bijwerkingen centrumlareb

Overview of reports with fatal outcome after COVID-19 vaccination in the first 8 weeks of Dutch vaccination campaign.

1. Introduction

The Dutch COVID-19 vaccination campaign started on January 6th,2021. The first vaccines went to corona-ward-related hospital- and ambulance staff, who were vaccinated on location in their hospitals, as well as nursing home staff at GGD locations. On January 18th, 2021 the first nursing home resident was vaccinated, kicking off a large scale vaccination of long-term residential care facilities. At the same time, vaccination of mobile, independently living elderly began, starting with the 90+ generation. This means, apart from the health care staff directly involved in COVID-19 care, the first weeks of the vaccination campaign were predominantly directed towards the most vulnerable population.

This is an overview of the 94 reports with a fatal outcome received by Lareb in the first 8 weeks of the Dutch COVID-19 vaccination campaign. Vaccination in elderly still continues and reports with fatal outcomes are being received. Therefore, after this first overview updates will follow.

Fatal outcome as such is not an adverse event, but can be the outcome of an adverse event, or an adverse event can contribute to a fatal outcome due to other causes. The goal of this overview is to give insights into:

1. background and description of the cases
2. patterns of adverse events and their relationship with fatal outcome
3. potential contribution of occurring adverse reaction to a fatal outcome

This report does not include analyses of signals for specific adverse events. In case of an indication to do so, these will be performed separately. Cases in this report that mention specific adverse events will also be taken into account in these analyses.

2. Vaccination

Since the start of the vaccination campaign, the Dutch National Institute for Public Health and the Environment (RIVM) publishes weekly cumulative reports on vaccination metrics. Pfizer's Comirnaty was the first vaccine to be approved in and delivered to the Netherlands. Therefore the vast majority of the elderly population received this vaccine. All people in this overview were vaccinated on or prior to Feb 22 (Table 1) .

Table 1: Vaccination figures 6 January to 21 February 2021

Target group	Start date	Vaccine	First dose	Second dose
Care workers providing direct COVID-19 care	06-01-2021	COM	40,000	40,000
General Practitioners	22-01-2021	MOD	14,300	3,000
Other care workers and elderly *	06-01-2021	COM/AZ	252,615	161,520
90 years and up living at home	26-01-2021	COM	53,280	106
85-89 years living at home	29-01-2021	COM	134,687	104
80-84 years living at home	05-02-2021	COM	109,727	154

Target group	Start date	Vaccine	First dose	Second dose
60-64 years and/or high risk of severe COVID-19 (estimated) living at home	15-02-2021	AZ	13,386	0
Long-term residential care institutions (estimated)				
• Nursing homes and care institutions with an institutional physician	18-01-2021	COM	152,061	16,829
• Small-scale residential facilities under GP care	25-01-2021	MOD/COM	25,270	0
Total			795,326	218,713

COM= Comirnaty=Pfizer vaccine MOD= MODERNA vaccine AZ= Astra Zeneca vaccine
*This number also includes elderly <80 year living at home, who started to be vaccinated from Mid-February.
Source: https://www.rivm.nl/sites/default/files/2021-02/Deelname%252520COVID19%252520vaccinatie%252520in%252520Nederland_2021_02_23.pdf

3.Reports

Lareb received 94 reports in which a fatal outcome was reported in the first 8 weeks of the Dutch COVID-19 vaccination campaign, with cutoff date of February 26, 2021, end of day. Excluded from this analysis are 4 reports, which only contained the information that a person had died after vaccination, without any further detail, 2 of these came from consumers and 2 were reported to Pfizer, the marketing authorization holder (MAH) of one of the vaccines.

Some serious cases reported prior to February 27 had evolved to a fatal outcome when the reporter was contacted again for additional information (follow up). In case the date of death was after February 26, these cases were not taken into account in the present overview, but will be included in a later update.

After receipt of reports, with the exception of those received indirectly through the MAH, Lareb evaluates the information received. If more information is needed , which is the case in the large majority of the reports, Lareb contacts the reporter and asks for follow-up information. If not received within a week, Lareb sends out reminder e-mails, up to two times, or contacts the reporter by phone. When this overview was written, not all follow up had yet been obtained for all reports.

