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# **ORIGINAL RESEARCH**

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# Epidemiology, clinical presentations and outcome of patients presenting to the emergency department after a COVID-19 vaccination: An observational study

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### Abstract

**Objective:** The World Health Organization declared the COVID-19 pandemic on 11 March 2020. In 2021, several vaccines were provisionally approved to reduce the risk of transmission and hospitalisation of COVID-19 infection. A surge in COVID-19 vaccination was seen between August and October 2021 in Victoria, Australia. We hypothesised this led to an increase in ED presentations.

*Methods*: Patients in the present study were adults who presented to the ED within 21 days of receiving a dose of a COVID-19 vaccine between 11 August 2021 and 14 November 2021. All cases underwent chart reviews to extract epidemiological features, clinical presentations, ED assessments, investigations and disposition.

*Results*: Notably, 968 patients were included in the study, comprising 6.1% of all ED presentations during

the study period. The median age was 31 years. 82.9% of patients were younger than 45 years. 20.1% of patients arrived by ambulance. Chest pain was the most common presenting complaint (43.6%), followed by head-ache (10.3%) and palpitations (8.2%). The most common investigations were a full blood examination (73.5%), an ECG (63.8%) and serum troponin (49.1%). 64.8% of patients were directly discharged home and 22.1% were sent home after a short stay admission. Only 2.2% of patients were admitted to the hospital.

**Conclusion:** A majority of patients who presented to the ED after their COVID vaccinations were young and discharged home after the initial assessment. These presentations have significantly increased the workload in prehospital settings and EDs, contributing to increased investigation usage, ED treatment space occupancy, and increased costs to the health system.

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## Key findings

- There was a significant surge in ED presentations after mass vaccination against COVID-19 gained momentum in Victoria during the sixth lockdown between August and October 2021.
- Only a small portion of vaccine-related presentations to the ED led to admission with 97.8% of cases being discharged home from the ED.
- Community vaccine awareness campaigns could reduce ED presentations, and improved clinician education should mitigate the rate of low-yield investigations during the pandemic when resource constraints are particularly acute.

**Key words:** AstraZeneca, COVID-19 vaccination, emergency presentation, Moderna, Pfizer.

#### Introduction

The World Health Organization (WHO) declared the COVID-19 (SARS-CoV-2) pandemic on 11 March 2020.<sup>1</sup> In response to a rapid increase in case incidence, the spread of the SARS-CoV-2 virus was initially controlled with a number of public health responses including face masks, hand hygiene, social distancing and restriction of social gatherings and movement through various 'lockdowns'. These measures

shifted after the production and local availability of approved vaccines.<sup>2</sup> The Therapeutic Goods Administration (TGA) provisionally approved Comirnaty (produced by Pfizer) on 2 January 2021, followed by Vaxzevria (produced by AstraZeneca) on 15 February 2021 and Spikevax (produced by Moderna) on 9 August 2021.<sup>4</sup> Vaccination has been proven to be effective at reducing the risk of transmission and hospitalisation due to the SARS-CoV-2 virus.5-7 Hence, the Australian public health strategy was to vaccinate at least 80% of the eligible Australian population in order to safely live with COVID-19, before gradually reopening interstate and international borders. The vaccination programme was a joint Commonwealth and State Government venture, which involved the use of Vaccination Hubs, Primary Care respiratory clinics, general practice and community pharmacists.

Multiple studies have described the adverse events and side effects (AESE) of the three TGA approved vaccines.<sup>9</sup> Common side effects reported for the Pfizer and Moderna vaccines include pain, swelling or erythema of the injection site, chills and fevers, loss of appetite, fatigue, headaches, myalgias, and arthralgias.<sup>9</sup> For

AstraZeneca. tiredness. headache. myalgia, back pain, joint pain, fever, chills and sleeplessness were reported as common side effects.<sup>10</sup> The more severe side effects are anaphylaxis, thrombosis with thrombocytopenia syndrome (TTS) after the AstraZeneca vaccine, and myocarditis and pericarditis after the Pfizer and Moderna vaccines.<sup>11</sup> While most of the side effects are not harmful in themselves, these symptoms are associated with temporary distress in vaccinated people with a proportion seeking medical assessment including presentation to the ED. Emergency clinicians managing these presentations may request unnecessary and extensive investigations, contributing to prolonged stays in the ED. Fear of missing one of the very uncommon though serious adverse events often prompted primary care practitioners to refer patients to the ED for further assessment.

