Norwegian
Medicines Agency

Reported suspected adverse reactions to COVID-19 vaccines as of 18.01.2022

Table of contents

About the report

- Since January 2021, the Norwegian Medicines Agency has published a weekly report presenting information on suspected adverse reactions to COVID-19 vaccines which have been assessed. From November 2021, these reports have been published less frequently. From January 2022, the report will be published every two weeks.
- The adverse reaction reports in the report are submitted by patients, health professionals and producers.
- Symptoms or illnesses that occur after vaccination are reported if there is any *suspicion* of a possible link. As a result, it cannot be assumed that there is a causal relationship between the suspected adverse reaction and the vaccine.
- The report summarises all reports of suspected adverse reactions that have been treated. As a result, there is a difference between the number of reports which have been received and those which have been assessed, because reports are continually being assessed.
- All reports are counted, regardless of whether or not the event being reported is believed to be linked to vaccination.
- The fact that a report has been assessed means that the severity of the incident has been determined, and the symptoms have been translated into international terminology and categorised (see Appendix 1).
- We prioritise and assess serious reports of suspected adverse reactions first. The reports therefore does not give a true picture of the distribution between serious and non-serious events.
- The reports provide a snapshot of the adverse reactions at the time of reporting and rarely contain complete information about the event. The interpretation and assessment of causality are based on the information that is available at the time of reporting.
- The reporting scheme is a vital tool in the monitoring of vaccines. The reports submitted by health professionals and members of the public give us signals as to whether there are any events that we should investigate further. It is not known with any certainty what proportion of these events are being reported, while a report does not necessarily indicate a causal relationship. As a result, the number of reports submitted to the Norwegian Medicines Agency cannot normally be used to determine how often or how many adverse reactions a vaccine could give rise to, or to compare the safety profiles of different vaccines.
- The term “temporal link” between vaccination and an adverse reaction is used in the report. “Temporal link” is not a precisely defined time period, but six weeks is often used as a guide for health professionals when they are assessing whether adverse reactions have occurred with a temporal link to vaccination. Some adverse reactions can occur after more than six weeks have elapsed and may still be suspected as being linked to vaccination. As long as the person submitting the report suspects there may be a link between vaccination and the adverse reaction, the report will be counted, regardless of how long has passed since vaccination.

Summary

This report is based on reports that are assessed until 18 December 2021. The assessed adverse reaction reports do not provide a basis for revising the current overall recommendations regarding the use of the vaccines.

A year of monitoring adverse reactions

The Norwegian Medicines Agency was one of the first medicines authorities in Europe to start publishing weekly overviews of suspected adverse reaction when it published its first report back on 14 January 2021. This was less than three weeks after the first dose of a COVID-19 vaccine had been administered. Since then, we have published a total of 47 reports and news articles about suspected adverse reactions reported by health care professionals and the public.

We have found that the reporting culture is good and that there is a low threshold for reporting suspected adverse reactions following vaccination. The reports often concern symptoms and conditions which are relatively common amongst the population. People also fall ill whether or not they have been vaccinated. At a time when so many people are being vaccinated, the challenge is to separate out conditions or symptoms which occur coincidentally following vaccination from genuine adverse reactions.

After the administration of more than 10.6 million vaccine doses in Norway, we have received 51,985 reports of suspected adverse reactions. Most reports (75%) are received from the public, while around 25% are submitted by health care professionals. In cooperation with the Norwegian Institute of Public Health (NIPH) and RELIS, we have assessed a total of 26,413 reports, equivalent to more than 100 reports per working day. Of these reports, a total of 4,766 are classified as serious and 21,647 as non-serious. Serious reports are given the highest priority, which means that essentially all reports that have not been assessed are non-serious.

Figure 1: Number of reports received from January 2021 to January 2022 from the general public and health professionals (HP) respectively. **Remarks:** A suspected adverse reaction may be reported by both health care professionals and the public (patient/next of kin).