Table 2. Reports received

Spontaneous reports received	94
Lareb Intensive Monitoring (LIM)	0
Reports excluded due to minimal information*	-4
Total included in this overview	90
Vaccines: • Pfizer • Moderna • Not reported	 81 (4 after second vaccination) 5 4
Reported by: • Elderly care physician • General practitioner • Consumer	 25 24 14 14

• Other physician • Other medical specialist • Nurse practitioner • Physician assistant • Nurse assistant (‘ziekenverzorgende”)	9 2 1 1

*reports only mentioned that a person had died after vaccination, without any further detail.

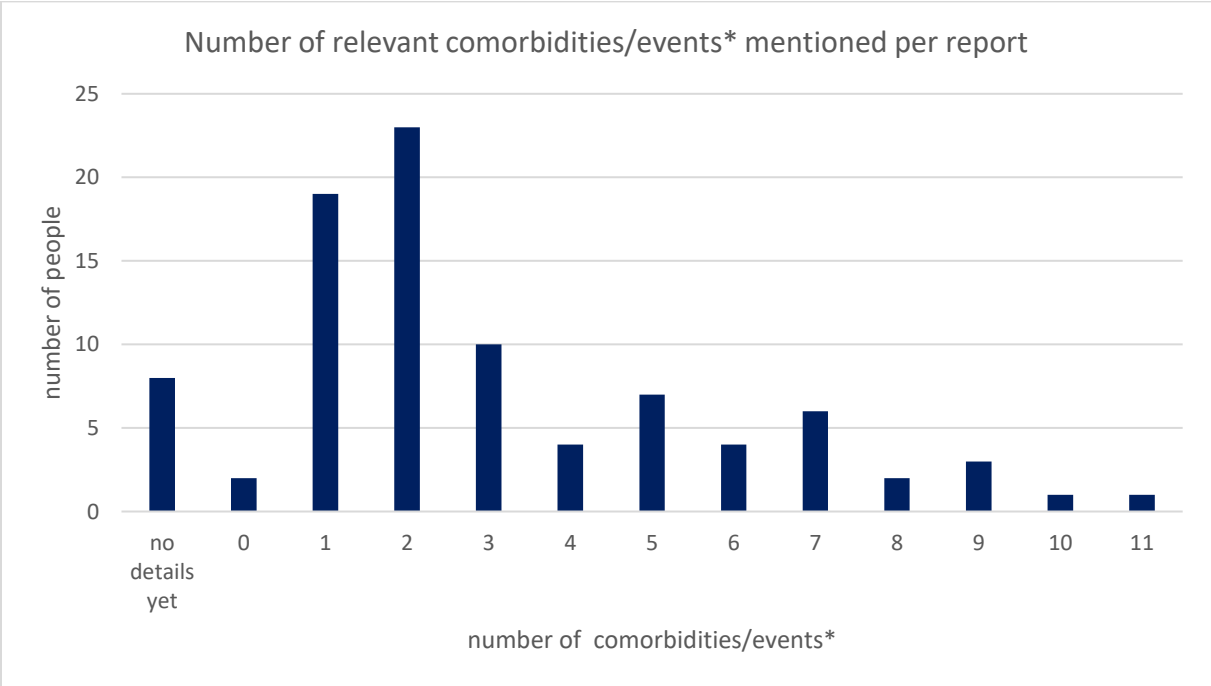
Lareb’s reporting forms do not ask for a specification whether the deceased was living independently or in a long term care facility. Only for reports from elderly care physicians (‘specialist ouderengeneeskunde’) it can be assumed with a high level of confidence that the person reported on was a long term care resident. Health care in the Netherlands, however, is organized in such a way that also general practitioners take part in the care of long term care residents, so the fact that they are reporting should not be read as a sign that the deceased did not live in a nursing home. "Other physicians” generally includes junior physicians in training in either the long term care facilities, the GP practices or hospitals.

Table 3. Gender and age

Age	Male	Female	Total
65-<80	8	8	16 (18%)
80-<90	14	18	32 (36%)
90+	14	26	40 (44%)
Unknown	1	1	2 (2%)
total	*37 (41%)*	*53 (59%)*	*90*

3.1 Comorbidities

Figure 1. Number of relevant comorbidities reported.



