



COVID-19 vaccination as a rare potential etiology for cause of death after medicolegal autopsy. A Finnish nationwide study.

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ABSTRACT

COVID-19 vaccinations began globally at the end of 2020. By the end of 2021, 9.8 million doses were given in Finland. Regarding safety, most vaccine-related adverse reactions have been mild, but severe and lethal ones have also occurred. Autopsies in post vaccination deaths may give insight to the extent of fatal health conditions with potential COVID-19 vaccine etiology and provide new hypotheses of possible causalities between vaccination and severe health conditions. We searched the complete documentation on all medicolegal autopsies in Finland between December 2020 and December 2021 to assess how often the indication for autopsy was a suspected fatal adverse reaction to COVID-19 vaccination, and whether vaccination remained a potential etiology for any health condition determined as a cause of death after the autopsy. We linked register-based data on individual COVID-19 vaccination course and pre-existing health conditions. We found 428 autopsy cases with a mention of COVID-19 vaccination, and prior to autopsy, vaccination was suspected to play a part in 76 deaths. Post autopsy, a forensic pathologist considered vaccination to be potentially related to underlying cause of death in five and contributory cause of death in seven autopsy cases. These included seven thromboembolisms, two diabetic ketoacidoses, one myocarditis, one acute pancreatitis, and one eosinophilic granulomatosis with polyangiitis. In relation to the number of vaccinations within Finland, medicolegal autopsies were rarely performed because of a possible vaccine-related severe adverse reaction. Among the autopsies performed for such reasons, only a few considered a vaccine-related severe adverse reaction as a cause of death, although considerable doubt remains in the accuracy of individual considerations, and autopsy cannot definitively confirm causality between vaccination and death. Regarding vaccination safety, continuing evaluation of suspected vaccine-related deaths is essential, and autopsy should be considered in cases of death where vaccine etiology is possible.

1. Introduction

During the COVID-19 pandemic, fast development of vaccines created several products that efficiently prevent severe illness and death caused by the SARS-CoV-2 virus [1]. The vaccines were proven to be safe enough to meet the agreed emergency use authorization criteria, and large-scale as well as long-term safety follow-up was to be done only post authorization [2]. Post-marketing safety surveillance has revealed rare

severe adverse events following immunization (AEFI, terminology used in this paper according to the European Medicines Agency guideline [3], is presented in Table 1), with some considered to be truly caused by the vaccines. Among the first severe adverse reactions were thromboembolic complications including cerebral venous sinus thrombosis (CVST) and other unusual thrombotic events which were related to adenoviral vector vaccine ChAdOx1 (Vaxzevria, AstraZeneca) as reported by European Medicines Agency in April 2021 [4]. Subsequently, an

Abbreviations: AEFI, adverse event following immunization; CVST, cerebral venous sinus thrombosis; TTS, thrombosis with thrombocytopenia syndrome; VITT, vaccine-induced immune thrombotic thrombocytopenia.

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Table 1
Definitions of vaccine-related incidents used in this paper.

Term	Definition
Adverse event following immunization (AEFI)	Any health condition or problem that occurs following immunization and which does not necessarily have a causal relationship with vaccination [3]
(Severe) adverse reaction	Noxious and unintended health condition in response to vaccination with a suspected causal relationship. Severe adverse reactions include health conditions which are life-threatening or result in death [3]
Unrelated health problems following vaccination	Health condition considered not to be caused by vaccine
Cause of death	Cause of death as stated in the death certificate determined by a forensic pathologist or another physician

association emerged between these thromboses and thrombocytopenia, as well as the occurrence of anti-platelet factor 4 antibodies in the patients, and this syndrome was named vaccine-induced immune thrombotic thrombocytopenia (VITT) [5], or thrombosis with thrombocytopenia syndrome (TTS) [6]. Notably, VITT is also considered an adverse reaction to another adenoviral vector vaccine, Ad26.COV2-S (COVID-19 Vaccine Janssen, Janssen Group) [5,7]. Additionally, cases of myocarditis and pericarditis have occurred shortly after vaccination, and these conditions have been shown to be associated with mRNA vaccines BNT162b2 (Comirnaty, BioNTech-Pfizer), and mRNA-1273 (Spikevax, Moderna) in several large epidemiological studies, especially in young men [8–10]. However, though myocarditis can be a severe condition, reports in young men show relatively mild outcomes and no mortality associated with myocarditis shortly after vaccination [11,12]. Furthermore, in a population-based study, deaths identified after vaccine-related myocarditis were rare, and not necessarily attributable to myocarditis [13].

A vast amount of unconfirmed and misinterpreted data without epidemiological support regarding vaccine-related morbidity and mortality has been of great concern from the beginning of COVID-19 vaccinations [14,15]. For an individual who dies within days or weeks following vaccination, the causes of death should be thoroughly examined on one hand because of individual legal protection, and, on the other hand, to reveal potential severe health conditions following immunization. The key investigation in this regard is an autopsy, either medicolegal or clinical, though it must be stressed that causality cannot generally directly be established between vaccination and the health conditions determined as causes of death. A growing number of autopsy case reports of deaths following COVID-19 vaccination have been published (e.g., systematic review by Sessa et al. [16]). However, few larger autopsy-based data have been published. The Finnish law requires that a medicolegal cause-of-death investigation must be done when death is considered unexpected, or if it has been caused or suspected to have been caused by non-natural causes such as medical treatment (Act on the Inquest Into the Cause of Death 459/1973). Thus, a medicolegal autopsy is generally instructed by the police when a vaccination is suspected to play a role in the process leading to death.

We set out to evaluate how often the basis for medicolegal autopsy was a suspected fatal adverse reaction to COVID-19 vaccination in Finland, and we describe cases in which COVID-19 vaccination remained as a potential etiology for a health condition considered as any cause of death after the autopsy. In this paper, we use the term “vaccination” in referring to all events related to vaccine products or the overall vaccination process. We also describe those cases in which the forensic pathologist considered COVID-19 vaccination not to have any part in the death process. We describe the medicolegal cause-of-death investigation procedure and discuss the remaining uncertainties in both the accuracy of case-selection for assessment, and in determining the potential vaccination etiology.

2. Material and methods

2.1. COVID-19 vaccinations in Finland

Since the beginning of the SARS-CoV-2-virus pandemic in 2020, several COVID-19 vaccines have been introduced to the market. In Finland, the first vaccines were given in December 2020. By the end of 2021, 9.8 million doses had been administered in the country [17], and nearly 90 % of the population aged 12 years or older had received at least one dose [18].

Initially prioritized groups for COVID-19 vaccinations were the elderly, adults with a risk for severe COVID-19 disease, and health care workers. Vaccination was gradually extended during 2021 to cover the whole adult population with priority by age group from older to younger, and finally to children over five years old. By the end of 2021, five vaccine products had gained conditional marketing authorization: BNT162b2 on Dec 21, 2020; mRNA-1273 on Jan 6, 2021; ChAdOx1 on Jan 29, 2021; Ad26.COV2-S on Mar 11, 2021; and NVX-CoV2373 (Nuvaxovid, Novavax) on Dec 20, 2021 [19]. Due to safety concerns related to coagulation disorders, the use of ChAdOx1 ceased on Mar 19, 2021 for those younger than 65 years, and altogether on Nov 30, 2021 [20]. Because of the suspected relationship of mRNA-1273 and myocarditis and pericarditis, the use of this vaccine ceased for men under 30 years of age on Oct 7, 2021 [21]. All vaccinations given in Finland are recorded in electronic health record systems and collected to the National Vaccination Register [22].

2.2. Medicolegal cause-of-death investigation process in suspected vaccine-related deaths in Finland

If a suspicion of a relationship between vaccination and death arises, the police instruct a medicolegal autopsy. Suspicion can be based on information from next-of-kin, from treating clinicians, from police investigation and/or in consultation with a forensic pathologist, and the suspicion can be fully subjective at this stage, based on clinical history, or other circumstances prior to death. The process needs to be actively initiated and the suspicion can be brought forward by any of the mentioned parties. Usually this happens when death occurs close to vaccination, unexpectedly, or when no other obvious cause of death can be determined based on available clinical data. Threshold for initiating the medicolegal process is kept low especially when a relative expresses the suspicion [23]. Finland has one of the highest autopsy rates among high income countries [24], with medicolegal autopsies carried out in 13.7 % during the study period (Table 2; [25]), and the overall autopsy rate being 17.6 % of all deaths in 2021 [26].