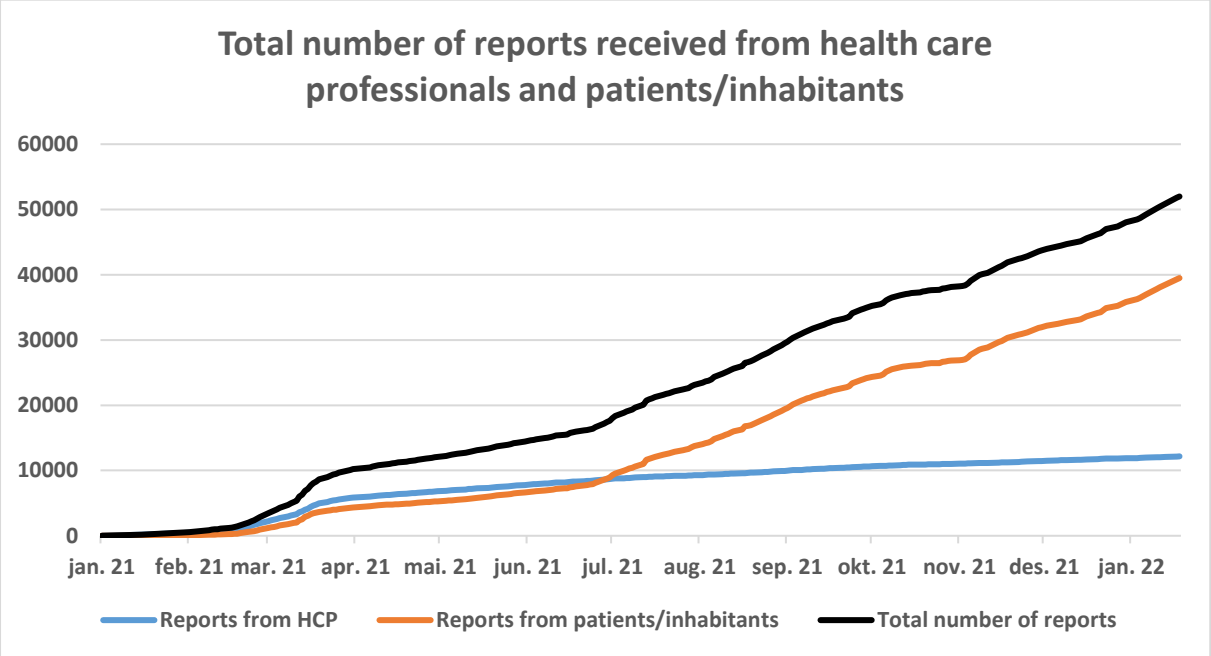
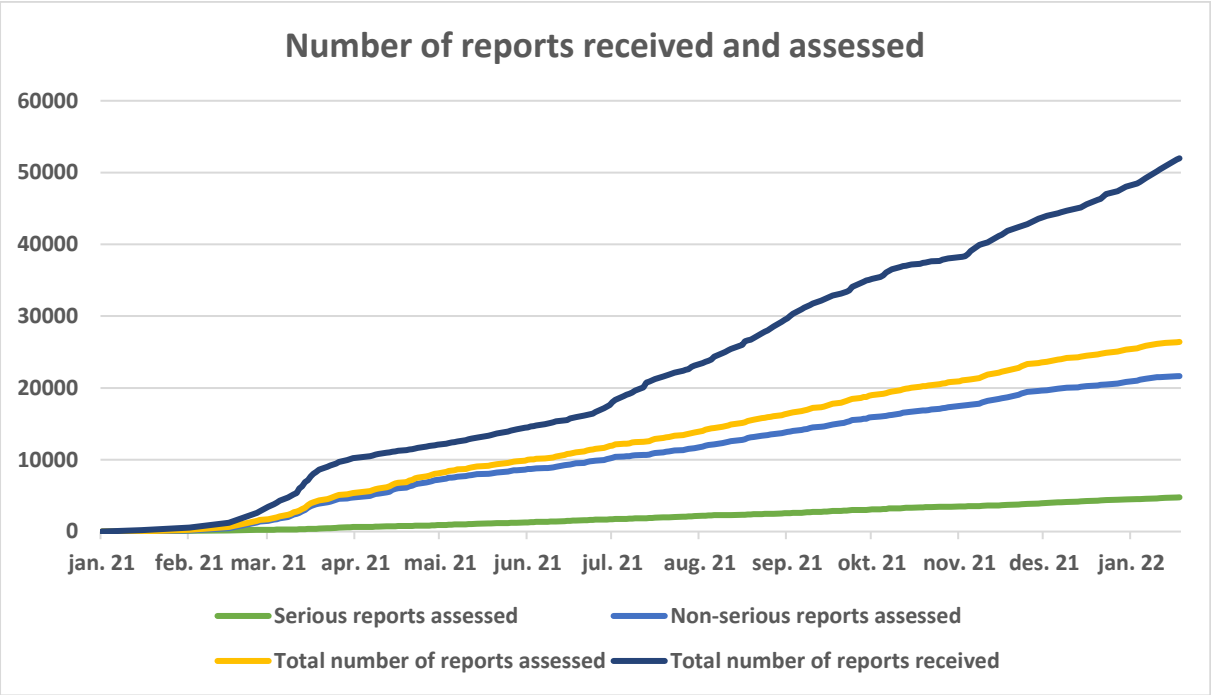


Figure 2: Number of reports assessed from January 2021 to January 2022 broken down according to serious and non-serious. **Remarks:** The fact that a report has been assessed means that the severity of the event has been determined, and the symptoms have been translated into international terminology and categorised. This does not mean that causality has been determined. We give serious reports the highest priority. As a result, the picture of the distribution between serious and non-serious reports is not entirely accurate, as the reports that have not been assessed are generally non-serious reports.



Electronic reports enable an overview to be obtained more rapidly

Since October 2020, it has been possible for both health professionals and the public to submit reports on suspected adverse reaction concerning vaccines electronically. This has not only lowered the threshold for reporting, but it has also more importantly made the monitoring of adverse reactions more effective. We are one of the few countries in the world to have near real-time data concerning reported suspected adverse reactions. The data is already structured when it is received, and raw data is searchable. This makes it much easier and quicker to obtain an overview of the information that is being reported. Incoming reports are reviewed to see whether any new combinations of symptoms, serious events or unusual symptoms have been reported, and we can select reports which must be given priority in our assessment. This enables us to quickly identify potential adverse reaction signals that should be investigated further.

Signal detectives

Once the adverse reaction reports have been assessed, we can sort the reports and analyse the information they contain. We then look for special conditions, the number of reports we have received, or other information which could lead us to suspect a possible new adverse reaction, known as an adverse reaction signal.

The Norwegian Medicines Agency's adverse reaction monitoring and signal work are supported by analyses and studies conducted by the Norwegian Institute of Public Health. By linking the Norwegian Adverse Drug Reaction Registry and the Norwegian Immunisation Registry (SYSVAK) to other health registries in the Norwegian Institute of Public Health's emergency Preparedness Register for COVID-19 (Beredt C19), we can investigate in more detail whether a medical condition is occurring more frequently than would be expected following vaccination. In addition to the use of health registry data from Beredt C19, the Norwegian Institute of Public Health and research institutions in many

countries are also conducting studies to look for the possible accumulation of conditions following vaccination, which are not necessarily being reported as suspected adverse reactions.