Currently, there are limited studies that have investigated presentations to the ED following COVID-19 vaccination. The period considered by the present study coincides with a sharp increase in vaccination rates over a short timeframe.<sup>12</sup> It is likely that this resulted in a proportionate increase in AESEs and heightened



Figure 1. Patient flow diagram.

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anticipation of such events by the population being vaccinated coupled with anxiety-provoking articles in the lay media and very risk-averse messaging by various health agencies.<sup>13,14</sup> We hypothesised that this led to an increase in ED presentations. This is the first Australian study to evaluate the epidemiology, clinical features and outcome of patients presenting to the ED following the administration of a COVID-19 vaccine.

#### Methods

#### Study design

We conducted a descriptive retrospective study, reviewing patient presentations to a single Metropolitan ED between 11 August 2021 and 14 November 2021. These dates correspond with 5 days following the commencement of the sixth lockdown in the State of Victoria, until 5 days before it officially ended on 19 November 2021. This period coincides with the state's highest vaccination rate.<sup>12</sup> During the period, both Pfizer and AstraZeneca were approved for the Australian adult population. in the middle of the study period, Moderna was approved for adult Australians.

#### Selection of cases

Patients included in the present study were adults, aged 18 years or older, presenting to the ED within 21 days of receiving a dose of a TGA approved COVID-19 vaccine (Comirnaty (Pfizer), Vaxzevria (AstraZeneca) and Spikevax (Moderna)) during the study period (Fig. 1). The case identifications were performed in two stages from the ED Patient Administration System (PAS). At first, we identified all possible cases who attended the ED after their vaccination. The following search strategies were used in stage 1 to identify potential cases to be included in the study:

- All cases with the ED discharge diagnosis of 'Anaphylaxis due to serum/vaccine/immunisation' or 'Serum sickness/reaction to vaccine' or 'Vaccination complication'. These are fixed ICD-10 codes.
- 2. A search of the wording of the ED triage notes to identify cases that contained the following:

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Covid, vaccine, vax, Pfizer, AZ, Moderna, allergy, reaction and adverse event. Different iterations of spelling were included in the search criteria (Table S1).

The triage notes for all identified cases were then reviewed by VD and HJ to identify cases for which the primary reason for presentation was related to recent COVID-19 vaccination. Patients were excluded if they met one or more of the following exclusion criteria (Table S2):

- Recently vaccinated but more than 3 weeks prior to presentation.
- Received a vaccine other than a COVID-19 vaccine (e.g. rabies, flu).
- Asymptomatic but recently vaccinated (e.g. presenting to obtain a diagnostic test for travel or professional purposes).
- The triage note mentioned COVID-19 vaccines as part of screening for vaccination status and not as part of the patients' presenting complaint.
- Requesting a COVID-19 vaccination.
- Recent positive case of COVID-19.
- Having a COVID-19 infection during their ED presentation.

To validate the inter-rater reliability of this stage, 30 cases were randomly selected by HA and the agreement was >99%.

#### Data collection

The included cases for the present study then underwent chart reviews to extract the following data: arrival date, sex, age, type and dose of vaccination, duration between vaccination and ED presentation, mode of arrival, triage category, main presenting complaints, ED management, length of stay in ED and disposition. Chart review was done by VD, HJ, BV, JM and HA. Due to the retrospective nature of the study, we were not able to collect the advice provided by the vaccinators. An example of participant factsheet after the Pfizer vaccine provided by the Australian Government can be found here: https://www.health.gov.au/sites/default/ files/documents/2021/09/covid-19vaccination-after-your-comirnaty-pfi

#### zer-vaccine-covid-19-vaccination-afteryour-pfizer-comirnaty-vaccine.pdf

Notably, 80 (8%) cases were randomly selected to check for the quality of the data and assess inter-rater reliability for the following data points: Arrival date, disposition, triage category, type of vaccination, dose of vaccination, duration between vaccination and ED presentation and chest X-ray. The quality of data and data check were performed by VD and CHJ. Agreement was >90% for all data points (Table S3).