The Finnish Institute for Health and Welfare conducts all medicolegal autopsies in its Forensic Medicine Unit, geographically distributed in five locations covering the whole country. The institute keeps a

Table 2
Medicolegal autopsies carried out in relation to total death during the study period, Dec 26, 2020 – Dec 31, 2021.

	Medicolegal autopsies	Total deaths [25]	Autopsy-percentage
End of follow-up	Dec 31, 2021	Dec 31, 2021	
Number of cases	8048	58,714	13.7
Sex			
Men	5597	29,697	18.9
Women	2451	29,017	8.5
Age, years			
< 18	80	214	37.4
18–34	531	646	82.2
35–64	2751	6862	40.1
≥ 65	4686	50,992	9.2

medicolegal database for all data related to cause-of-death investigation including autopsy reports, death certificates, police reports, and other related documents.

2.3. Individual assessment of causes of death in medicolegal autopsy

Along with a complete macroscopic examination, each autopsy case includes a routine analysis of histological samples. Most cases also include a toxicological analysis to rule out intoxication, or to assess the use of alcohol, narcotics, and medications. Based on individual consideration, the forensic pathologist may request further auxiliary investigations, such as neuropathology, microbiological analyses in suspected infections, or serum tryptase level in suspected anaphylaxis (e.g. [27] for further reference).

After all relevant investigations, the forensic pathologist determines the most likely *underlying cause of death, intermediate causes of death, the immediate cause of death, and contributory causes of death* to be recorded in death certificate. Determining and reporting the causes of death follow the international guidelines by WHO, the underlying cause of death being the most relevant and used in the comparative mortality statistics [28].

Causes of death, including statements regarding causality, are always approximations based on a case-by-case assessment and hence involve uncertainty. In a case of suspected vaccine etiology, currently no exact analysis or procedure exists regarding the COVID-19 vaccines in use, upon which a fatal health condition could definitively be determined as to be caused by a vaccine dose given. When assessing vaccination as a potential etiology for any cause of death, the forensic pathologist should consider several questions including, as suggested by WHO [29]: 1) is there strong evidence for other causes; 2) is there a known causal association with the vaccine or vaccination; and 3) was the event within the time window of increased risk? Regarding the second and third questions, one must refer to the current, constantly developing scientific knowledge when determining vaccine as an etiology for any given health condition. Likewise, no exact analysis exists upon which vaccination could with certainty be excluded as an etiology for a given health condition. Notably, a forensic pathologist must largely rely on published data, mostly epidemiologic, when assessing the causal connection between vaccination and death.

2.4. Selection of medicolegal autopsy cases for further examination

Data in the medicolegal database are structured and include sex, age, causes of death, the date and location of death, and the personal identification code, which is given to all permanent residents of Finland upon birth or immigration. We examined all medicolegal autopsy cases in Finland with both the date of death and the date of autopsy between Dec 26, 2020 (the start of vaccinations in Finland) and Dec 31, 2021 (8048 autopsy cases). We first excluded cases in which homicide, accident, suicide, or occupational disease was the only grounds for medicolegal autopsy, as no vaccine-related deaths were expected among these. Then, we also excluded from further evaluation all cases with no mention of having received COVID-19 vaccination in any document recorded in the medicolegal database (police report, autopsy referral, any attached patient records, other related documents, or notably also the autopsy report and death certificate). To catch all potential vaccine-related deaths, we selected for further evaluation all the remaining autopsy cases in which vaccination was mentioned in any part of the medicolegal documentation. Finally, based on autopsy records, one of the researchers, a forensic pathologist (L.P.), determined, whether an actual suspicion of a relationship between vaccination and death had arisen prior to autopsy, or whether vaccination was mentioned without such suspicion.

2.5. Linkage to vaccinations data and risk factors from the national population-wide registers

We linked data between registers and autopsy cases using the personal identification code. We report the sex, age, and vaccination characteristics of the autopsied individuals, along with data from all vaccinated individuals in Finland for comparison. For this purpose, we identified all individuals, whose last known permanent address was in Finland according to the Population Information System, and who received COVID-19 vaccinations according to the Finnish National Vaccination Register between Dec 26, 2020 and Dec 31, 2021 [22]. The vaccination register includes the date and vaccine brand of each given COVID-19 vaccination.

For descriptive purposes, we also linked our cases, along with those COVID-19 vaccinated based on the vaccination register, with data from the care register for health care and the medical reimbursements register on the most relevant pre-existing risk factors predisposing to severe COVID-19 disease as described in the study of Salo et al. [30]. These risk factors, together with age group, were important determinants of the priority and the number of recommended vaccinations for individuals in Finland, and they are also risk factors of death from any cause. These risk factors were: cardiovascular diseases, cognitive disorders, other neurological disorders, diabetes, chronic kidney diseases, chronic liver diseases, pulmonary diseases, immunosuppressive diseases (including malignancies), Addison's disease, schizophrenia, and Down syndrome. Furthermore, data on 24-h service housing and institutional care were gathered from the same registers. We gathered this risk data starting from Jan 1, 2015 until the first vaccine dose, or until death if no record of vaccination was found in the register. Medical reimbursement data was available starting from Jan 1, 2018.

2.6. Ethics

This descriptive study was conducted as part of the Finnish Institute for Health and Welfare's responsibility to monitor the safety of vaccines used in the national vaccination program and to investigate potential adverse events suspected to be linked with vaccination as dictated by the Finnish law (Act on the National Institute for Health and Welfare 668/2008; Government Decree on the National Institute for Health and Welfare 675/2008; and the Communicable Diseases Act 1227/2016). Based on this, Finnish Institute for Health and Welfare has the statutory right, notwithstanding confidentiality provisions, to access necessary information in cause-of-death investigation documents and to link this information with other relevant register data. Accordingly, this study was approved by the Finnish Institute for Health and Welfare's Director of Health Security department, Director of Government Services department, as well as the Deputy Director General of Research, Development and Innovation. The data on the medicolegal autopsies was originally collected according to the Act on Determining the Cause of Death (459/1973).

3. Results

A total of 428 autopsy cases with a mention of having received COVID-19 vaccination were found, and their records were further investigated for the current report by a forensic pathologist (L.P.). A suspicion of vaccine etiology arose in 76 cases prior to autopsy (Fig. 1). After the autopsy and auxiliary investigations, 12 cases emerged, in which the forensic pathologist who wrote the death certificate considered the COVID-19 vaccination as a potential etiological factor for any cause of death: in five cases for the underlying cause of death, and in seven cases for a contributory cause of death (Table 3). Three of these cases had no pre-autopsy suspicion of vaccine etiology, and, thus, were not part of the 76 cases (Fig. 1).

Details of the vaccinations preceding death existed in the Vaccination register for 417 cases, including all the 12 cases with potential