* The numbers include both comorbidities, such as diabetes mellitus, as well as relevant medical history events, such as myocardial infarctions, TIA's etc. "1" includes several initial reports that spontaneously mentioned 1 comorbidity, but follow up to obtain a complete list had not been received at time of this report.

In 43 cases the deceased were described by the reporters as being in a very frail and vulnerable stage of their lives. They were generally living in long term care facilities, often suffering from a large number of comorbidities, many already on a gradual or fast downward slope prior to receiving their vaccinations. A small portion was even already on a palliative end-of-life trajectory. In another 18 cases the deceased were generally described as vulnerable, but physically fairly stable prior to their vaccinations. They too tended to live in nursing homes, had underlying disease and a short remaining life span, but were not in a situation of imminent death. In 7 cases the reporters, sometimes relatives of the deceased, described the deceased as previously "healthy" or even "very healthy", or "healthy for their age". Apart from one person, who's age is unknown, the age of these 7 people was between 83 and 94 years old and some were reported to have medication that indicated some relevant medical history. Finally, in 22 cases (currently) available documentation did not allow for an evaluation of their state of vulnerability.

Table 4. Medical history/comorbidity -details

	Number of reported conditions (nr. of patients)	**Most frequently reported conditions (not mutually exclusive)**	
Cardiovascular Disease			
Cardiac disorders	**41 (30)**	Cardiac failure	21
		Atrial fibrillation	5
		Ischemic Heart Disease	4
		Other type of arrhythmia	3
		Valve disorders	2
Vascular disorders	**27(23)**	Hypertension	17
		Venous insufficiency	3
		Peripheral Arterial Occlusive Disease	2
Nervous system disorders			
Total, excl Mental Impairment Disorders	**28(26)**		
		Cerebral Vascular Accident	8
		Transient Ischemic Attack	4
		Parkinson(ism)	5
		Epilepsy/Seizure	3
Mental Impairment	**31(31)**	Dementia (unspecified)	15
		Vascular dementia	6
		Alzheimer	3
Respiratory disorders			
Total	**17(15)**		
		Chronic Obstructive Pulmonary Disease	8
Infections			
Total	**24(22)**		

		(Suspected) COVID	12
		Urinary Tract Infections	5
Renal &Urinary			
Total	**10(9)**		
		Renal insufficiency	5
		Renal failure	4
Malignancies			
Total	**13(11)**		
		Breast Cancer	5
Other			
Total	**85(47)**		
		Diabetes Mellitus	17
		Anemia	5
		Fractures	4
		(Thrombocytic)Purpura, Immune Thrombocytopenia	3
		GERD, Hiatus hernia	3
		Hypercholesterolemia	3

3.2 Comedication

Whether and which medication was used was reported in 82 out of 90 cases, follow up information has been asked for in the remaining 8 cases. Table 5 lists the medication that has been reported. Off note, anticoagulants and cardiovascular drugs are the most prominently used. Half (45) of the reported deceased had been on some type of cardiovascular medication, often in combination with anticoagulants and/or various other drugs.

Table 5 Comedication

	Number (patients)	**Most frequently reported (not mutually exclusive)**	
Cardiovascular	**93 (45)**		
		Diuretics	29
		ACE inhibitors	16
		Betablockers	12
		Calcium Antagonists	11
		Statins	11
		ARB's	6
		Various others	6
Antithrombotic	**32 (32)**		
		Platelet aggregation inhibitors	17
		Vitamin K Antagonists	9
		DOAC's	6
Opioids	**12 (12)**	Oxycodon	5
		Fentanyl	3
		Morphine	3
		Tramadol/Paracetamol	1
OTHER MEDICATION:			

Vitamins, Minerals etc.		Various	49
Gastro-Intestinal		Laxatives (Macrogol etc.)	22
		Antacids(Omeprazole etc.)	22
		Antiemetics/antidiarrhea	5
Bronchodilatation/inhalers		Various	20
Analgesics		Paracetamol, other	16
Benzodiazepines +other sleep		Various	12
Antidiabetics		Metformin and other oral	16
		Insulin	3
Antidepressants		Various	10
Antibiotics		Various	9
Antipsychotics		Various	6
Prostrate/Urology		Various	6
Anti-epileptics/pregabalin		Various	5
Corticosteroids		Prednisone/solon, Dexamethasone	3
Other			11

In 6/90 cases the reporters have named comedication as “co-suspect” for potential roles in the events leading to the deaths. Drugs named were bumetanide in 2 cases, apixaban in one, as well as clozapine and opioids: oxycodone, fentanyl and morphine (with midazolam and paracetamol).