Before the summer, there was a sharp rise in the number of reports being received concerning menstrual disorders. By this time, many women had been vaccinated. Menstrual disorders are common, and we therefore had to use other tools to assess whether the increase in the number of reports being received was simply a coincidence, or whether it could be linked to vaccination. NIPH therefore followed up the issue with questions in its ongoing population surveys. Initial results showed an increased incidence of menstrual disorders following vaccination in the 18-30 age group. As a result, NIPH issued advice concerning further vaccination to women who had experienced menstrual disorders after being vaccinated with a COVID-19 vaccine.

The Norwegian Medicines Agency closely monitors signals of possible adverse reactions and reports new adverse reaction signals to the European Medicines Agency (EMA) and the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC). PRAC then considers whether it is necessary to update the summary of product characteristics and the package leaflet for the vaccines concerned with new safety information.

Rare adverse reactions

Even though thorough studies are carried out before approval, we can never guarantee that very rare adverse reactions will not occur when vaccines are administered to large population groups. The ongoing monitoring of adverse reactions is therefore vital. The purpose of the reporting system is to identify signals that can then be investigated further.

It was observant doctors and an effective monitoring system which enabled Norway to help identify the rare cases where the Vaxzevria (AstraZeneca) vaccine causes a sever combination of symptoms involving blood clots, low platelet counts and haemorrhaging (VITT). As a result of this, the product information was updated, and Vaxzevria was withdrawn from the Norwegian vaccination programme.

When the first signals of inflammatory conditions of the heart became apparent, studies were quickly initiated which subsequently established that vaccination with the mRNA vaccines increases the risk of inflammation of the heart (pericarditis and myocarditis). This resulted in updates being made to the product information for the vaccine, along with changes to the recommendations for use. Spikevax (Moderna) is not recommended for young people under the age of 30, as this group is at a higher risk of experiencing rare adverse reactions relating to the heart.

The Norwegian Institute of Public Health continually monitors a wide range of diseases using data from the Preparedness Register for Covid-19 to compare incidences amongst vaccinated and unvaccinated persons. Amongst the diseases being monitored are blood clots in the lungs, deep vein thrombosis, cardiac infarction and stroke. No link has so far been confirmed between the vaccines used in the Norwegian vaccination programme and the risk of any of these conditions.

What do we know about delayed adverse reactions?

So far, no delayed adverse reactions to COVID-19 vaccines have been identified, i.e., adverse reactions which occur long after vaccination. Globally, almost 10 billion vaccine doses have been administered during the year, and it is believed that around 60% of the world's population have now received at least one vaccine dose. We therefore have a good understanding of the adverse effect profile of the COVID-19 vaccines. We have never learned so much about any other vaccine in such a short period of time before.

In most cases, adverse reactions occur during the first few weeks following vaccination, and it is very

rare that symptoms that occur more than six weeks after vaccination can be linked to vaccines.

Transparency is vital

Communication concerning reported adverse reactions is challenging, because such reactions are reported based on *suspicions.* Even if an event is reported, we do not know whether the vaccine is the actual cause. It is a reporting system which aims to identify what we need to investigate further, not a counting system which tells us the actual number of cases of adverse reactions.

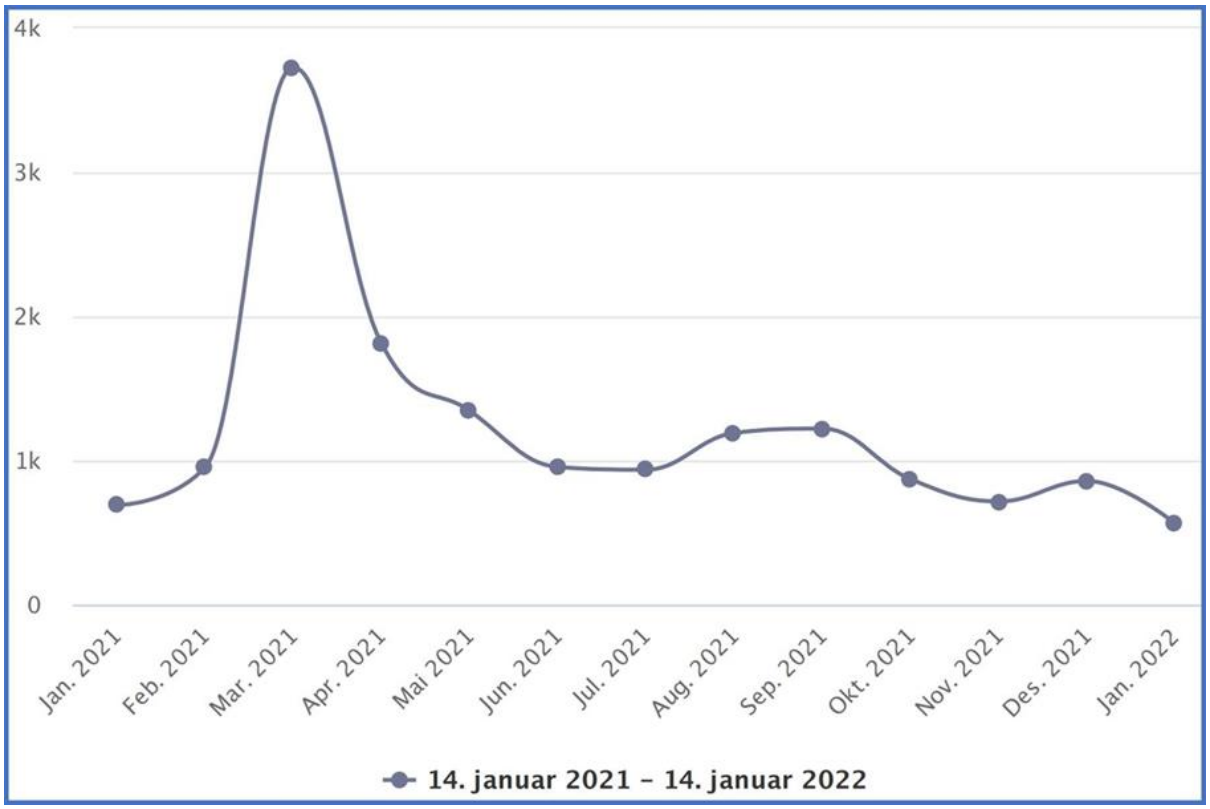
All reports are included in the report, regardless of whether the event is believed to be linked to vaccination. As a result, the figures cannot be used to assess causalities or determine how often an adverse reaction occurs.