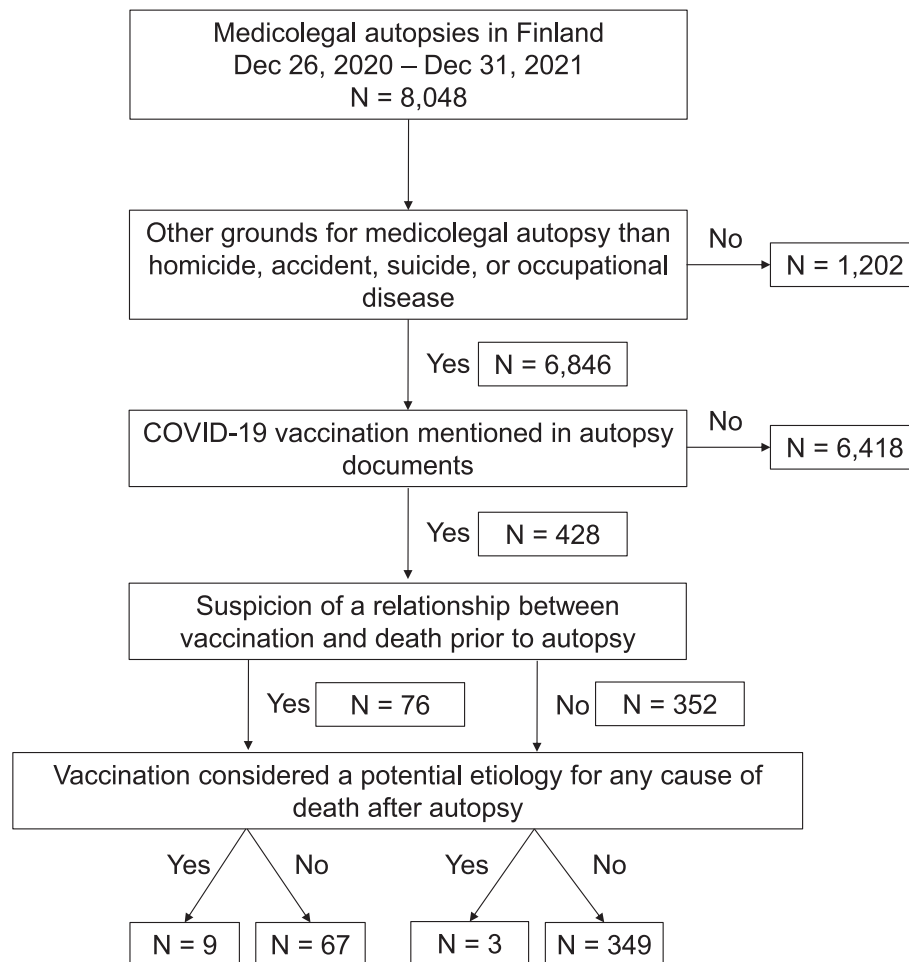


Fig. 1. Flow chart presenting the selection of autopsy cases. Vaccination data was obtained from Finnish National Vaccination Register.

vaccine etiology. In further 4 cases, the medicolegal data included a mention of vaccination with details, and in 7 cases, only a mention of vaccination without any details.

Most causes of death with potential vaccine etiology ($n = 12$, see Table 3) were thromboembolic events (7/12) including one VITT with CVST, and one CVST without VITT-association, three cases of pulmonary embolisms, one case of acute myocardial infarction, and one case of recurring cerebral hemorrhage. Furthermore, potential vaccine etiology arose in one case of acute myocarditis, in two cases of diabetic ketoacidosis, in one case of acute pancreatitis, and in one case of eosinophilic granulomatosis with polyangiitis (EGPA). Symptoms related to the underlying cause of death occurred within 12 days in 9/12 cases, and death within 30 days after vaccination in 10/12 cases. Within the 428 cases, the median time between last vaccination and death was 10 (range 0–230) days and 35 (0–290) days in cases with and without initial suspicion of vaccine etiology prior to autopsy, respectively. Median time of developing symptoms was 3 (0–79) days after vaccination (cases with initial suspicion of vaccine etiology). The median number of vaccine doses was 1 (1–3) and 2 (1–3) in cases with and without initial suspicion of vaccine etiology prior to autopsy, respectively. The deaths without a considered vaccine etiology (67/76) were mostly caused by diseases, mainly of cardiovascular origin (Table 4).

Prior to autopsy, the suspicion of a relationship between vaccination and death came from treating clinicians in 28 (36.8 %) cases, a relative in 24 (31.6 %) cases, forensic pathologist in 8 (10.5 %) cases, and the police in 1 (1.3 %) case (more than one source was possible in each individual case). Twenty-two (28.9 %) cases had a mention of a health condition preceding death suspected to be a vaccine-related (mild)

adverse reaction, but no actual suspicion of it causing death was stated. Death occurred at home in 48 (63.2 %), in a health care unit in 16 (21.1 %), in a social welfare unit in 5 (6.6 %), and in other places in 7 (9.2 %) cases. As regards the 12 cases with potential vaccine etiology, the location of death was home in five cases, health care unit in six cases, and other in one case.

The 12 deaths with potential vaccine etiology occurred in all adult age groups and equally in both sexes (Table 5). Half the cases were autopsied in Helsinki, which has proportionally the most autopsies, and all five autopsy locations had at least one case. Four deaths occurred after each first, second, and third dose, while the number of total administered COVID-19 vaccinations were 4.3, 4.1, and 1.3 million, respectively. Ten of the 12 deaths (83 %) occurred after vaccination with BNT162b2, which was the vaccine brand with the largest number of vaccinations administered out of all vaccinations (7.9 M / 9.8 M, 81 %). All 12 cases with potential vaccine etiology had one or more chronic health conditions according to the person level register linkage (Table 3): 7/12 (58 %) cases had a record of at least one known pre-existing risk factor, which was a larger proportion than with those vaccinated (1.0 M / 4.3 M, 23 %, Table 5). In 8/12 cases, including the remaining five cases without a register record of risk factors, forensic pathologist determined at least one corresponding chronic condition as one of the causes of death after the autopsy.

4. Discussion

In this nationwide analysis, we searched all 8048 medicolegal autopsies in Finland from Dec 26, 2020 to Dec 31, 2021. For comparison,

Table 3

Details of all cases in Finland in which a forensic pathologist considered a cause of death to have COVID-19 vaccine etiology.

Cause of death considered to have vaccine etiology ¹	Brand of last vaccine dose	Number of doses	Days between vaccination and symptoms	Days between vaccination and death	Age group	Predisposing risk factors according to register data ²	Other causes of death ¹
VITT with CVST (U)	ChAdOx1	1	9	11	35–64	Diabetes, neurological condition	–
CVST without VITT-association (U)	BNT162b2	2	23	40	18–34	–	Coagulation disorder (factor V Leiden) (C), morbid obesity (C)
Acute myocarditis (U)	BNT162b2	1	4	4	35–64	–	Coronary artery disease (C), alcohol use (C)
Acute pancreatitis (U)	BNT162b2	3	1	3	35–64	Cardiovascular disease, immunosuppressive diseases, pulmonary diseases	–
Contribution to pulmonary embolism (C)	BNT162b2	3	10	10	≥65	Cardiovascular diseases, Cognitive disorders, 24-h service housing	Cognitive disorder (U), pneumonia (I), coronary artery disease (C), sequelae of cerebral infarction (C), pulmonary embolism (C)
Contribution to pulmonary embolism (C)	BNT162b2	3	12	24	≥65	Cardiovascular disease	Pulmonary embolism (U)
Contribution to pulmonary embolism (C)	BNT162b2	2	27	27	≥65	Immunosuppressive diseases	Myocardial hypertrophy (U), deep vein thrombosis (INT), pulmonary embolism (I)
Eosinophilic granulomatosis with polyangiitis (U)	BNT162b2	1	24	170	35–64	Pulmonary diseases	Pulmonary embolism (I)
Worsening of glucose balance, ketoacidosis (C)	ChAdOx1	1	1	6	35–64	Diabetes, immunosuppressive diseases, Addison's disease	Type 1 diabetes (U), coronary artery disease (C)
Onset of diabetes, ketoacidosis (C)	BNT162b2	2	2	17	18–34	–	Type 1 diabetes (U), cerebral oedema (I), pneumonia (C)
Contribution to recurring cerebral hemorrhage (C)	BNT162b2	2	5	12	≥65	–	Cerebral amyloid angiopathy (U), intracerebral hemorrhage (INT), pneumonia (I)
Contribution to myocardial infarction (C)	BNT162b2	3	9	9	≥65	–	Coronary artery disease (U), myocardial infarction (I)

CVST, cerebral venous sinus thrombosis; VITT, vaccine-induced immune thrombotic thrombocytopenia.

¹ Cause of death was U = underlying, INT = intermediate, I = immediate, or C = contributory.² Note that the risk factor data were originally collected for population-level analyses and may not be conclusive on individual level.**Table 4**

Causes of death in cases with suspected relationship between COVID-19 vaccination and death prior to autopsy but with no vaccine etiology considered after medicolegal autopsy.