SPSS Version 27 software (IBM, Armonk, NY, USA) was used for statistical analysis of the data. Qualitative data were presented as numbers and percentages while the quantitative data were presented as median and interquartile range (IQR). We used the nonparametric Kruskal–Wallis *H* and post-hoc Mann–Whitney test to assess differences between vaccination type and time to present to the ED.

The study was approved by the Human Research Ethics Committee at St Vincent's Hospital Melbourne (Reference number LRR 010/22).

#### Results

The initial search identified 1805 potential presentations related to vaccine side effects during the study period between 11 August 2021 and 14 November 2021. After removing non-related vaccine presentations, 968 presentations remained in the study. The total ED attendance during this period was 15 956; hence, 6.1% of all presentations were COVID vaccine-related (968/15956, 95%)

confidence interval [CI] 5.7–6.4). 66.7% of these presentations were related to the Pfizer vaccination (646/968, 95% CI 63.7–69.7), while 28.3% were due to AstraZeneca (274/968, 95% CI 25.5–31.3) and only 4.6% were related to Moderna (44/968, 95% CI 3.3–6.1). The type of vaccination was not recorded in four (0.4%) cases.

The median age of the patients was 31 years (interquartile range [IQR] 12). 82.9% of patients were younger than 45 years (802/968, 95% CI 80.3–85.2)) (Fig. 2). 20.1% of patients arrived at the ED by ambulance (195/968, 95% CI 17.7–22.8). 65.1% of the ambulance arrivals were younger than 45 years (127/195, 95% CI 58.0–71.8) (Table 1).

The median duration between vaccination and presentation to the ED was 4 days (IQR 6). This period was longest among the AstraZeneca group (5 days [IQR 8]) in comparison to the Pfizer group (4 days [IQR 6]) or the Moderna group (3 days [IQR 6]). As the assumption of the homogeneity was not met, the non-parametric Kruskal-Wallis H test showed a significant difference between the vaccination type (H[2] = 12.27, P = 0.002). A post-hoc Mann-Whitney U test showed that the duration between vaccination and ED presentation was only significant between the AstraZeneca and Pfizer groups (P = 0.02).

Chest pain was the most common presenting complaint among patients presenting to the ED after their COVID-19 vaccination (43.6%, 422/968, 95% CI 40.4–46.8), followed by headache (10.3%, 100/968, 95%



**Figure 2.** Bar graph depicting the age group categorised by the type of vaccination. Age group: (**n**), <25; (**n**), 25–35; (**n**), 35–45; (**n**), 45–55; (**n**), 55–65; (**n**), 65–75; (**n**), 75–85; (**n**), >85.

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	Vaccination type				
	AstraZeneca $(n = 274)$	Pfizer ( <i>n</i> = 646)	Moderna $(n = 44)$	Not recorded $(n = 4)$	Total ( <i>n</i> , %)
Sex					
Male	124 (12.8%)	304 (31.4%)	23 (2.4%)	2 (0.2%)	453 (46.8%)
Female	149 (15.4%)	339 (35%)	21 (2.2%)	2 (0.2%)	511 (52.8%)
Other	1 (0.1%)	3 (0.3%)	0 (0%)	0 (0%)	4 (0.4%)
Dose					
First dose	167 (17.3%)	326 (33.7%)	28 (2.9%)	2 (0.2%)	523 (54%)
Second dose	75 (7.7%)	287 (29.6%)	16 (1.7%)	1 (0.1%)	379 (39.2%)
Third dose	0 (0%)	4 (0.4%)	0 (0%)	0 (0%)	4 (0.4%)
Not recorded	32 (3.3%)	29 (3.0%)	0 (0%)	1 (0.1%)	62 (6.4%)
Days between vaccination and ED presentation, days (IQR)†	5 (8)‡	4 (5)‡	3 (6)	NA	4 (6)
Presenting complaints§					
Chest pain	62 (6.4%)	337 (35%)	22 (2.3%)	1 (0.1%)	422 (43.6%)
Headache	67 (7%)	31 (3.2%)	2 (0.2%)	0 (0%)	100 (10.3%)
Palpitations	10 (1%)	63 (6.5%)	5 (0.6%)	1 (0.1%)	79 (8.1%)
Short of breath	15 (1.6%)	37 (3.8%)	3 (0.3%)	0 (0%)	55 (5.7%)
Febrile illness/malaise	20 (2%)	26 (2.7%)	3 (0.3%)	1 (0.1%)	50 (5.2%)
Triage category					
1	1 (0.1%)	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)
2	18 (1.9%)	46 (4.8%)	5 (0.5%)	0 (0%)	69 (7.1%)
3	117 (12.1%)	314 (32.6%)	16 (1.7%)	1 (0.1%)	448 (46.3%)
4	133 (13.8%)	280 (29%)	22 (2.3%)	3 (0.3%)	438 (45.2%)
5	5 (0.5%)	6 (0.6%)	1 (0.1%)	0 (0%)	12 (1.2%)
Mode of arrival					
Ambulance	61 (6.3%)	124 (12.9%)	10 (1%)	0 (0%)	195 (20.1%)
Own transport	119 (12.3%)	300 (31.1%)	25 (2.6%)	2 (0.2%)	446 (46.1%)
Public transport	31 (3.2%)	85 (8.8%)	3 (0.3%)	0 (0%)	119 (12.3%)
Police vehicle	0 (0%)	0 (0%)	1 (0.1%)	0 (0%)	1 (0.1%)
Not specified	63 (6.5%)	137 (14.2%)	5 (0.5%)	2 (0.2%)	207 (21.4%)