Unfortunately, we have found that figures from the adverse reaction reports have been used and taken out of context. In social media, we have seen numerous examples of our information being misused and disseminated along with false information. We therefore urge the general public to be critical of the information sources they use and what they share with others.

We were prepared for the strong interest that the COVID-19 vaccines and adverse reactions would inevitably attract. We are in urgent need of more information and, it is important that we are as accessible as possible to the media (see Figure 3). In our communication, we have always been open about both what we know and what we do not know. Transparency and the provision of balanced information concerning the benefits and risks associated with the vaccines are important to ensure that people can trust the advice and recommendations that are issued by the authorities.

Figure 3: Overview of media coverage

Approx. 16,000 articles in the Norwegian media about the Norwegian Medicines Agency, COVID-19 vaccines and suspected adverse reactions.



Vaccines in the COVID-19 vaccination programme

- Comirnaty (BioNTech/Pfizer), mRNA vaccine
- Spikevax (Moderna), mRNA vaccine

Vaccines withdrawn from or offered outside the COVID-19 vaccination programme:

- The Janssen COVID-19 vaccine is offered, but not as part of the vaccination programme.
- Vaxzevria (AstraZeneca): In May 2021, the government decided to withdraw this vaccine from the Norwegian vaccination programme.

Key figures as of 18.01.2022

From the start of the vaccination programme in Norway on 27 December 2020 through to 18 January 2022, **51,985** reports of suspected adverse reactions have been received following COVID-19 vaccination; **26,413 (51 %)** of these have been assessed. The fact that the reports have been assessed means that they have been classified and sorted, but not necessarily that a final assessment of causality has been made in all cases.

The number of reports must be interpreted in light of the number of people who have been vaccinated. As of 18 January 2022, a total of **10,601,000** doses of COVID-19 vaccines have been administered in Norway. Over **4,301,000** people have received their first dose of vaccine, over **3,964,000** have received their second dose and over **2,335,000** received their third dose (Source: SYSVAK, https://statistikk.fhi.no/sysvak).

Table 1: Distribution of reports by gender

Gender	Female	Male	Unknown gender
Total number of reports	21 263	5 111	39
Number of serious reports	3 224	1 530	12
** The table shows number of reports that have been assessed.*			

Comment on Table 1:

Numerous studies have indicated that women are more likely than men to contact the health service and report adverse reactions.

Table 2: Distribution of reports by age

Age group											
	12-17	**18-29**	**30-39**	**40-49**	**50-59**	**60-69**	**70-79**	**80-89**	**90+**	**Unknown age**	**Total**
Serious reports	58	659	776	874	864	569	435	282	127	121	4 765
Non serious reports	355	4 778	5 355	4 638	3 291	1 408	570	309	127	797	21 628
Total	413	5 437	6 131	5 512	4 155	1 977	1005	591	254	918	26 393
The table shows number of reports that have been assessed. *Excluding reports concerning the under 12 age group. See the separate section in the remarks below.*											

Comment on Table 2:

Breastfed infants:

A total of 20 reports have been received regarding children under the age of 12 who are being breastfed, but who have not been vaccinated. Various symptoms have been reported in the children concerned after the mother received a vaccine dose, including fever, abdominal pain, nausea, anxiety, rash or cold. In most of the breastfed children, the symptoms appeared 0-3 days after the mother had been vaccinated. Such symptoms are very common in infants and toddlers and are probably not due to the mother receiving the mRNA vaccine. The mRNA from the vaccines is not passed in breast milk.

- Ten reports concern symptoms in the child after the mother received Vaxzevria (AstraZeneca)
- Eight reports concern symptoms in the child after the mother received Comirnaty (BioNTech/Pfizer)
- Two reports concern symptoms in the child after the mother received Spikevax.

One of the reports is classified as serious due to the child being admitted to hospital. There is generally a low threshold for admitting young children to hospital. The child was recovering when the suspected adverse reactions were reported.

Events following vaccination are reported on the basis of suspicions and there is not necessarily any causal relationship. All reports are included in the report, regardless of whether or not an event is believed to be linked to vaccination.

Young people and adverse reaction reports

Experience has shown that adverse reactions are more commonly reported in younger adults than in older adults. This can be attributed to the fact that younger people have a stronger immune response and more noticeable common adverse reactions, or that reports are issued more frequently for younger people in order to clarify whether the reaction is an adverse reaction to the vaccine or not. Younger people also tend to be more likely to report adverse reactions themselves.

Reports classified as serious

So far, 4,766 reports of events which are classified as serious have been assessed. This accounts for 18 % of all reports which have been assessed. We prioritise the assessment of serious reports first, so that reports that have not been assessed are virtually all non-serious reports.

What types of events are classified as serious

Reports of adverse reactions are generally classified as serious when the event:

- results in or extended a stay in hospital
- results in a prolonged reduction in function level
- results in life-threatening illness or death
- results in birth defects/congenital malformations
- is on the EMA's list of important medical events (Important medical event (IME) list)

Hospital admission is the most common reason why an event is classified as serious, and this applies to 51 %* of serious reports. In these cases, the descriptions provided by the person submitting the report cover everything from patients who are only kept under observation for a short period of time and go on to recover quickly, to patients with a life-threatening symptoms and illness which results in

permanent injury.