4.Reported reactions and events

In 18 of the 90 reports ‘death’ was the only event reported. In 44 reports, hence about half of the cases, the SmPC-labelled side effects that are signs of local (e.g. injection site pain) or systemic (pyrexia, malaise, nausea etc.) reactogenicity were reported.

Table 6. Reactions reported after vaccination

Reactions reported (not mutually exclusive):	
Malaise	24
(Hyper)pyrexia, body temperature increased	22
Nausea (14x)/Vomiting(4x),Both 2x	20
Fatigue	12
Chills	6
Headache	3
Myalgia	3
Injection site pain	3
Arthralgia	3

4.1 Latency

In all reported cases, the vaccination date is known. In 65/90 reported cases, an exact day of death and hence an exact latency between vaccination and the death can be calculated. In the remaining

25 cases a 'maximum latency' can be calculated from the difference between vaccination date and reporting date. They are listed in table 7. The longest latency in this data set is 26 days, which is based on actual knowledge of day of death.

Table 7. Latency between vaccination and death

Latency (days)	Day of death reported	Day of death unknown: max latency derived from reporting date	Total
0-1	8	3	11 (12%)
2-7	37	7	44(49%)
8-14	14	8	22(24%)
>14	6	7	13(14%)
Total	65 (72%)	25 (28%)	90

4.2 Reported causes of death

Reported causes of death are listed in table 8. In 32 cases, the primary cause is currently "unspecified." In some of these cases follow up information has been asked for, but has not yet been received. In some cases the physicians who reported the initial death are not in a position to provide any details, e.g. because they only saw the patient in their capacity of medical examiner to legally certify the death, or because they were emergency unit physicians without access to further details. In others, the deceased were found death, without a clear picture of what happened in the hours or even days prior to the death, so these will remain unspecified. In only a few cases obduction has been done.

In 4 cases the fatal outcome occurred after the second vaccination. These cases were not different from the overall picture. They were 3 sudden fatalities, with latencies of 0-3 days and one late event, all patients were nursing home residents and/or in fragile health status.

Table 8 Reported primary causes of death

Cardiac		
	Acute coronary syndrome	1
	Arrhythmia	1
	Cardiac arrest	1
	Cardiac death	2
	Cardiac disorder	1
	Cardiac failure	6
	Cardiac failure acute	2
	Cardiogenic shock	1
	Heart arrest	1
	Myocardial infarction	1
	Sudden cardiac death	1
	Total Cardiac	**18**
Cerebral Vascular Accidents		
	Basilar artery thrombosis	1
	Cerebral haemorrhage	2

	Cerebral infarction	1
	Cerebrovascular accident	3
	Ischaemic cerebral infarction	3
	Total Cerebral Vascular	**10**
Gastro-Intestinal		
	Gastro intestinal hemorrhage	2
	Intestinal Ischemia	1
	Total GI-ischemic/hemorrhagic	**3**
Pulmonary		
	Acute Respiratory Failure	1
	Aspiration Pneumonia	4
	Asthma	1
	Pneumonia	2
	Oxygen saturation decreased	2
	Total Pulmonary	**10**
Infectious		
	COVID-19	3
	Hepatitis C	1
	Respiratory Tract Infection	2
	Infection	1
	Total Infectious	**7**
Unspecific/Other		
	Cachexia	1
	Decreased appetite	1
	Dementia	1
	Hyperpyrexia	1
	Pyrexia	2
	Malaise	2
	Renal failure	1
	Vomiting	1
	Total Unspecific	**10**
Unspecified		
	Death	17
	Sudden death	3
	Unknown	12
	Total unspecified	**32**

Table 9 combines tables 4, 5 and 8.