Cause of death	Number of cases (%)
Disease	62 (92.5)
Cardiovascular diseases	43 (64.2)
• Acute myocardial infarction	9 (13.4)
• Arrhythmia	1 (1.5)
• Other / unknown mechanism	33 (49.3)
Cerebrovascular diseases	2 (3.0)
Alcohol-related diseases	1 (1.5)
Gastroenterological diseases	3 (4.5)
Malignancies	2 (3.0)
Pulmonary embolism	5 (7.5)
Pulmonary diseases	2 (3.0)
Endocrinopathies and nutritional diseases	2 (3.0)
Neurodegenerative diseases and dementia	2 (3.0)
Accident	4 (6.0)
Undetermined	1 (1.5)
Total	67 (100.0)

58,714 deaths from all causes occurred during this time (Table 2; [25]), among which were 952 deaths caused by COVID-19 infection in 2021 [31]. Moreover, 9.8 million COVID-19 vaccinations were given in Finland, and Finnish Institute for Health and Welfare has estimated that the vaccinations prevented more than 7300 deaths from COVID-19 disease and more than 1000 deaths with COVID-19 disease as a contributory factor in the country by the end of March 2022 [32]. According to our data, 76 cases included a pre-autopsy suspicion of a

relationship between COVID-19 vaccination and death, and, after the autopsy, forensic pathologist considered COVID-19 vaccination as a potential etiology for five underlying, and seven contributory causes of death, mainly from thromboembolic causes (7/12). In comparison to the total vaccinated population, the 12 deaths with potential vaccine etiology occurred in both sexes and all adult age groups but included more of those with a third dose and those with known pre-existing risk factors. Due to the remaining uncertainties in catching the right cases, and in considerations about the etiology for the causes of death, the interpretations from the data need to be extremely cautious.

To the best of our knowledge, this is the largest published systematic case report series on autopsies conducted in deaths suspected to have COVID-19 vaccine etiology. Most autopsy studies have been single case reports as reviewed by Sessa et al. [16], and a growing number of similar anecdotal reports have been published since. In a Japanese study including 54 cases with death within seven days post vaccination that were autopsied, five cases were concluded to have possible causal relationship between vaccination and death [33]. A study from Singapore included 29 autopsy cases from deaths within 72 h after receiving mRNA-type vaccination, but they did not find any potential causative relationship between vaccination and death in these cases [34]. Schneider et al. [35] reported 18 autopsy cases in which death occurred 1–14 days after vaccination in Germany. Of these, five deaths had a potential vaccine etiology including four cases of VITT and one myocarditis [35]. Also in Germany, Schwab et al. [36] described 25 autopsy cases with death within 20 days post vaccination, of which five cases died from myocarditis with a potential mRNA-vaccine etiology. Chaves et al. [37] could not find any deaths potentially related to COVID-19 vaccination among the 121 autopsies of deceased that had

Table 5
Data on demographics, vaccinations, and pre-existing health conditions.

	COVID-19 vaccine considered as etiology for any cause of death after medicolegal autopsy	Suspicion of a relationship between COVID-19 vaccine and death prior to medicolegal autopsy	Exposed population
End of follow-up	Death	Death	Dec 31, 2021 ¹
Number of cases	12	76	4,345,346
Sex			
Men	6	34	2,100,677
Women	6	42	2,244,669
Age, years			
< 18	0	0	323,599
18–34	2	4	930,650
35–64	5	23	1,888,942
≥ 65	5	49	1,202,155
Most recent vaccine dose of the deceased vs. population vaccinated with cumulative number of doses			
1	4	45	4,345,346
2	4	19	4,135,987
3	4	9	1,265,677
4	0	0	3042
Vaccinations			
ChAdOx1	2	19	553,426
BNT162b2	10	46	7,909,387
mRNA-1273	0	8	1,285,369
Ad26.COVS.2	0	1	206
Other	0	0	1664
Total			9,750,052
Number of pre-existing risk factors ²			
0	5	19	3,328,945
1	3	15	804,011
2	2	17	176,518
≥3	2	25	35,872
Nursing home residency	0	1	28,763
Need for 24-h care	1	10	65,532

¹ Date for calculating age at first dose.

² Pre-existing risk factors for severe COVID-19 disease as described in the study of Salo et al. [30] up until the first given vaccine dose, (each as 0 or 1): cardiovascular diseases, cognitive disorders, other neurological disorders, diabetes, chronic kidney diseases, chronic liver diseases, pulmonary diseases, immunosuppressive diseases (including malignancy), Addison's disease, schizophrenia, and Down syndrome.

received vaccination in Colombia, nor did Dul-amnuay among 34 autopsies in deaths within 30 days of vaccination in Thailand [38]. In the light of these case series studies, research is needed to reveal to what extent COVID-19 vaccine-related deaths do occur, and to expose new possible causalities between vaccines and severe health conditions. However, no conclusions can be made on the frequency of potential vaccine-related deaths based on autopsy-studies alone, as the selection criteria for autopsy differ between studies and, more importantly, between countries.

In seven of the twelve deaths in our data, forensic pathologist writing the death certificate considered COVID-19 vaccination a potential etiological factor for a diagnosed thromboembolism, which were also the most frequent causes of death considered vaccine-related in previous reports [16]. Among these seven cases, only one case of VITT with CVST was identified. Another CVST without thrombocytopenia was also detected. Due to the relatively early cessation of vaccination with ChAdOx1, exposure to this vaccine brand was a minority in Finland (Table 5), which may have limited the occurrence of these potentially lethal adverse reactions. The estimated cumulative 28-day-incidence of VITT has been between 1/26,500 and 1/1000,000 first doses of ChAdOx1 with lower incidences for subsequent doses [5,39–41]. According

to See et al. [41], the incidence of VITT after vaccination with Ad26.COVS.2 was 1/583,000 doses. The estimated incidence for VITT with CVST after receiving the first dose of ChAdOx1 was 12.3 / 1000,000 persons when the condition was first recognized as an adverse reaction [42]. The rate is clearly higher than the background cumulative 28-day incidence of 0.18 / 1000,000 [43]. Mortality caused by VITT in the COVID-19 vaccinated is unknown, but it is thought to be extremely low [39]. However, among patients with diagnosed VITT, the mortality rates have varied 23–73 % [5], though with early recognition and adequate care, the prognosis has improved [44]. Post vaccination CVST can occur with or without the context of VITT, but with significantly better outcomes, when no thrombocytopenia-association is present [42,45].

Of the seven cases with thromboembolism, three deaths were from pulmonary embolisms, one death from acute myocardial infarction, and one death from recurring cerebral hemorrhage. Deep vein thrombosis and pulmonary embolism are common entities, and the latter is frequently the cause of sudden death in the medicolegal context. Case reports of post vaccination pulmonary embolisms have been published [46], but further population-based studies on ChAdOx1 [47], and BNT162b2 [48] found no evidence of any increased incidence of pulmonary embolisms after vaccination. However, in a self-controlled case series study in the French population, a slight increase in risk for pulmonary embolism was associated with the first dose of ChAdOx1 (relative incidence 1.41, confidence interval 1.13–1.75) but not with BNT162b2 or mRNA-1273 [49]. Myocardial infarctions and other acute cardiovascular events are common manifestations in the general population, and they occur after vaccination as well. It has been suggested that COVID-19 vaccination could contribute to cardiovascular events through enhancing prothrombotic state or, unspecifically, as a stress factor [50]. As with pulmonary embolism, Botton et al. [49] found an increase in the risk for myocardial infarction after the first dose of ChAdOx1 (relative incidence 1.29, confidence interval 1.11–1.51), and after Ad26.COVS.2 (relative incidence 1.75, confidence interval 1.16–2.62), but not with the mRNA-type vaccines. Again, no increased risk for myocardial infarction arose in connection with BNT162b2 in other large study settings as reviewed by Yong et al. [51]. Hence, although COVID-19 vaccination was, according to the medicolegal assessment, considered a potential etiological factor for pulmonary embolism in three of our cases and myocardial infarction in one case, all vaccinated with BNT162b2, we found no epidemiological evidence from the literature to support these decisions.