* The Norwegian Medicines Agency previously made an error when it calculated the proportion of adverse reactions that resulted in hospital admission. We calculated the proportion relative to the number of severity criteria specified in the reports. This is incorrect, as an adverse reaction report can fulfil several severity criteria.

The aim has always been to calculate the proportion of reports that have resulted in hospital admission relative to the total number of serious reports. The percentage share was corrected from the report on adverse reactions as of 4 January 2022 onwards.

IME-list

The EMA has compiled a list of important medical events which are always to be classified as serious (the IME list). The summary below lists the conditions on the IME list which are most frequently reported following COVID-19 vaccination (in descending order).

- Pericarditis
- fainting (syncope)
- vaginal bleeding after menopause
- blood clot in the lungs
- myocarditis
- deep vein thrombosis
- anaphylactic reaction
- blood clots (thrombosis)
- abnormal heart rhythms (arrhythmia)
- blood clots or bleeding in the brain

Most of the serious suspected adverse reactions which have been reported concern medical conditions which are relatively common in the population. The timing of the events may therefore be coincidental.

Reactions which health professionals should be aware of

Other serious events have also been observed following vaccination where no causal relationship has been established. The Norwegian Medicines Agency wishes healthcare professionals to be aware of the following conditions in persons who are vaccinated:

- chest pain and breathing difficulties
- numbness
- reduced sensation and paralysis
- lasting symptoms, such as long-lasting headache or vaginal bleeding

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

Vaccine	Comirnaty (BioNTech/Pfizer)			Spikevax (Moderna)			Vaxzevria (AstraZeneca)	COVID-19 Vaccine Janssen
Number of doses administered	1.dose	2. dose	3. dose	1.dose	2. dose	3. dose	1.dose	1.dose
	3 601 734	2 923 760	1 806 999	550 711	1 036 395	532 243	142 562 ***	6 239
Total number of reports	**13 156***			**4 486***			**8 872***	**26***
Number of reports involving death	227**			15**			6**	0**
Serious reports other than death	2 980			935			661	4
Non-serious reports	9 949			3 536			8 205	22
	**The table shows number of reports that have been assessed* ***The fact that a person dies soon after being vaccinated does not necessarily mean that there is a causal relationship.* ****Vaxzevria has not been administered in Norway since 11 March, but number of doses administered may continue to increase as it reflects post-registraton of doses administered abroad. Post-registration of vaccines administered abroad may effect the number of doses administered for all the coronavirus vaccines*.							

Comment on Table 3:

The data concerning the various coronavirus vaccines are not directly comparable. The vaccines have been administered to a different number of people with different disease profile and ages.

Reports on deaths

So far, 248 reports of deaths have been assessed. There is a temporal link between some of the deaths and vaccination, while other deaths are due to Covid-19 in fully vaccinated people several months after the last dose. Most deaths have occurred amongst elderly persons receiving nursing care and residents of nursing homes.

Amongst the 248 deaths, 16 reports relate to deaths in fully vaccinated people who have been diagnosed with COVID-19. The patients who died was diagnosed with COVID-19 from 2 to 10 months after vaccination, and the events are reported due to suspected vaccination failure. Breakthrough infection was discussed in the report from 28. September 2021.

Persons over the age of 60

Every week, more than 300 residents die in Norwegian nursing homes and other similar institutions. Many of the elderly nursing home residents who have been vaccinated are very frail or terminally ill patients. It is therefore to be expected that deaths will occur with a temporal link to vaccination, without there necessarily being any causal link to the vaccine. The reports on many of these deaths in the elderly state that no link with vaccination is suspected, and that the death is being reported for

the sake of completeness.

An expert group of geriatric specialists have looked into the first 100 deaths that were reported after Comirnaty. There is some uncertainty regarding the assessments, but in 10 cases a causal relationship between vaccination and death was considered to be "probable". In these cases, it was apparent that common vaccine adverse reactions may have contributed to more serious illness.

Persons under the age of 60
We have received 18 reports of deaths following vaccination in people under the age of 60. Four of these cases concern deaths resulting from the very rare, but serious adverse reaction known as thrombosis with thrombocytopenia syndrome (TTS) following vaccination with Vaxzevria.
For the remaining deaths, the causal relationship with vaccination is uncertain.

Reports on pericarditis and myocarditis after vaccination with mRNA-vaccine

A number of cases of pericarditis (inflammation of the lining around the heart) and myocarditis (inflammation of the heart muscle) have been observed in persons who have been vaccinated with Comirnaty or Spikevax. Persons of all ages have been affected, but most cases of myocarditis have been reported in men under 30 years of age.

As of 18 January 2022, 242 cases of pericarditis and 133 cases of myocarditis have been reported in Norway after vaccination with mRNA-vaccine.

In addition there are 3 reports on pericarditis after vaccination with Vaxzevria.

It is not yet known whether those who have developed pericarditis or myocarditis after covid vaccination are at risk of recurrence after their next dose and, as a precaution, the Norwegian Institute of Public Health therefore recommends that persons who have developed these inflammatory conditions should refrain from further covid vaccination.

Table 4: Age distribution of reports on pericarditis and myocarditis after mRNA-vaccine

	Aldersgruppe							
	12-29	**30-39**	**40-49**	**50-59**	**60-69**	**70-89**	**Ukjent alder**	**Total**
Perikarditt	55	44	41	37	37	26	2	242
Myokarditt	60	14	21	13	12	11	2	133

Table 5: Gender distribution of reports on pericarditis and myocarditis after mRNA-vaccine

	Kvinner	**Menn**
Perikarditt	94	148
Myokarditt	36	97

Reports of suspected adverse reactions in the 12 – 17 age group

We highly prioritise the assessment of reports in the 12 -17 age group. We are closely monitoring the situation and are particularly alert to reports of serious events following vaccination.