Table 9 Comorbidities and medication used per reported cause of death-group level

Cause of Death	Medical history reported in this population			Comedication reported in this population	
Cardiac N=18	Cardiac Failure	9		Diuretics	13
	Hypertension	5		Vitamin K antagonists	5
	Atrial fibrillation	3		Other Antithrombotics	4
	Other arrythmias	3		ACE Inhibitors	5

	Vascular Parkinsonism /Vascular Dementia	3		Bètablocker	3
	Other Cardiovascular	5		Other Cardiac	7
	Other (COPD, Diabetes COVID-19 etc.)	2		Statins	2
				Unspecified	1
	Number of people without any of the above comorbidity	0		Number of people without any of the above medication	3
Cause of Death	**Medical history reported in this population**			**Comedication reported in this population**	
Cerebral Vascular Accidents N=10	Hypertension	6		ACE inhibitor, Betablocker, Calcium antagonist	8
	Other vascular	5		Antithrombotic	3
	Vascular Dementia, Epilepsy	3		Statins	2
				Diuretics	2
	Number of people without any of the above comorbidity	1		Number of people without any of the above medication	3
Cause of Death	**Medical history reported in this population**			**Comedication reported in this population**	
Gastro-Intestinal Ischemic or Hemorrhagic N=3	Gastro intestinal disease or risk factor	1		Cardiac medication	2
	Vascular Disease or Risk Factor	2		Antithrombotic medication	2
	Number of people without any of the above comorbidity	1		Number of people without any of the above medication	1
Cause of Death	**Medical history reported in this population**			**Comedication reported in this population**	
Pulmonary	Pneumonia existing prior to vaccination	3		Cardiovascular medication	4
N=10	Institutionalized patients with severe cognitive dysfunction	6		Respiratory medication	1
	Current or past COVID-19	4			
	GERD	2			
	COPD	1			
	Number of people without any of the above comorbidity	1		Number of people without any of the above medication	6
Cause of Death	**Medical history reported in this population**			**Comedication reported in this population**	

Infectious N=7	Nursing home resident and/or vulnerable and/or palliative	7		No relevant drug pattern. Off note: 6/7 were on antidepressants and/or antipsychotics and/or benzodiazepines	6
	Number of people without any of the above comorbidity	0		Number of people without any of the above medication	1
Cause of Death	**Medical history reported in this population**			**Comedication reported in this population**	
Unspecific /Other N=10	Dementia	5		Very little medication use in this population, not patterns	
	Palliative	1			
	Number of people without any of the above comorbidity	4		Number of people without any of the above medication	n/a
Cause of Death	**Medical history reported in this population**			**Comedication reported in this population**	
Unspecified cause of death N=32	Cardiac Failure	10		Anti-hypertensive and other cardiac medication, excl. diuretics	20
	Diabetes Mellitus	7		Diuretics	11
	Cerebrovascular Events	6		Antithrombotics (Vit K antagonist, DOAC, platelet aggregation inhibitor)	15
	Hypertension	5		Oral antidiabetics	5
	Cognitive and confusional disorders/states	8		Medication information not yet reported	5
	Renal failure	4			
	Various cardiac	3			
	Malignancies	3			
	Anemia	2			
	Thrombotic disease	2			
	Other relevant	1			
	None reported but the use of medication is highly suggestive of an underlying disease	4			
	Comorbidity not (yet) reported	3			
	Number of people without any of the above	0		Number of people without any of the above	6