One case of post vaccination fatal acute myocarditis with potential vaccine etiology was present in our study population in the age group 35 to 64 years. A link between myocarditis and mRNA-type COVID-19 vaccines has been established in large cohort studies [10,11]. The highest risk for developing myocarditis has occurred in young men after receiving the second dose [52]. Case reports of vaccination-associated myocarditis deaths have been published [36,53], but, in large study settings, post-vaccination myocarditis has rarely been associated with death [8,10,13,52,54]. Furthermore, uncertainty remains as to the role of vaccine-associated myocarditis in these deaths since competing causes of death may have been left unnoticed, as suggested previously [13]. Notably, myocardial injury associated with a clinical diagnosis of myocarditis after COVID-19 vaccination has been reported mild, as reviewed by Garg et al. [55].

In the present study, forensic pathologist considered COVID-19 vaccination as contributory cause of death in two cases with type 1 diabetes mellitus and diabetic ketoacidosis. In one of them, the vaccine was a potential etiological factor for the onset of diabetes, and in the other, it potentially contributed to the worsening of glucose balance in a patient with previously diagnosed diabetes. Many case reports and case series have been published describing post vaccination hyperglycemia, hyperosmolar hyperglycemic syndrome, and diabetic ketoacidosis regardless of the COVID-19 vaccine type as reviewed by Samuel et al. [56]. However, we could find only one self-controlled case series analysis regarding acute diabetic complications in patients with type 2

diabetes receiving BNT162b2 [57]. According to the study of Wan et al. [57], no ketoacidoses emerged among the 141,224 cases given BNT162b2, and no increased risk for other diabetic complications was observed, either. We did not find any large-scale studies about the effects of COVID-19 vaccines on the onset or on the clinical picture of type 1 diabetes. While case series of new onset diabetes after COVID-19 vaccination exist (as reviewed by Chen et al. [58]), strong evidence supporting a causal association remains lacking, and more robust epidemiological studies on this topic are needed.

Herein, one case of fatal acute pancreatitis emerged with COVID-19 vaccination as its potential etiology. A few case reports about non-fatal post vaccination pancreatitis have been published, mainly concerning BNT162b2 (e.g., [59,60]), but we did not find any epidemiological studies addressing the potential association of vaccination and pancreatitis. Lastly, we had one autopsy case who had EGPA, a small-vessel vasculitis, determined as the underlying cause of death, and COVID-19 vaccine considered as potential etiology for the disease. As with pancreatitis, only a few case reports of new onset or relapse of EGPA after COVID-19 vaccination have been published, all regarding mRNA vaccines [61–64]. Our findings suggest that further research on acute pancreatitis and EGPA after COVID-19 vaccination is warranted.

We used data of the most relevant pre-existing risk factors that associate with severe COVID-19 disease for descriptive purposes. According to data on the risk factors and on contributing causes of death, all 12 cases of death with potential vaccine-etiology had one or more chronic health conditions which probably predisposed to the lethal outcome. This finding is similar to other iatrogenic deaths, among which few patients have no previous health conditions [65].

5. Limitations

As we have described in the methods, determining as well as excluding vaccination as an etiology for any cause of death involves a lot of uncertainty, and should be based on epidemiological evidence of association between the vaccination and the adverse event which contributed to the fatality [29]. Also, it must be stressed that we only examined the outcomes of the cause-of-death investigation as done by each individual forensic pathologist, and, as such, we did not re-evaluate the possibility of vaccine-etiology in any of the cases. The medicolegal cause-of-death investigation process comprises of gathering information regarding patient history (known diseases, possible symptoms, and findings prior to death) and other circumstances preceding death, as well as examining data received from the autopsy and auxiliary investigations. Based on these, the forensic pathologist generates a most likely scenario including the causes of death and the potential etiologies involved. This scenario is then presented in the autopsy report along with discussion of the uncertainties in each case. Hence, the final assessment is an expert opinion, and as such, subjectivity can never fully be eliminated even though objectivity is pursued.

Pomara et al. [66] proposed an approach to assess potential causality in individual cases of death combining the WHO criteria [29] with comprehensive autopsy protocol in two deaths occurring after vaccination and hospitalization. While this kind of thorough protocol undoubtedly provides a strong base to consider individual cases, the data and samples required to complete the assessment entirely are rarely available, considering, for example, that nearly 80 % of cases with pre-autopsy suspicion, and half the cases with post-autopsy suspicion of vaccine-related death occurred out of healthcare in the current study. Also, as we only retrospectively observed causes of death determined by forensic pathologists, it was not possible to apply this kind of approach here. Nonetheless, the systematic protocol proposed by Pomara et al. [66] should be applied in considering potential vaccine-related deaths whenever possible.

It is possible that true vaccine-related deaths were missed, and some of these may even be among the 67 cases in which the forensic pathologist did not consider vaccination as potential etiology. However, the

lack of epidemiological support, and the fact that more plausible etiologies were present (e.g. malignancy in case of pulmonary embolism) argue against a significant proportion of true vaccine-related deaths missed in our study. The same applies to the cases in which vaccine-etiology was considered, ie. etiologies other than vaccination may have been more relevant, especially where support from epidemiological data is lacking.

The temporal relationship between vaccination and potential vaccine-related symptoms or death is an important aspect when assessing the potential vaccine etiology in individual cases [29]. The median time between last vaccine dose and death was 10 days, when an adverse event was initially suspected, and 35 days, when such event was not suspected. Symptoms developed within 12 days in 9/12 cases, and death occurred within 30 days of the last vaccination in 10/12 cases with vaccination considered as an etiology for a cause of death. In the remaining three cases, the time frame for symptoms was longer, 23–27 days. A time limit of 21 days has been proposed, after which vaccine-etiology should be ruled out [66]. This recommendation was based on two publications describing the development of thromboembolic complications after vaccination [67,68]. Truly, the longer the time window in post-vaccination symptoms, the more unlikely the vaccination-etiology becomes. WHO guidelines [29], on the other hand, state that a plausible time window should be taken into account when considering potential AEFIs, but no rigid time frame is proposed. In this study, we only report the causes of death determined by forensic pathologists and, hence, did not exclude cases based on temporal restrictions. Then again, it must be stressed that a temporal relationship by itself does not imply causal association. All-cause mortality following COVID-19 vaccination has been studied on population level in Finland, and the hazard of death did not increase within 63 nor within 21 days of COVID-19 vaccination in Finland [69]. Also, a meta-analysis including three self-controlled case series studies totaling 750,000 patients found no association between COVID-19 vaccination and all-cause mortality [70].

Because the initiation of the medicolegal process in a suspected vaccine-related death is dependent on a suspicion being brought up, not all cases end up in the hands of forensic pathologist, as seen in the context of iatrogenic deaths [65]. This can more often be the case in deaths among elderly people with several chronic illnesses than in deaths deemed more unexpected, as is evident when comparing the medicolegal autopsy rates between 18 and 34-year-olds (82 %) and 65-year-olds and older (9 %).

Prior to autopsy, the suspicion of the role of COVID-19 vaccine in death was brought forward mostly by treating clinicians. Health care personnel are in a key position in spotting potential iatrogenic deaths, and they are required by law to report such cases to the police in Finland. The systems of investigating suspected iatrogenic deaths differ greatly between countries [71] depending partly on whether it is looked at from the viewpoint of clinical risk management, or whether actual malpractice claims have been raised [23].

In many cases, the suspicion of a relationship between COVID-19 vaccine and death was also expressed by the deceased's next-of-kin, which is in line with today's growing numbers of medical malpractice issues [72]. COVID-19 vaccinations have been the topic of extensive public discussions globally, and views discouraging against vaccination on account of alleged hazards have occasionally gained ground [14]. Because of this, it is essential to investigate all suspected COVID-19 vaccine-related deaths thoroughly and openly to address these concerns and, if so indicated, maintain the public's confidence in vaccinations. These cases highlight the utility of a comprehensive autopsy practice as part of investigation of suspected COVID-19 vaccine-related deaths.