As of 18 January 2022, over 439,000 doses have been administered to children and adolescents aged 12 to 17. During the period December 2020 to 18 January 2022, we have received and assessed 413 adverse reaction reports concerning this age group. 58 of these are classified as serious.

Adolescents normally experience the same common and transient adverse reactions as adults following vaccination. Amongst the more rarely known adverse reactions are inflammation of the heart muscle (myocarditis) and inflammation of the heart lining (pericarditis). We have so far received five adverse reaction report concerning this in this age group. Look out for symptoms such as chest pain, wheezing or rapid or irregular heart rate which particularly occurs during the first week after vaccination. Fever and cough may also occur.

Over 79% of the adverse reaction reports in this age group are from girls. Many reports concern menstrual disorders. Most of these are classified as non-serious.

Menstrual cycle and uterine bleeding disorders

We have so far assessed 3,045 reports of menstrual disorders. Most of these reports concern women between the ages of 20 and 49. 303 of these reports are classified as serious.

"In many of these cases, it is not the menstrual disorder, but other ailments that have been reported at the same time, which means that the report is classified as serious overall," says Ingrid Aas, Senior Consultant at the Norwegian Medicines Agency.

If menstrual disorders are prolonged and affect the person’s ability to work and carry out other daily chores, the report will also often be classified as serious.

We have also received 236 reports concerning women who have suffered unexpected vaginal bleeding after menopausal age. 230 of these are classified as serious. Unexpected vaginal bleeding after menopausal age is always classified as serious if it occurs more than one year after the last menstruation.

The Norwegian Institute of Public Health (NIPH) is conducting a major study in an attempt to determine whether or not there is a link between COVID-19 vaccines and bleeding disorders. Preliminary results from NIPH's population survey show that there is an increased incidence of menstrual disorders following COVID-19 vaccination in young women aged between 18 and 30.

How can we detect new adverse reactions?

We work systematically to analyse the reports so that we can respond quickly if new combinations of symptoms arise, or if common medical conditions occur more frequently following vaccination than we would expect. We work in three different ways:

1. **Health professionals assess individual cases of medical conditions and report when they suspect adverse reactions. The government authorities assess the reports in order to look**

for unknown combinations of symptoms or to determine whether there are any factors associated with the progression of the conditions which would indicate a link with vaccination.

E.g.: It was a combination of observant doctors at Oslo University Hospital, a robust and fast electronic monitoring system and analyses by the University Hospital of Northern Norway and the Preparedness Register which enabled Norway to help reveal that, in rare cases, Vaxzevria can give rise to a serious combination of symptoms involving blood clotting and low blood platelet counts.

2. **We carry out statistical analyses where we investigate whether the number of reports of a combination of symptoms is higher than expected.**

   E.g.: Such statistical analyses of reported adverse reactions have shown that serious allergic reactions occur more frequently following COVID-19 vaccination than with vaccination with influenza vaccines. It is also such analyses that have led to myocarditis and pericarditis being included as rare adverse reactions in the product information for Comirnaty (BioNTech/Pfizer) and Spikevax (Moderna).

3. **Health registers and population-based cohorts are used to assess and investigate further, and to confirm or disprove possible links between vaccination and reported symptoms or diagnoses. This is done in partnership with the Norwegian Institute of Public Health.**

   E.g.: Further investigation of possible links concerning symptoms reported via the spontaneous reporting system can be carried out by linking the Norwegian Immunisation Register (SYSVAK) to other health registers, to see whether any diagnoses occur more frequently following vaccination than is otherwise the case.

   The Norwegian Institute of Public Health and research institutions in many countries are also conducting registry studies to see whether there is any increase in the prevalence of diseases amongst vaccinated people that are not necessarily identified through the adverse reaction reports.

Appendix 1:

Number of suspected adverse reactions according to category

A single adverse reaction report can include a number of suspected adverse reactions or symptoms. Suspected adverse reactions are presented below, grouped according to the category to which they belong for each vaccine type and the types of suspected adverse reactions which have been reported most frequently. 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.

Suspected adverse reactions to mRNA vaccines Comirnaty (BioNTech/Pfizer) and Spikevax (Moderna)

The most frequently reported symptoms following vaccination with the mRNA vaccines 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. Headache, dizziness and drowsiness after vaccination are also frequently

Figure 1: Reported suspected adverse reactions by category for mRNA vaccines Comirnaty and Spikevax

