Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

A Decision by the Deputy Health and Disability Commissioner

(Case 21HDC02050)

Executive summary

1. This report concerns the care provided to a woman by a locum general practitioner (GP) after the woman received a COVID-19 Pfizer Comirnaty vaccine. The woman had a rare genetic disorder and following the vaccine her condition began to deteriorate. She presented at an urgent care clinic, where she was assessed by the locum GP.

2. An ECG taken at the clinic showed abnormal results, but the woman was discharged home without further investigation by the GP and, sadly, the woman passed away four days later.[1]

3. This report highlights the importance of timely and appropriate follow-up actions when presented with abnormal test results.

4. The Deputy Commissioner emphasised that the purpose of this report is not to determine the woman's cause of death, but to assess the standard of care provided to the woman at the time of the events.

[1] The Coroner ruled that the woman's death was due to natural causes.

Names have been removed (except the advisor) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

Findings

5. The Deputy Commissioner found that the GP breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code) by failing to take the additional and appropriate follow-up actions after the ECG returned an abnormal result. In particular, the GP failed to discuss the results with a relevant specialist or compare it with one of the woman's previous ECGs.

Recommendations

6. The Deputy Commissioner recommended that the GP provide a written apology to the woman's whānau.

Complaint and investigation

7. The Health and Disability Commissioner received a complaint from whānau about the services provided to Ms A at an urgent care clinic. At the time, GP Dr B[2] was working at the clinic as a locum GP, and he saw Ms A following a deterioration in her condition after she had received a vaccination that day.

8. A formal investigation was commenced into the care provided by Dr B to Ms A.

9. This report is the opinion of Dr Vanessa Caldwell, Deputy Health and Disability Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

10. The parties directly involved in the investigation were:

Sister of consumer	Complainant
Dr B	GP
Mrs C	Ms A's mother
Urgent care clinic	Healthcare provider

11. Further information was received from the Coroner and Medsafe.

12. Clinical advice was obtained from GP Dr David Maplesden (Appendix A).

Introduction

13. E te whānau ka mihi aroha ki a koutou i tō tino mamae, tō pōuritanga o tō kōtiro ātaahua kua whetūrangitia. Kāore he kupu, he whakaaro hei whakaora te ngaro ka waenganui a koutou. Nō reira ka tuku a mātou nei aroha, a mātou nei rangimārie ki a koutou katoa — Mauri Ora.

14. Ms A attended a medical centre and received her first dose of the Pfizer Comirnaty COVID-19 vaccine. Ms A had a rare genetic disorder that can be complicated by cardiovascular disease. Soon after receiving the vaccine, Ms A's condition deteriorated, and four days later

[2] Dr B has been vocationally registered as a GP since 2014.

she passed away. The post-mortem report stated that there was no indication that Ms A had suffered an acute reaction to the COVID-19 vaccine, and that given her pre-existing conditions, 'there was a risk of sudden death which could have occurred at any time'. The Coroner found that Ms A died of natural causes (discussed further below).

15. Whilst I acknowledge that Ms A's whānau's concerns regarding the care she received are broader than the scope of this report, it is necessary for HDC to focus its resources on the investigation of matters where there is evidence that may suggest a breach of the Code of Health and Disability Services Consumers' Rights (the Code). I am satisfied that the matters I consider have already been addressed adequately by the providers concerned and do not need to be repeated in this report. That this Office has not investigated all concerns raised does not diminish the importance of those matters to the whānau, and they may wish to resolve their additional concerns through alternative avenues as appropriate.

Events leading up to complaint

16. Ms A attended the medical centre with her mother, Mrs C, and they both received their first dose of the COVID-19 Comirnaty vaccine around 2pm.[3] Ms A's whānau told HDC that Ms A entered the medical centre with good colouring and movement of her body, warm hands, and normal breathing.

