- Reports of serious events are processed first. The report therefore does not give a true picture of the distribution between serious and non-serious events at any one time.
- Symptoms or illnesses that occur after vaccination are reported if there is any *suspicion* of a possible link. As a result, no causal link between the suspected adverse reaction and the vaccine has been established.
- This report contains all processed reports of suspected adverse reactions regardless of any possible causal link.
- The data concerning the various coronavirus vaccines are not directly comparable. This is partly because they have different adverse reaction profiles, because they were punt into use at different time points and because the vaccines have been administered to different numbers of people with different disease profiles and ages.
- The distribution between age and gender must be viewed in the context of the gender and age distribution amongst those who have been vaccinated.
- Each report is assessed on an ongoing basis, and weekly reports are published with a summary of adverse reactions that have been reported following vaccination with the coronavirus vaccines.

Summary

The reports do not provide a basis for revising the current recommendations regarding the use of the coronavirus vaccines. The benefits of administering the vaccine are expected to outweigh the risks.

There are currently no new signals of unexpected or serious adverse reactions in Norway. The suspected adverse reactions, which have been observed following vaccination, are generally in line with the product information.

Most of the reports relate to known adverse reactions, such as transient malaise, fever, fatigue, nausea and body pain. These usually appear on the first or second day after vaccination and last around 2-3 days. The vast majority of those who have been vaccinated appear to have suffered no adverse reactions.

Amongst the reports that have been processed, there were 30 deaths with a temporal relationship to vaccination. In several of these, the reporter states that no relationship to

vaccination is suspected. The fact that some nursing home residents die soon after being vaccinated does not imply that there is a causal relationship. In order to analyse whether there could be a causal relationship, other data and advanced analyses are normally required.

For some of the patients, it cannot be ruled out that relatively mild adverse reactions following the vaccination of frail elderly people contributed to a more severe course in their general condition or underlying illness, leading to death of the patient.

Coronavirus vaccines in use in Norway

Two coronavirus vaccines are approved for use in Norway: Comirnaty (BioNTech/Pfizer) and COVID-19 Vaccine Moderna (Moderna). Both are mRNA vaccines, given in two doses a few weeks apart.

Statistics concerning reports of suspected adverse reactions as of 21.01.2021

To date, 104 reports of suspected adverse reactions following coronavirus vaccination have been processed following the vaccination of approximately 63,000 people with a coronavirus vaccine.

So far, there has only been processed reports on Comirnaty.

Distribution of reports by gender

Gender	Female	Male
Number	75	29

Table 1: Gender breakdown amongst patients in the reports

Distribution of reports by age

Age group						
18-39	40-59	60-69	70-79	80-89	90+	Unknown age
11	9	5	13	33	29	4

Table 2: Age distribution of patients in the reports

Residents in nursing homes, persons over 85 years of age and older, and selected groups of healthcare professionals and other employees in the health and care services have so far been given priority in the vaccination programme. This is also reflected in the gender and age distribution of the patients in the reports.

The weekly report at FHI.no shows the number and proportion of persons vaccinated in different age groups and gender distribution nationwide.

Distribution of reports by severity

Total number of reports	Number of reports involving death	Reports of serious events other than death	Reports of non-serious events
104	30	16	58

Table 3: Distribution of reports of suspected adverse reactions according to severity

Reported events following vaccination are classified as serious when:

- *the event resulted in/extended a stay in hospital*
- *the event is considered to be a medically important event*
- *the event resulted in a prolonged reduction in function level*
- *the event resulted in a life-threatening illness (e.g. anaphylaxis) or death.*
- *the event resulted in birth defects/congenital malformations*

Reports on death

Many of the nursing home residents who have been vaccinated so farare very frail or terminally ill patients. Every day, an average of 45 people die in Norwegian nursing homes or other similar institutions. The fact that some nursing home residents die soon after being vaccinated does not imply that there is a causal relationship. The reported deaths have occurred within a period of 1-9 days following vaccination.

In several of the fatal reports, the reporter states that no link with vaccination is suspected, and that the death is being reported for the sake of completeness. Many of the patients were also frail prior to vaccination. However, in the case of some of the most frail patients, it cannot be ruled out that relatively mild adverse reactions following vaccination contributed to a more severe course in their general condition or underlying illness, leading to death of the patient..

These individual case reports do not currently constitute a signal of a new adverse reaction and therefore do not provide a basis for revising the product information for the vaccine.

Number of suspected adverse reactions according to category

A single adverse reaction report can include a number of suspected adverse reactions or symptoms. Table 4 show suspected adverse reactions grouped according to the category to which they belong and the types of suspected adverse reactions which have been reported most frequently.

The distribution is categorised according to the origin of the suspected adverse reaction (e.g. the heart), or the cause of the suspected adverse reaction (e.g. infections). The categories are the highest level in a hierarchical, standardised medical terminology, which is used internationally (MedDRA). Using this terminology makes it possible compare reports internationally.

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	84
Gastrointestinal symptoms E.g.: Stomach pain, nausea, vomiting, diarrhoea	31
Neurological symptoms E.g.: Headache, dizziness, drowsiness	30
Respiratory tract symptoms E.g.: Difficulty breathing, shortness of breath, cough, irritation of the respiratory tract	28
Musculoskeletal symptoms E.g.: Muscle pain, joint pain, muscle stiffness	15
Examinations E.g.: Abnormal pulse, reduced blood pressure	12
Psychiatric symptoms E.g.: Sleep abnormalities, restlessness, lethargy, anxiety	6
Infections E.g.: Pneumonia	6
Skin symptoms E.g.: Rash, itching, redness	5
Vascular symptoms E.g.: Flushes, pallor	4
Metabolic and nutrition-related symptoms E.g.: Reduced appetite	4
Cardiac symptoms E.g.: Abnormal heart rate	3
Kidney and urinary tract symptoms E.g.: Urinary tract infection	2
Eye symptoms E.g.: Blurred vision	2
Immune system symptoms E.g.: Allergic reaction	1
Ear symptoms E.g.: Discomfort in the ear	1

Table 4: Reported suspected adverse reactions broken down by category of mRNA vaccine

The most frequently reported symptoms primarily consist of known adverse reactions within the general symptoms category, and include reactions at the vaccine injection site, decreased general condition, fever and general malaise. Gastrointestinal symptoms such as diarrhoea, nausea and vomiting have also been reported, as well as neurological symptoms such as headaches and dizziness. The symptoms have arisen within 1-2 days after vaccination and have generally disappeared within a few days.