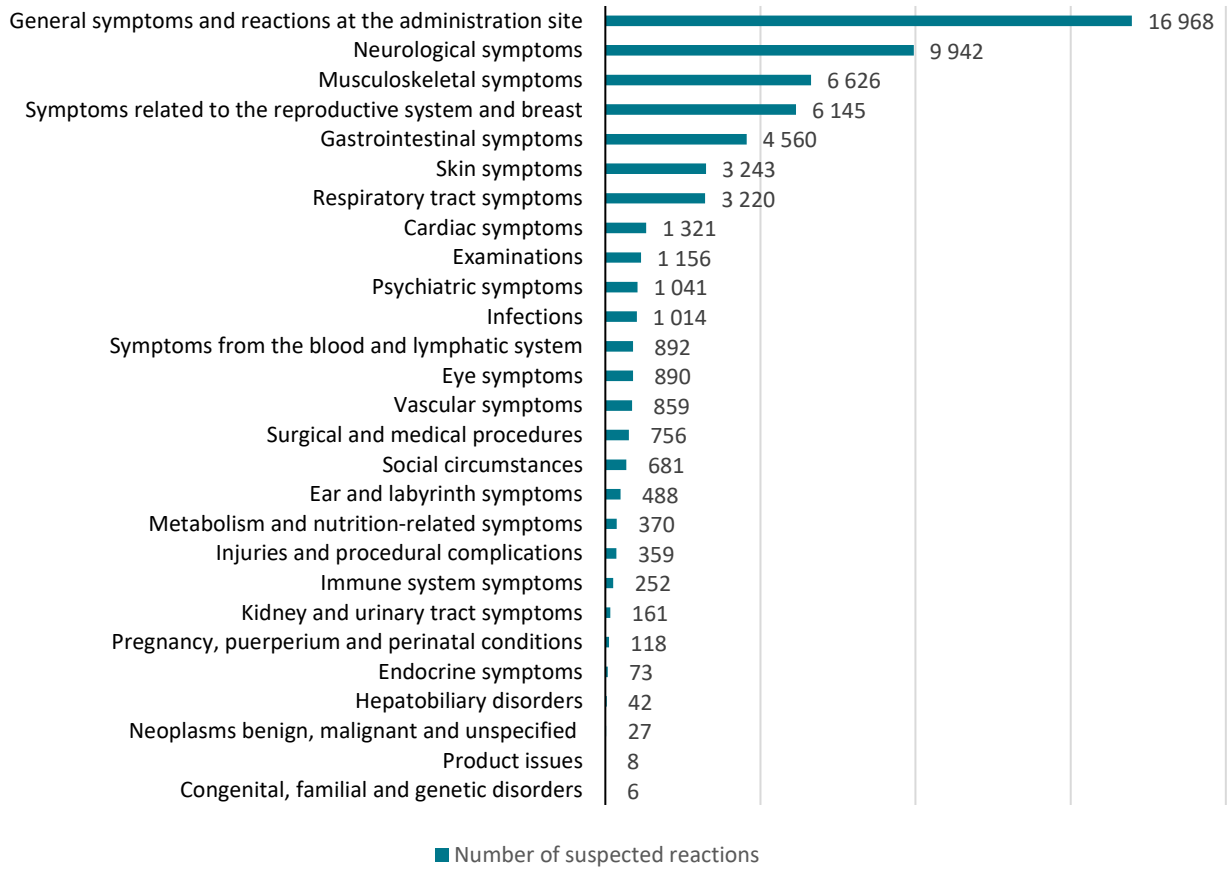


Table 6: Reported suspected adverse reactions by category for Comirnaty and Spikevax

A report can cover several adverse reactions and there will therefore be many more adverse reactions than reports.

Category	Number of suspected adverse reactions
General symptoms and reactions at the vaccine administration site E.g.: Pain and reactions at the injection site, discomfort, fever, fatigue, decreased general condition	16 968
Neurological symptoms E.g.: Headache, dizziness, drowsiness, syncope, loss of smell and taste	9 942
Musculoskeletal symptoms E.g.: Muscle pain, joint pain, muscle stiffness, pain in the extremities	6 626
Symptoms relating to the reproductive organs and breast E.g.: Breast pain and menstrual disorder	6 145
Gastrointestinal symptoms E.g.: Stomach pain, nausea, vomiting, diarrhoea	4 560
Skin symptoms E.g.: Rash, itching, redness, cold sweats, acne, night sweat	3 243
Respiratory tract symptoms E.g.: Difficulty breathing, shortness of breath, cough, irritation of the respiratory	3 220
Cardiac symptoms E.g.: Bradycardia, tachycardia, pericarditis, atrial fibrillation, extrasystoles	1 321
Examinations E.g.: Abnormal and raised heart rate, decreased blood pressure, decrease in oxygen saturation	1 156
Psychiatric symptoms E.g.: Sleep abnormalities, restlessness, lethargy, hallucination	1 041
Infections E.g.: Pneumonia, cold symptoms, shingles	1 014
Symptoms from the blood and lymphatic system E.g.: Swollen lymph nodes	892
Eye symptoms E.g.: Blurred vision, twitch, itchy eyes, photophobia, double vision, eye pain	890
Vascular symptoms E.g.: Flushes, pallor, low blood pressure**,** haemorrhage, deep vein thrombosis	859
Surgical and medical procedures E.g.: Hospitalisation, oxygen therapy, revaccination with other Covid-19 vaccine	756
Social circumstances E.g.: Bedridden, impaired work ability	681
Ear and labyrinth symptoms E.g.: Discomfort in the ear**,** tinnitus	488
Metabolic and nutrition-related symptoms E.g.: Reduced appetite, dehydration, high blood sugar	370
Injuries and procedural complications E.g.: Fall, bruise, wound	359
Immune system symptoms E.g.: Allergic reaction	252

Kidney and urinary tract symptoms E.g.: Urine retention, frequent urination, acute kidney injury	161
Pregnancy, puerperium and perinatal conditions E.g.: Spontaneous abortion, bleeding during pregnancy	118
Endocrine symptoms E.g.: Hypothyroidism, hyperthyroidism, thyroiditis	73
Hepatobiliary disorders E.g.: Portal vein thrombosis, hepatitis, gallstone	42
Neoplasms benign, malignant and unspecified	27
Product issues	8
Congenital, familial and genetic disorders	6

Suspected adverse reactions to viral vector vaccines Vaxzevria (AstraZeneca) and COVID-19 Vaccine Janssen (Janssen Cilag International NV)

These vaccines are not part of the Norwegian vaccination programme. Vaxzevria has not been administered in Norway since 11 March 2021. The Janssen COVID-19 vaccine is offered, but not as part of the vaccination programme. The number of suspected adverse reactions will increase if new reports are assessed. The number of suspected adverse reactions may also decrease if there are multiple reports of the same adverse reaction for the same patient (duplicates). The reports will then be merged and one of them deleted.