Table 10 Latency and causes of death, history and medication

Latency (days)	Number of reports	Reported causes of death	Relevant Medical History	Relevant Co-medication
0-1	11	• 7x (sudden)death or unknown • 2x cardiac • 2x cerebrovascular	• 9x cardio- and/or cerebrovascular medical history • other 2 no reported history, but CV-medication	• 9x cardiovascular, of which 5x also antithrombotics • 1x antithrombotics • 1 not yet reported
2- 7	44	• 14x (sudden)death or unknown • 6x cardiac failure/disorder • 5x sudden cardiac • 5x (aspiration) pneumonia • 3x cerebrovascular • 3x GI hemorrhagic/ischemic • 2x infections • 4x other	• 22 x cardiovascular medical history • 4x cerebrovascular medical history • 13 x fragile, vulnerable, palliative or potentially fatal situation prior to vaccination • 2 no reported history, but CV-medication • 3 no information	• 23x cardiovascular, of which 14x also antithrombotics • 4x antithrombotics • 15x other comedication • 2x unknown
8-14	22	• 7x (sudden)death or unknown • 4x cerebrovascular • 3x infectious • 2x acute cardiac • 6x other	• 14 x fragile, vulnerable, palliative or potentially fatal situation prior to vaccination • 4x no information • 4x other underlying disease	• 6x cardiovascular, of which 4x also antithrombotics • 4x antibiotics • 5x unknown • 3x other relevant • 4x none
>14	13	• 4x unknown • 3x cardiac • 2x infectious • 4x other	• 9x cardiovascular or cerebro-vascular history • 2x infectious • 2x other	• 4x cardiovascular + antithrombotics • 3x cardiovascular • 3x unknown • 3x others

4.3 Special cases

As listed in table 4, there were 3 reports where in the medical history, thrombotic purpura and immune thrombocytopenia were mentioned. All these cases concerned women in the 80+- age group, 2 died from cardiac causes, 1 unknown. All 3 were on cardiovascular medication and 2/3 were on antithrombotics. Two died shortly after vaccination, the other >14 days later.

5.Assessment of reports

5.1 Method of assessment

All reports are assessed taken into account following aspects:

- latency time of events after vaccination
- the presence of a clear deterioration of a preexisting potentially fatal condition or occurrence of a new potentially fatal condition in the weeks prior to vaccination
- could health events that occurred after vaccination be attributed to the vaccination?
- could adverse events of the vaccination have contributed to decompensation of an already vulnerable state?

5.2 Outcome of assessments

5.2.1. Lack of information: 31 cases

About half of these 31 reports an assessment was not possible due to a lack of data on the patients' health status in the days and weeks prior to the vaccination and/or sequence of events after vaccination.
The others were a mixture of the following:
- Vulnerable patients who were already deteriorating prior to vaccination or suffered from an acute intercurrent disease that had started just prior to vaccination, in whom it was impossible to establish whether reactions such as further malaise or fever after the vaccination were due to the vaccination or the intercurrent disease.
- Patients who had experienced adverse events from the vaccination but died suddenly many days after they had already recovered from the adverse events.
- Patients found death in whom it could not be established what the cause of death was, nor what had happened in the hours or even days prior to their death.

Some of these cases might be cleared further if additional follow-up information will be obtained.

5.2.2 Other causes more likely: 41 cases

In 10 of these cases a cerebral vascular accident (CVA) occurred in patients without any reported signs of reactogenicity to the vaccination. In 8 of them there were clear signs in the medical history for underlying illness identifying a risk for CVA, such as hypertension, TIA, use of anticoagulants, antihypertensives etc. The latency between vaccination and CVA varied between 0-10 days, with 3 occurring on the day of vaccination, likely before the systemic effects of the intramuscular vaccination would have kicked in. Latency between vaccination and death was <7days in 50% and ≥ 7 days in the remaining 50%. In one case apixaban was also mentioned as suspected drug.

Nine concerned deaths that were reported under various descriptions of sudden cardiac-related death. All but 1 of the patients had clear cardiovascular risk, indicated by their medication: 5 patients were on anticoagulants, 7 patients on at least 1 antihypertensive medication, as well as by their rich medical history, such as cardiac failure (in 4 patients), TIA, cerebral infarction, CVA, atrial fibrillation and prior myocardial infarctions and (severe) COPD. Only two patients had reactogenicity related adverse events of the vaccination.

Nine cases were sudden deaths, without any further specification. All but one were described by their various reporters, all physicians, as fragile, to extremely fragile patients. Three were already on a very clear downhill path, 5 died suddenly without any evidence of events related to reactogenicity from the vaccination. In one case bumetanide was marked as (co) suspected drug. Five of them had (type II) diabetes mellitus, 6 were on anticoagulant drugs, 7 anti-hypertensive treatment and 8/9 had cardio and/or cerebral vascular events in their medical history, in addition to various other serious diseases and/or events.