**TABLE 1.** Demographics and clinical features of patients presenting to the ED after the COVID-19 vaccination group by the type of vaccination

CI 8.9–12.4) and palpitations (8.2%, 79/968, 95% CI 6.5–10.1) (Fig. S1). Chest pain and palpitations were seen mainly in patients following Pfizer vaccination, while headache was a common presentation after an AstraZeneca vaccination (Table 1).

The most common investigations were a full blood examination (73.5%, 712/968, 95% CI 70.6–76.3),

a 12-lead ECG (63.8%, 618/968, 95% CI 60.7–66.9) and serum troponin (49.1%, 475/968, 95% CI 45.9– 52.3). 29.8% of patients had a chest X-ray radiograph (288/968, 95% CI 26.9–32.7), while advanced imaging modalities (CT brain/venogram, CT chest/CT pulmonary angiogram or both) were requested for 5% of patients (55/968, 95% CI 4.3–7.3). Only 0.3% of cases (3/968, 95% CI 0.1–0.9) were reported with an abnormal CT pulmonary angiogram study while no abnormal CT brain was reported (Table 2).

64.8% of patients were directly discharged home from the ED (627/968, 95% CI 61.7–67.8) and 22.1% were sent home after an ED short stay admission (214/968, 95%

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	Vaccination type			
	AstraZeneca	Pfizer	Moderna	Total† ( <i>n</i> , %)
Symptoms				
Chest pain	84 (31%)	388 (60%)	28 (64%)	501 (51.8%)
Short of breath	60 (22%)	217 (34%)	16 (36%)	293 (30.3%)
Headache	101 (37%)	91 (14%)	8 (18%)	201 (20.8%)
Fatigue/lethargy/malaise	47 (17%)	90 (14%)	7 (16%)	144 (14.9%)
Palpitations	16 (6%)	108 (17%)	12 (27%)	136 (14%)
Nausea/vomiting	31 (11%)	61 (9%)	4 (9%)	96 (9.9%)
Investigations				
FBE	218 (80%)	457 (71%)	34 (77%)	712 (74%)
Troponin	79 (29%)	369 (57%)	26 (59%)	475 (49%)
D-dimer	150 (55%)	117 (18%)	7 (16%)	274 (28%)
ECG	131 (48%)	456 (71%)	30 (68%)	618 (64%)
CXR	62 (23%)	214 (33%)	12 (27%)	288 (30%)
CT brain	17 (6%)	13 (2%)	3 (7%)	33 (3%)
CT chest (including CTPA)	5 (2%)	13 (2%)	2 (5%)	20 (2%)

TABLE 2.	Main symptoms of	<i>t patients in the ED</i>	and emergency investigations
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†Including all cases (recorded and unrecorded vaccination type). CT, computed tomography; CTPA, computed tomography pulmonary angiogram; CXR, chest X-ray; ECG, electrocardiogram; FBE, full blood examination.