6. Conclusions

In the context of total vaccinated population and of the number of given vaccine doses, only a few suspicions of vaccine-related deaths

arose in the first year of COVID-19 vaccinations in Finland. Even fewer were the number of deaths, in which the forensic pathologist performing the cause-of-death investigation considered vaccine as a potential etiological factor for a cause of death. All cases remained without a certainty of vaccine etiology. Although autopsy is a crucial tool in determining the causes of death through detection and documentation of tissue reactions, it cannot by itself be used to establish causality between vaccination and the causes of death. Other settings, such as large epidemiological studies, should be performed to support individual case-assessment. Our study highlights the need for further research related to diabetes, acute pancreatitis and EGPA as potential severe adverse reactions of COVID-19 vaccines. Also, deaths associated with thromboembolic events and myocarditis after vaccination need closer examination. A continuing evaluation of suspected COVID-19 vaccine-related deaths is essential in monitoring vaccination safety, and can provide insights into potential mechanisms of severe vaccine-related health conditions.

CRedit authorship contribution statement

Lasse Pakanen: Writing – review & editing, Writing – original draft, Project administration, Methodology, Formal analysis, Data curation, Conceptualization. **Tuomo Nieminen:** Writing – review & editing, Writing – original draft, Methodology, Formal analysis, Data curation, Conceptualization. **Paula Kuvaja:** Writing – review & editing, Data curation, Conceptualization. **Hanna Nohynek:** Writing – review & editing, Data curation, Conceptualization. **Sirkka Goebeler:** Writing – review & editing, Data curation, Conceptualization. **Miia Artama:** Writing – review & editing, Data curation. **Petteri Hovi:** Writing – review & editing, Writing – original draft, Methodology, Formal analysis, Data curation, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Hanna Nohynek reports a relationship with World Health Organization that includes: board membership. Lasse Pakanen reports a relationship with AstraZeneca PLC that includes: equity or stocks. Lasse Pakanen reports a relationship with Novo Nordisk A/S that includes: equity or stocks. Lasse Pakanen reports a relationship with Orion Corporation that includes: equity or stocks. Tuomo Nieminen reports a relationship with GlaxoSmithKline Inc. that includes: funding grants. Tuomo Nieminen reports a relationship with Pfizer Inc. that includes: funding grants. Tuomo Nieminen reports a relationship with Sanofi Pasteur Inc. that includes: funding grants. Hanna Nohynek reports a relationship with Finnish Institute for Health and Welfare that includes: board membership. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Data availability

All data generated or analyzed during this study are included in this published article.

References

- [1] Zheng C, Shao W, Chen X, Zhang B, Wang G, Zhang W. Real-world effectiveness of COVID-19 vaccines: a literature review and meta-analysis. *Int J Infect Dis* 2022; 114:252–60. <https://doi.org/10.1016/j.ijid.2021.11.009>.
- [2] World Health Organization. *Covid-19 vaccines: Safety surveillance manual*. 2nd ed. Geneva, Switzerland: World Health Organization; 2021.
- [3] European Medicine Agency.. Guideline on good pharmacovigilance practices (GVP), Annex I - Definitions (Rev 4). 2017. https://www.ema.europa.eu/document/s/scientific-guideline/guideline-good-pharmacovigilance-practices-annex-i-definitions-rev-4_en.pdf. Accessed 21/04/2023.
- [4] European Medicines Agency.. AstraZeneca's COVID-19 vaccine: EMA finds possible link to very rare cases of unusual blood clots with low blood platelets. 2021. <https://www.ema.europa.eu/en/news/astrazenecas-covid-19-vaccine-ema-finds-possible-link-to-very-rare-cases-of-unusual-blood-clots-with-low-blood-platelets>. Accessed 28/01/2023.
- [5] Klok FA, Pai M, Huisman MV, Makris M. Vaccine-induced immune thrombotic thrombocytopenia. *Lancet Haematol* 2022;9(1):e73–80. [https://doi.org/10.1016/S2352-3026\(21\)00306-9](https://doi.org/10.1016/S2352-3026(21)00306-9).
- [6] European Medicines Agency.. EMA raises awareness of clinical care recommendations to manage suspected thrombosis with thrombocytopenia syndrome. 2021. <https://www.ema.europa.eu/en/news/ema-raises-awareness-clinical-care-recommendations-manage-suspected-thrombosis-thrombocytopenia>. Accessed 15/03/2023.
- [7] Sharifian-Dorche M, Bahmanyar M, Sharifian-Dorche A, Mohammadi P, Nomovi M, Mowla A. Vaccine-induced immune thrombotic thrombocytopenia and cerebral venous sinus thrombosis post COVID-19 vaccination; a systematic review. *J Neurol Sci* 2021;428:117607. <https://doi.org/10.1016/j.jns.2021.117607>.
- [8] Bozkurt B, Kamat I, Hotez PJ. Myocarditis with COVID-19 mRNA vaccines. *Circulation* 2021;144(6):471–84. <https://doi.org/10.1161/CIRCULATIONAHA.121.056135>.
- [9] Husby A, Hansen JV, Fosbøl E, Thiesson EM, Madsen M, Thomsen RW, et al. SARS-CoV-2 vaccination and myocarditis or myopericarditis: population based cohort study. *BMJ* 2021;375:e068665. <https://doi.org/10.1136/bmj-2021-068665>.
- [10] Karlstad Ø, Hovi P, Husby A, Härkänen T, Selmer RM, Pihlström N, et al. SARS-CoV-2 vaccination and myocarditis in a Nordic cohort study of 23 million residents. *JAMA Cardiol* 2022;7(6):600–12. <https://doi.org/10.1001/jamacardio.2022.0583>.
- [11] Oster ME, Shay DK, Su JR, Gee J, Creech CB, Broder KR, et al. Myocarditis cases reported after mRNA-based COVID-19 vaccination in the US from December 2020 to august 2021. *JAMA* 2022;327(4):331–40. <https://doi.org/10.1001/jama.2021.24110>.
- [12] Husby A, Kober L. COVID-19 mRNA vaccination and myocarditis or pericarditis. *Lancet* 2022;399(10342):2168–9. [https://doi.org/10.1016/S0140-6736\(22\)00842-X](https://doi.org/10.1016/S0140-6736(22)00842-X).
- [13] Husby A, Gulseth HL, Hovi P, Hansen JV, Pihlström N, Gunnes N, et al. Clinical outcomes of myocarditis after SARS-CoV-2 mRNA vaccination in four Nordic countries: population based cohort study. *BMJ Med* 2023;2:e000373. <https://doi.org/10.1136/bmjmed-2022-000373>.
- [14] Pullan S, Dey M. Vaccine hesitancy and anti-vaccination in the time of COVID-19: a Google trends analysis. *Vaccine* 2021;39(14):1877–81. <https://doi.org/10.1016/j.vaccine.2021.03.019>.
- [15] Gisondi MA, Barber R, Faust JS, Raja A, Strehlow MC, Westafer LM, et al. A deadly infodemic: social media and the power of COVID-19 misinformation. *J Med Internet Res* 2022;24(2):e35552. <https://doi.org/10.2196/35552>.
- [16] Sessa F, Salerno M, Esposito M, Di Nunno N, Zamboni P, Pomara C. Autopsy findings and causality relationship between death and COVID-19 vaccination: a systematic review. *J Clin Med* 2021;10(24):5876. <https://doi.org/10.3390/jcm10245876>.
- [17] European Centre for Disease Prevention and Control.. COVID-19 vaccine tracker. 2023. <https://vaccinetracker.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#summary-tab>. Accessed 28/01/2023.
- [18] Finnish Institute for Health and Welfare.. COVID-19 vaccinations in Finland. 2023. https://sampo.thl.fi/pivot/prod/en/vaccreg/cov19cov/fact_cov19cov?&row=cov_vac_dose-533170.533164.639082.&row-area-518327.518294.518309.518306.518320.518377.518303.518340.518369.518295.518335.518322.518353.518298.518343.518354.518351.518300.518366.518323.518349.518362.&column=cov_vac_age-518413&column=660963L&filter=measure-533185. Accessed 28/01/2023.
- [19] Finnish Institute for Health and Welfare.. Arranging COVID-19 vaccinations in Finland. 2023. <https://thl.fi/en/web/infectious-diseases-and-vaccinations/wh-at-s-new/coronavirus-covid-19-latest-updates/vaccines-and-coronavirus/arranging-covid-19-vaccinations-in-finland>. Accessed 28/01/2023.
- [20] Finnish Institute for Health and Welfare.. Koronarokotusten järjestäminen Suomessa [Finnish]. 2023. <https://thl.fi/fi/web/infektiaudit-ja-rokotukset/ajankohtaista/ajankohtaista-koronaviruksesta-covid-19/rokoiteet-ja-koronavirus/koronarokotusten-jarjestaminen-suomessa>. Accessed 16/02/2023.
- [21] Finnish Institute for Health and Welfare.. THL issues instructions that men under 30 years of age should only be offered the Comirnaty coronavirus vaccine. 2021. <https://thl.fi/en/web/thlfi-en/-/thl-issues-instructions-that-men-under-30-years-of-age-should-only-be-offered-the-comirnaty-coronavirus-vaccine>. Accessed 28/01/2023.
- [22] Baum U, Sundman J, Jääskeläinen S, Nohynek H, Puumalainen T, Jokinen J. Establishing and maintaining the National Vaccination Register in Finland. *Euro Surveill* 2017;22(17):30520. <https://doi.org/10.2807/1560-7917.ES.2017.22.17.30520>.
- [23] Pakanen L, Keinänen N, Kuvaja P. Presumed adverse events in health care are a frequent indication for medico-legal autopsy in Finland. *Forensic Sci Med Pathol* 2020;16(1):65–70. <https://doi.org/10.1007/s12024-019-00193-4>.