The most frequently reported symptoms following vaccination with the viral vector vaccines 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. Headache, dizziness and drowsiness after vaccination are also frequently

Figure 2: Number of reported suspected adverse reactions by category for viral vector vaccines Vaxzevria and COVID -19 Vaccine Janssen

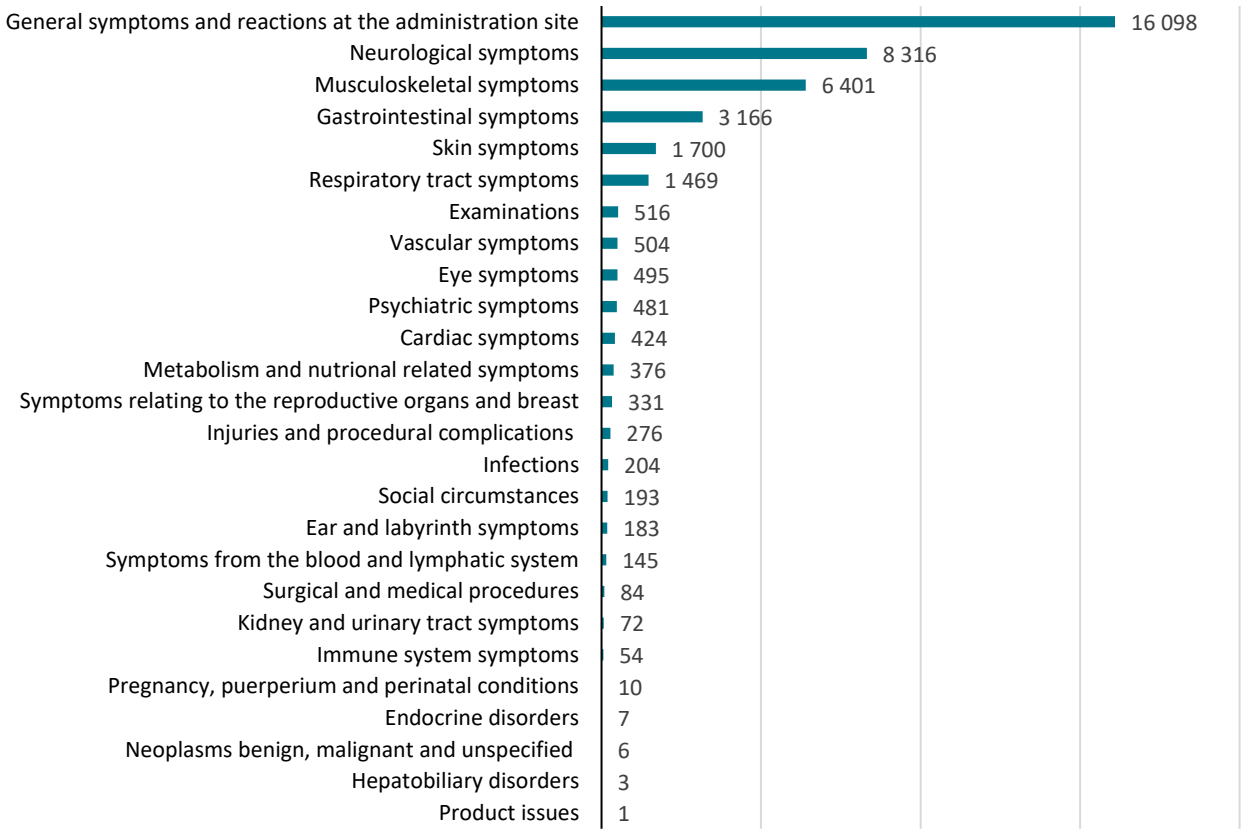


Table 7: Reported suspected adverse reactions by category for Vaxzevria and COVID-19 Vaccine Janssen

A report can cover several adverse reactions and there will therefore be many more adverse reactions than reports.

Category	Number of reported adverse reactions*
General symptoms and reactions at the vaccine administration site E.g.: Pain and reactions at the injection site, discomfort, fever, fatigue, decreased general condition	16 098
Neurological symptoms E.g.: Headache, dizziness, drowsiness, numbness	8 316
Musculoskeletal symptoms E.g.: Muscle pain, joint pain, back pain	6 401
Gastrointestinal symptoms E.g.: Stomach pain, nausea, vomiting, diarrhoea	3 166
Skin symptoms	1 700

E.g.: Rash, skin pain, cold sweats	
Respiratory tract symptoms E.g.: Difficulty breathing, hyperventilation, nasal congestion, pain and swelling of pharynx	1 469
Examinations E.g.: Abnormal and raised heart rate	516
Vascular symptoms E.g. Flushing	504
Eye symptoms E.g.: Blurred vision, twitch, eye pain	495
Psychiatric symptoms E.g.: Sleep abnormalities, insomnia	481
Cardiac symptoms E.g.: Palpitations	424
Symptoms relating to the reproductive organs and breast E.g. Pain in reproductive organs and nipples	376
Metabolic and nutrition-related symptoms E.g.: Reduced appetite	331
Injuries and procedural complications E.g. Contusion	276
Infections E.g. Sinus infection, cold symptoms	204
Social circumstances E.g.: Bedridden	193
Ear and labyrinth symptoms E.g.: Discomfort in the ear, sound sensitivity	183
Symptoms from the blood and lymphatic system E.g.: Swollen lymph nodes	145
Surgical and medical procedures E.g.: revaccination with different COVID-19 vaccine	84
Kidney and urinary tract symptoms E.g.: Frequent urination	72
Immune system symptoms E.g.: anaphylactic reaction, allergic reaction	54
Pregnancy, puerperium and perinatal conditions E.g.: spontaneous abortion	10
Endocrine symptoms	7
Neoplasms, benign, malignant and unspecified	6
Hepatobiliary disorders	3
Product issues	1

** The number of reported adverse reactions may also decrease if there are multiple reports of the same adverse reaction for the same patient (duplicates). The reports will then be merged and one of them deleted*