CI 19.5-24.9). 10.9% of patients left the ED without being seen by medical staff, after partial treatment or after nursing triage advice (105/968, 95% CI 9.0-13.0). Only 2.2% of patients (22/968, 95% CI 1.4-3.4) were admitted to an inpatient unit within the hospital. One in five patients were seen and managed by the ED Rapid Assessment Team (a rapid review team consisting of an emergency physician and nurse, tasked with facilitating early assessment and management of patients in the ED's waiting room) (194/968, 95% CI 17.6-22.7). One patient was transported to the ED from a correctional centre. Only eight admissions out of 22 were directly related to the COVID vaccines. One patient with severe thrombocytopenia, two patients with pulmonary embolism, and five patients with pericarditis or myopericarditis. All cardiac patients were discharged from the hospital after 1 day.

Six patients presented three times to the ED and 27 patients presented twice. The median length of stay in the ED was 175 min (IQR 115). The three most frequent discharge diagnoses were 'chest pain, NEC (not elsewhere classified)' (30.7%, 297/968, 95% CI 27.8–33.7), 'COVID-19 vaccines causing adverse effect in therapeutic use' (10.3%, 100/968, 95% CI 8.5–12.4), and 'headache/facial pain' (5.8%, 57/968, 95% CI 4.5– 7.6). The discharge diagnosis was missed for 9.6% of cases because of an incomplete ED assessment (93/968, 95% CI 7.8–11.6).

#### Discussion

This is the first study to evaluate the impact of mass COVID-19 vaccination on emergency presentations in Australia by reporting on the epidemiology, clinical features and final disposition of patients. During the 3-month study period, approximately 3.1 million vaccine doses were administered within Victoria, attesting to a noticeable acceleration in vaccination rates when compared to the 1.6 million vaccine doses given in the 6 months immediately prior to August 2021.<sup>12</sup> We observed a significant increase in vaccine-related presentations to the ED, which added to an already-challenging workload and imposed extra burdens on the severely constrained health services. This increase in ED presentations is multifactorial, with an increased level of anxiety in the community about side effects of new vaccines, a lack of resources and GP availability to address the increased presentations of vaccine side effects, and high awareness within the population of symptoms of potential and serious side effects of the vaccines. It is noteworthy that one in five vaccine-related presentations utilised an ambulance service to present to the ED, with adverse implications for the delivery of prehospital services.

The patients presenting to our ED with vaccination-related complaints were relatively young, and the majority had received the Pfizer vaccination. Based on the Australian Government vaccination data registry, 78.2% of people receiving a vaccination during the study period were <50 years old, suggesting this younger group of patients were somewhat more likely to

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present to the ED with vaccinationrelated complaints.<sup>12</sup> Additionally, Fed-Government acceptance eral of Australian Technical Advisory Group on Immunisation (ATAGI) advice to reduce criteria for the recommendation of the AstraZeneca vaccine was almost certainly a contributing factor to the higher proportion of Pfizer vaccination presentations. Midway through the present study period, the Moderna vaccine was approved by the TGA. Our findings are in clear contrast to the US study, which reported older patient ED presentations (70.3 years) and a 2.2% mortality rate 10 days after COVID-19 vaccination.<sup>15</sup> In Kewan's study, investigators assessed every ED presentation among patients who had received a COVID-19 vaccination in the 10 days prior to the presentation, irrespective of the main presenting complaint. In our study, we only reported patient presentations that were clearly related to the recent COVID-19 vaccination to accurately represent the effect of mass COVID-19 vaccination on the EDs. The vast majority of presentations did not require hospitalisation, with the admission rate being 2.2% (the average admission rate for our health service is 40%). Only a quarter of admissions was directly related to the COVID vaccine and the majority was discharged after a one-day hospital stay.