- [24] Lunetta P, Lounamaa A, Sihvonen S. Surveillance of injury-related deaths: medicolegal autopsy rates and trends in Finland. *Inj Prev* 2007;13(4):282–4. <https://doi.org/10.1136/ip.2006.012922>.
- [25] Official Statistics of Finland.. Deaths. ISSN=1798–2545. Helsinki, Finland: Statistics Finland; 2023.
- [26] Statistics Finland. 11c1 – Autopsies and other means to determine cause of death by age and sex of deceased, 1975–2021. 2023. https://pxdata.stat.fi/PxWeb/pxweb/en/StatFin/StatFin_ksyyt/statfin_ksyyt_pxt_11c1.px/ Accessed 28/01/2023.
- [27] Madea B, editor. *Handbook of forensic medicine*. Hoboken, NJ: Wiley-Blackwell; 2014.
- [28] World Health Organization.. WHO recommendations for conducting an external inspection of a body and filling in the medical certificate of cause of death. Geneva, Switzerland: World Health Organization; 2022.
- [29] World Health Organization. Causality assessment of an adverse event following immunization (AEFI): user manual for the revised WHO classification. 2nd ed. Geneva, Switzerland: World Health Organization; 2018. <https://apps.who.int/iris/handle/10665/259959> Accessed 28/01/2023.
- [30] Salo H, Lehtonen T, Auranen K, Baum U, Leino T. Predictors of hospitalisation and death due to SARS-CoV-2 infection in Finland: a population-based register study with implications to vaccinations. *Vaccine* 2022;40(24):3345–55. <https://doi.org/10.1016/j.vaccine.2022.04.055>.
- [31] Statistics Finland. Causes of death. Reference period: 2021. Helsinki, Finland: Statistics Finland. 2022. <https://www.stat.fi/en/publication/cktdrxr6o4sv90b62jy6t7qbg> Accessed 28/01/2023.
- [32] Finnish Institute for Health and Welfare.. Study: Coronavirus vaccines prevented around 7,300 deaths due to COVID-19 in Finland by the end of March 2022. 2023. <https://thl.fi/en/web/thlfi-en/-/study-coronavirus-vaccines-prevented-around-7-300-deaths-due-to-covid-19-in-finland-by-the-end-of-march-2022>. Accessed 28/01/2023.
- [33] Suzuki H, Ro A, Takada A, Saito K, Hayashi K. Autopsy findings of post-COVID-19 vaccination deaths in Tokyo Metropolis, Japan, 2021. *Legal Med* 2022;59:102134. <https://doi.org/10.1016/j.legalmed.2022.102134>.
- [34] Yeo A, Kuek B, Lau M, Tan SR, Chan S. Post COVID-19 vaccine deaths - Singapore's early experience. *Forensic Sci Int* 2022;332:111199. <https://doi.org/10.1016/j.forsciint.2022.111199>.
- [35] Schneider J, Sottmann L, Greinacher A, Hagen M, Kasper H-U, Kuhnen C, et al. Postmortem investigation of fatalities following vaccination with COVID-19 vaccines. *Int J Legal Med* 2021;135(6):2335–45. <https://doi.org/10.1007/s00414-021-02706-9>.
- [36] Schwab C, Domke LM, Hartmann L, Stenzinger A, Longenich T, Schirmacher P. Autopsy-based histopathological characterization of myocarditis after anti-SARS-CoV-2-vaccination. *Clin Res Cardiol* 2023;112(3):431–40. <https://doi.org/10.1007/s00392-022-02129-5>.
- [37] Chavez JJ, Bonilla JC, Chavez-Cabezas V, Castro A, Polo JF, Mendoza O, et al. A postmortem study of patients vaccinated for SARS-CoV-2 in Colombia. *Rev Esp Patol* 2023;56(1):4–9. <https://doi.org/10.1016/j.patol.2022.09.003>.
- [38] Dul-amnuay A. Case study of autopsy findings in a population of post-COVID-19 vaccination in Thailand. *Am J Forensic Med Pathol* 2024;45(1):45–50. <https://doi.org/10.1097/PAF.0000000000000900>.
- [39] Aleem A, Nadeem AJ. Coronavirus (COVID-19) vaccine-induced immune thrombotic thrombocytopenia (VITT). In: *StatPearls [internet]*. Treasure Island, FL: StatPearls Publishing; 2022.
- [40] Pai M. Epidemiology of VITT. *Semin Hematol* 2022;59(2):72–5. <https://doi.org/10.1053/j.seminhematol.2022.02.002>.
- [41] See I, Su JR, Lale A, Woo EJ, Guh AY, Shimabukuro TT, et al. US case reports of cerebral venous sinus thrombosis with thrombocytopenia after Ad26.COV2.S vaccination, March 2 to April 21, 2021. *JAMA* 2021;325(24):2448–56. <https://doi.org/10.1001/jama.2021.7517>.
- [42] Perry RJ, Tamborska A, Singh B, Craven B, Marigold R, Arthur-Farraj P, et al. CVT after immunisation against COVID-19 (CAIAC) collaborators. Cerebral venous thrombosis after vaccination against COVID-19 in the UK: a multicentre cohort study. *Lancet* 2021;398(10306):1147–56. [https://doi.org/10.1016/S0140-6736\(21\)01608-1](https://doi.org/10.1016/S0140-6736(21)01608-1).
- [43] Hovi P, Palmu AA, Nieminen TA, Artama M, Jokinen J, Ruokokoski E, et al. Incidence of sinus thrombosis with thrombocytopenia—a nation-wide register study. *PLoS One* 2023;18(2):e0282226. <https://doi.org/10.1371/journal.pone.0282226>.
- [44] van de Munckhof A, Krzywicka K, Aguiar de Sousa D, Sánchez van Kammen M, Heldner MR, Jood K, et al. Declining mortality of cerebral venous sinus thrombosis with thrombocytopenia after SARS-CoV-2 vaccination. *Eur J Neurol* 2022;29(1):339–44. <https://doi.org/10.1111/ene.15113>.
- [45] Sánchez van Kammen M, Aguiar de Sousa D, Poli S, Cordonnier C, Heldner MR, van de Munckhof A, et al. Characteristics and outcomes of patients with cerebral venous sinus thrombosis in SARS-CoV-2 vaccine-induced immune thrombotic thrombocytopenia. *JAMA Neurol* 2021;78(11):1314–23. <https://doi.org/10.1001/jamaneurol.2021.3619>.
- [46] Ifeanyi N, Chinenye N, Oladiran O, David E, Mmonu C, Ogbonna-Nwosu C. Isolated pulmonary embolism following COVID vaccination: 2 case reports and a review of post-acute pulmonary embolism complications and follow-up. *J Community Hosp Intern Med Perspect* 2021;11(6):877–9. <https://doi.org/10.1080/20009666.2021.1990825>.
- [47] Østergaard SD, Schmidt M, Horváth-Puhó E, Thomsen RW, Sørensen HT. Thromboembolism and the Oxford-AstraZeneca COVID-19 vaccine: side-effect or coincidence? *Lancet* 2021;397(10283):1441–3. [https://doi.org/10.1016/S0140-6736\(21\)00762-5](https://doi.org/10.1016/S0140-6736(21)00762-5).
- [48] Jabagi MJ, Botton J, Bertrand M, Weill A, Farrington P, Zureik M, et al. Myocardial infarction, stroke, and pulmonary embolism after BNT162b2 mRNA COVID-19 vaccine in people aged 75 years or older. *JAMA* 2022;327(1):80–2. <https://doi.org/10.1001/jama.2021.21699>.