17. Shortly after receiving the vaccine, Ms A's physical condition deteriorated and there was concern that she had suffered an adverse reaction to it. I note that there is some uncertainty around exactly what time Ms A received the vaccine, but it is clear that Ms A was unwell shortly after it had been administered.[4] Ms A's whānau said that Ms A's reaction was 'immediate and obvious' and that the family are still in shock at the very noticeable change they saw in Ms A. Ms A's mother stated that while in the recovery area, Ms A's 'hands were very cold and her colour had changed'.

18. The clinical notes for that time state: '? reaction to COVID vaccine … [Ms A] felt heavy and weak after COVID vaccine … [blood pressure]=112/98 … Pulse=130, Cold hands.' It was noted that these were 'unusual observations for this patient'. The vaccination site coordinator advised that Ms A attend the urgent care clinic at the public hospital for a medical review. As there was temporary difficulty with viewing and printing Ms A's recorded observations,[5] Ms A and her mother were provided with a handwritten note recording the above assessment and history, to be passed on to staff on arrival at the hospital.

19. The medical centre said that at the time, staff attempted to submit an adverse event report to the Centre for Adverse Reactions Monitoring (CARM) via the relevant Ministry of Health

[3] Clinical records note that Ms A's cardiologist had recommended that Ms A receive the COVID-19 vaccine.
[4] Ms A's COVID-19 vaccination consent form records the time of vaccine as 12.56pm whilst the clinical notes record her change in condition, which occurred shortly after receiving the vaccine, at 1.55pm. A further time of 1.25pm is noted in the Coroner's report.
[5] It was recorded in the clinical notes that the observations were 'lost', but the medical centre told HDC that they had in fact been recorded electronically, and by the time Ms A arrived at the hospital, the observations were able to be viewed electronically.

online system, but due to technical issues with the system, the adverse event report was not completed until four days later.

20. Ms A's mother drove Ms A to the hospital, which took approximately 20 minutes. Medical centre staff documented that prior to leaving for the hospital, Ms A was feeling better and 'alert and oriented'.

21. Ms A arrived at the hospital at around 3.20pm with her mother and sister, who had driven with them after being informed of Ms A's condition. After around half an hour, a nurse called in Ms A for an assessment, and Ms A's mother gave the nurse the handwritten note from the medical centre containing Ms A's observations. The nurse carried out new observations, which included a temperature of 37.3°C, pulse of 115 beats per minute, and blood pressure of 110/80mmHg.

22. An ECG was also performed. The ECG form stated: '[S]inus tachycardia[6] … [consistent with] anteroseptal infarct … Heart rate: 143BPM … consider acute ischemia. Abnormal ECG.'

23. Ms A's mother said that at that time Ms A was unable to move her left arm and still had very cold hands. Nursing notes state that Ms A denied having any chest pain or tightness, and that Ms A would be reviewed by the duty doctor, Dr B.

24. At the time, Dr B was contracted by the urgent care clinic as a locum GP for five weeks. The outcome of Dr B's review was that Ms A could be discharged home without further intervention. The review is discussed in further detail below. Dr B's clinical notes record that he gave reassurance to the whānau and advised them to seek review from Ms A's regular GP or cardiologist if required.

25. Four days later, Ms A's mother found Ms A unresponsive in bed, and, following attendance by an ambulance crew, she was confirmed deceased. The medical centre was informed the same day, and it submitted a CARM adverse event report regarding Ms A's death. An incident form completed by the medical centre stated:

> 'Possible Covid vaccine reaction — Both CARM [and] Coroner's investigation ongoing. Possible missed opportunity to intervene during urgent clinic assessment on day of vaccination.'

26. The medical centre told HDC:

> 'We would again wish to acknowledge the ongoing unresolved grief [Ms A's] whānau are experiencing and our wish to support them in any way we can. We have met with them on a number of occasions since her death and have talked in detail about our understanding of events and tried to answer their questions as well as we have been able to … We again would like to reiterate our willingness to fully participate in further

[6] An abnormally fast heartbeat.

> discussions with [Ms A's] whānau … [I]t is our fervent desire to restore and continue our relationship with [Ms A's] whānau and to help them in any way we can.'