A further 8 cases concerned confirmed COVID-19 cases and/or (aspiration) pneumonia. In all these cases there was either clear evidence or strong suspicion that these conditions already existed prior to vaccination. Latency was 1 to up to 3 weeks past vaccination in the majority of these cases. In one case morphine was identified as (co) suspect drug.

Finally in 5 cases various other primary death causes were reported, including 4 cases were deterioration was clearly present prior to vaccination and barely any reactogenicity related adverse events were observed. Latency in these cases was up to 15 days. Fentanyl dermal patch was (co)suspect in one case.

5.2.3 Adverse events may have contributed – 18 cases.

In the cases mentioned in 5.2.1 and 5.2.2., physicians often described their patients as being in extremely fragile and vulnerable health states. In the 18 cases here, however, fragility was described in a different way, description were used as “healthy for his/her age”, “fragile, but physically stable” or “slow deterioration since admission to nursing home, but no expectation of sudden death”. The description of the days after vaccination in these patients invariably report reactogenicity related adverse events that are described by reporters as clear turning points in the patients’ health state and could have contributed to the prelude of the fatal outcomes. Ten cases report that body temperature was increased, often in the higher temperature ranges, 8 report malaise, 8 report nausea, in one case accompanied by vomiting. In general latency is short for all these reactions, e.g. the body temperature increase appeared within 1 day in almost all. In addition all but one of them report various other adverse events, such as headaches, dyspnea, dizziness, somnolence, fatigue and many more. In one case oxycodon is mentioned as (co)suspect, in another case clozapine.

Half of these cases report a cardiac death, 7 of these are described as cardiac failure and 1 as cardiac disorder. Seven of them either had cardiac failure or hypertension or both in their medical history, 2 are also known with renal failure. Their medication lists also indicate underlying cardiovascular issues in most cases. Their ages range from 78-98 years.

The other cases are a mix of infections and other causes of death, including 3 aspiration pneumonias, 2 of which were linked by the reporters to the nausea and vomiting triggered by the vaccination.

6. DISCUSSION

The large publicity around the vaccination campaign may have contributed to a higher number of reports than anticipated, based on historical data. (e.g. influenza campaigns). The public scrutiny as well as the Dutch guideline telling health care professionals (HCP's) to report, even if causality is not clear, may also have contributed to more reports from HCPs. As such, Lareb is a proponent of the possibility for anybody to report with the lowest possible hurdle. However, as a consequence a fair share of reports do not contain enough details to be able to properly evaluate the case to make a reliable assessment. Therefore in the large majority of the reports, Lareb has contacted the reporter to ask for follow-up information. When this overview was written, follow up had not yet been obtained for all reports. In a substantial part of the cases, however, with or without follow up, a clear picture of what happened in the hours or even days prior to the death, and the primary cause of death is not available and these cases will remain not assessable.

A fatal outcome after vaccination does not imply a causal relationship. The background rate of mortality within the vaccinated age-group is relatively high. In the years prior to the pandemic, on average, every day 357 people aged 65+ years, including 228 of age 80+ died in the Netherlands, of all causes. Cardiovascular death was the leading cause of death in this age group, responsible for around 30% of fatalities.

In the large majority of cases, vulnerable and often already progressively deteriorating health states and/or recent development of potentially fatal conditions unrelated to the vaccine, seem to be the most logical explanations for the cause of the events.

The cases present a large variety of disease courses, events before and after vaccination, and causes of death. They do not seem to point towards any unusual causes of death in this age range. At this moment in time, Lareb does not see any patterns that point towards serious adverse events leading to fatal outcome.

In some of the deceased reported, the vaccination caused reactogenicity related adverse events that led to a clear bend in their health state. These adverse events, such as fever, nausea, malaise are in themselves not causes of death, but may have contributed to deterioration of an already vulnerable health state or condition.

This signal has been raised on April 1, 2021. It is possible that in the meantime other information became available. For the latest information, including the official SmPC's, please refer to website of the MEB www.cbg-meb.nl