- [49] Botton J, Jabagi MJ, Bertrand M, Baricault B, Drouin J, Le Vu S, et al. Risk for myocardial infarction, stroke, and pulmonary embolism following COVID-19 vaccines in adults younger than 75 years in France. *Ann Intern Med* 2022;175(9):1250–7. <https://doi.org/10.7326/M22-0988>.
- [50] Aye YN, Mai AS, Zhang A, Lim OZH, Lin N, Ng CH, et al. Acute myocardial infarction and myocarditis following COVID-19 vaccination. *QJM* 2021;hcab252. <https://doi.org/10.1093/qjmed/hcab252>.
- [51] Yong SJ, Halim A, Halim M, Al Mutair A, Alhumaid S, Al-Sihati J, et al. Rare adverse events associated with BNT162b2 mRNA vaccine (Pfizer-BioNTech): a review of large-scale, controlled surveillance studies. *Vaccines* 2022;10(7):1067. <https://doi.org/10.3390/vaccines10071067>.
- [52] Mevorach D, Anis E, Cedar N, Bromberg M, Haas EJ, Nadir E, et al. Myocarditis after BNT162b2 mRNA vaccine against Covid-19 in Israel. *N Engl J Med* 2021;385(23):2140–9. <https://doi.org/10.1056/NEJMoa2109730>.
- [53] Choi S, Lee S, Seo J-W, Kim M-J, Jeon YH, Park JH, et al. Myocarditis-induced sudden death after BNT162b2 mRNA COVID-19 vaccination in Korea: case report focusing on histopathological findings. *J Korean Med Sci* 2021 Oct 18;36(40):e286. <https://doi.org/10.3346/jkms.2021.36.e286>.
- [54] Patone M, Mei XW, Handunnetthi L, Dixon S, Zaccardi F, Shankar-Hari M, et al. Risks of myocarditis, pericarditis, and cardiac arrhythmias associated with COVID-19 vaccination or SARS-CoV-2 infection. *Nat Med* 2022;28(2):410–22. <https://doi.org/10.1038/s41591-021-01630-0>.
- [55] Garg R, Hussain M, Friedrich MG. Phenotyping myocardial injury related to COVID and SARS-CoV-2 vaccination: insights from cardiovascular magnetic resonance. *Front Cardiovasc Med* 2023;10:1186556. <https://doi.org/10.3389/fcvm.2023.1186556>.
- [56] Samuel SM, Varghese E, Triggler CR, Büsselberg D. COVID-19 vaccines and hyperglycemia—is there a need for postvaccination surveillance? *Vaccines* 2022;10(3):454. <https://doi.org/10.3390/vaccines10030454>.
- [57] Wan EYF, Chui CSL, Mok AHY, Xu W, Yan VKC, Lai FTT, et al. mRNA (BNT162b2) and inactivated (CoronaVac) COVID-19 vaccination and risk of adverse events and acute diabetic complications in patients with type 2 diabetes mellitus: a population-based study. *Drug Saf* 2022;45(12):1477–90. <https://doi.org/10.1007/s40264-022-01228-6>.
- [58] Chen Y, Xu Z, Wang P, Li XM, Shuai ZW, Ye DQ, et al. New-onset autoimmune phenomena post-COVID-19 vaccination. *Immunology* 2022;165(4):386–401. <https://doi.org/10.1111/imm.13443>.
- [59] Caccac R, Jamali A, Jamali R, Nemovi K, Vosoughi K, Bayraktar Z. Acute pancreatitis as an adverse effect of COVID-19 vaccination. *SAGE Open Med Case Rep* 2022;10:2050313X221131169. <https://doi.org/10.1177/2050313X221131169>.
- [60] Kalra RK, Jayadeep S, Ball AL. Acute pancreatitis in an adolescent following COVID vaccination. *Clin Pediatr* 2022;61(3):236–40. <https://doi.org/10.1177/00099228211067678>.
- [61] Costanzo G, Ledda AG, Ghisu A, Vacca M, Firinu D, Del Giacco S. Eosinophilic granulomatosis with polyangiitis relapse after COVID-19 vaccination: a case report. *Vaccines* 2021;10(1):13. <https://doi.org/10.3390/vaccines10010013>.
- [62] Chan-Chung C, Ong CS, Chan LL, Tan EK. Eosinophilic granulomatosis with polyangiitis after COVID-19 vaccination. *QJM* 2022;114(11):807–9. <https://doi.org/10.1093/qjmed/hcab273>.
- [63] Ibrahim H, Alkhatib A, Meysami A. Eosinophilic granulomatosis with polyangiitis diagnosed in an elderly female after the second dose of mRNA vaccine against COVID-19. *Cureus* 2022;14(1):e21176. <https://doi.org/10.7759/cureus.21176>.
- [64] Nappi E, De Santis M, Paoletti G, Pelaia C, Terenghi F, Pini D, et al. New onset of eosinophilic granulomatosis with polyangiitis following mRNA-based COVID-19 vaccine. *Vaccines* 2022;10(5):716. <https://doi.org/10.3390/vaccines10050716>.
- [65] Kuvaja P, Keinänen N, Pakanen L. The incidence of iatrogenic deaths in the Finnish cause-of-death statistics: a retrospective study. *J Forensic Leg Med* 2022 Feb;86:102302. <https://doi.org/10.1016/j.jflm.2021.102302>.
- [66] Pomara C, Sessa F, Ciaccio M, Dieli F, Esposito M, Giammanco GM, et al. COVID-19 vaccine and death: causality algorithm according to the WHO eligibility diagnosis. *Diagnostics* 2021;11(6):955. <https://doi.org/10.3390/diagnostics11060955>.
- [67] Wolf ME, Luz B, Niehaus L, Bhogal P, Bätzner H, Henkes H. Thrombocytopenia and intracranial venous sinus thrombosis after “COVID-19 vaccine AstraZeneca” exposure. *J Clin Med* 2021;10(8):1599. <https://doi.org/10.3390/jcm10081599>.
- [68] Greinacher A, Thiele T, Warkentin TE, Weisser K, Kyrle PA, Eichinger S. Thrombotic thrombocytopenia after ChAdOx1 nCov-19 vaccination. *N Engl J Med* 2021;384(22):2092–101. <https://doi.org/10.1056/NEJMoa2104840>.
- [69] Nieminen T, Hovi P, Härkönen T, Kaukonen M, Hohnynek H. Kuolleisuus välittömästi koronarokottamisen jälkeen : Koronarokotusten turvallisuus Suomessa [Finnish] [Hazard of death immediately following COVID-19 vaccination]. Helsinki, Finland: Finnish Institute for Health and Welfare (THL); 2022. <https://urn.fi/URN:ISBN:978-952-343-981-8>. Accessed 15/09/2023.

- [70] Marchand G, Masoud AT, Medi S. Risk of all-cause and cardiac-related mortality after vaccination against COVID-19: a meta-analysis of self-controlled case series studies. *Hum Vaccin Immunother* 2023;19(2):2230828. <https://doi.org/10.1080/21645515.2023.2230828>.
- [71] Ferrara SD, Baccino E, Bajanowski T, Boscolo-Berto R, Castellano M, De Angel R, et al. EALM working group on medical malpractice. Malpractice and medical liability. European guidelines on methods of ascertainment and criteria of evaluation. *Int J Legal Med* 2013;127(3):545–57. <https://doi.org/10.1007/s00414-013-0836-5>.
- [72] Ferrara SD. Medical malpractice and legal medicine. *Int J Legal Med* 2013;127(3): 541–3. <https://doi.org/10.1007/s00414-013-0839-2>.