The impact of mass vaccination on ED presentations is not a completely new concept. A study by Nainani et al.<sup>16</sup> in 2017 demonstrated that following the introduction of the Group B Meningococcal vaccine in the United Kingdom, ED attendances of children because of suspected adverse vaccination events increased threefold. This increase was associated with a higher admission rate, unnecessary invasive investigations and the administration of intravenous antibiotics.<sup>16</sup> We have identified a similar pattern of care in the present study. Most of the patients in our study underwent laboratory and imaging studies following initial assessment. This represents a significant resource requirement associated with this cohort of presentations given the very low prevalence of significant vaccine-related adverse events. The costs incurred from medical imaging alone, as per the Medicare Benefits Schedule,<sup>17</sup> was \$27 465 over the

period studied, or an average of \$28.37 per patient presentation.

Prothrombotic complications in the setting of the AstraZeneca vaccination were a prominent concern in the community during the period studied. Only 0.3% of the study population received a diagnosis of pulmonary embolism. Two of these patients had a D-dimer >1.0 mol/L. while the third patient had an already-diagnosed deep vein thrombosis prior to their presentation to the ED. It is important to point out the 1-2% threshold of missing rate for certain serious conditions in the EDs such as acute myocardial infarction and pulmonary embolism is acceptable given that attempting to reduce the miss rate further adds significant cost, over-investigation and has been associated with additional harms.<sup>18</sup> The rate of admission of this group in our study was 2.2% while the rate of serious side effects was lower. The yield from CT pulmonary angiograms in the present study was comparable to other studies in the general population of ED presentations.<sup>19</sup> A standardisation of the process of assessment for each major vaccination-related complication, along with a rationalisation of the investigations required, could potentially reduce the resource constraints, time and costs incurred in future booster vaccination drives. The current guideline endorsed by the Australian Department of Health recommends initial assessment and investigation in a general practice or an ambulatory outpatient cardiology setting for well and stable patients while reserved ED presentation for unwell and high-risk patients.<sup>20</sup> During the present study, a number of issues affected the ability of patients to access general practitioner. their These included GP concerns with their lack of access to PPE and the decision by the clinic not to review patients with respiratory symptoms due to safety concerns to staff. However, a limited number of primary care clinics were open to patients with respiratory symptoms, but only pre-existing patients of these clinics were able to access appointments, meaning that most of the population was unable to attend their GP when experiencing dyspnoea.

Although outside the scope of the present study, we speculated that insufficient public education, limited validated and reliable information for public consumption about management of adverse vaccination events, a significant and sustained media focus on rare but serious side effects of the COVID vaccines, and questionable preparation for mass vaccination campaigns by governments were contributing factors to the increased presentations to the ED post COVID-19 vaccination.

Public education to utilise a dedicated government national coronavirus helpline on 1800 020080, using statebased nurse telephone assessment services, and simple brochures for distribution to patients after vaccination may substantially reduce anxietyrelated presentation to EDs. The UK study states that parental education regarding post-vaccination fever and paracetamol pharmacotherapy diminished ED presentations.<sup>16</sup> It is a matter of urgency and importance to further explore such initiatives and channel to support and educate the public, as our population is currently in the midst of expanded mass vaccination programmes, via extended eligibility to younger population cohorts, the need for third vaccine doses, and the prospect of further COVID-19 vaccinations to contend with future variants and waning immunity. In addition, revised investigations algorithms and dedicated adverse effects clinics may reduce ED presentations.

We acknowledge some limitations with the present study. The present study was confined to a single site, and further multi-site research is required to confirm the findings. There are inherent limitations because of the observational retrospective nature of the present study design. It is possible that some cases were missed during the screening process and some data may have been missed due to operator error, despite a high inter-rater reliability agreement. Triage data were only reviewed to identify whether presentations were related to recent COVID-19 vaccine. The present study lacks sufficient power to identify serious side effects of the COVID vaccines. Further research on presentations to primary care settings following COVID-19 vaccine will complement the findings of the present study.

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#### **Competing interests**

None declared.

#### Data availability statement

Data available on request from the authors.

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#### Supporting information

Additional supporting information may be found in the online version of this article at the publisher's web site:

Table S1. Search criteria and their iterations used on the triage notes to identify possible cases during the study period.

Table S2. Examples of the triage note that were reviewed for selection in the study. The terms used for the search are in bold.

 Table S3. Inter-rater reliability data.

Figure S1. Frequency of presenting complaints of patients attending to the ED following their recent COVID vaccine. Chest pain is the most common presenting complaints followed by headache.