27. Ms A's whānau met with the Clinical Director and CEO to discuss their immediate concerns, and the whānau thanked them for 'accepting and acknowledging that more could have been done for [Ms A] at the hospital'. They stated:

> 'We are not looking to place blame on any individual as we do appreciate many in our health system do an outstanding job. At this time we are concentrating on healing and ensuring whānau with their own "[Ms A]" do not experience the same grief we are.'

28. Dr B conveyed his sincere condolences to Ms A's whānau for their loss.

Subsequent events

29. A post mortem was conducted by a forensic pathologist, who concluded that the direct cause of death was most likely a pulmonary thromboembolism (blood clot) in the left lung.[7] The post-mortem report also noted that other significant conditions contributing to Ms A's death included severe coronary atherosclerosis (narrowing of the coronary arteries),[8] a rare genetic disorder, hypertensive heart disease, and mitral valve[9] disease. The post-mortem report noted:

> 'The degree of coronary atherosclerosis was such that a sudden death could have occurred at any time as a result of myocardial ischaemia causing a fatal cardiac arrhythmia. There was no evidence of acute myocardial infarction [heart attack].'

30. The Coroner found that Ms A died of natural causes, with the direct cause being thromboembolism.

31. Following CARM's receipt of the adverse event report, the COVID-19 Vaccine Independent Safety Monitoring Board reviewed whether Ms A's decline was as a result of the COVID-19 vaccination. The Board noted that the cause of death had been established by the pathologist, and that it was highly unlikely that the death was linked to the vaccine.

Responses to provisional opinion

The whānau

32. The whānau were given the opportunity to comment on the 'Events leading up to complaint' section of the provisional opinion. They told HDC that this has been a very painful time for them, and they wish that Ms A had been able to get the help that she so needed. Ms A's whānau 'wanted [their] voices to be heard for [their] [Ms A]' and emphasised the importance of their family speaking for her now as she can no longer speak for herself.

[7] The pathologist found that there were blood clots present 'throughout the left upper and lower lobes', and that '[t]he right lower lobe showed moderate congestion'.
[8] The pathologist noted that atherosclerosis is a 'chronic process that develops over time (years)'.
[9] The mitral valve ensures that blood flows properly from the left atrium to the left ventricle of the heart. If the mitral valve is not working properly, it may put strain on the heart.

33. HDC acknowledges the thorough and detailed response to the provisional opinion provided by whānau and, where appropriate, these comments have been incorporated into the report.

Urgent care clinic

34. The urgent care clinic was given an opportunity to comment on the provisional opinion and, where relevant, its response has been incorporated into this report.

35. The clinic told HDC that overall, it found that the provisional opinion provided a comprehensive overview of the incident through its 'analysis, commentary, and outcome decision'.

36. The clinic also acknowledged the scope of the report and the need to focus the report on potential breaches of the Code.

Dr B

37. Dr B was given an opportunity to comment on the provisional opinion and told HDC that he had no comments on the substance of the provisional opinion. He accepted HDC's recommendation to provide an apology to the whānau of Ms A.

Opinion: Introductory comment

38. I acknowledge that the whānau has raised concerns that the administration of the COVID-19 vaccine may have led to Ms A's blood clot and death. However, it is not within my jurisdiction, and is outside of the scope of this investigation, to determine cause of death. The Coroner has found that Ms A died of natural causes, and my opinion must proceed on that basis.

39. However, the whānau's concern in this regard is understandable given the timing of events, and, in an effort to acknowledge their concerns about the vaccine and any known associated risk of blood clotting, HDC sought information from Medsafe to pass on to the whānau. Following a review of the risk of rare cases of blood clots with bleeding that have been reported internationally with some COVID-19 vaccines, Medsafe's position (unchanged since 27 April 2021) is that there is no evidence of a risk of blood-clotting complications with the Comirnaty vaccine[10] (Medsafe's full response is included as Appendix B). Medsafe continues to monitor the safety of the vaccine concerning any risks. I support Ms A's whānau and others in raising any safety concerns about medicine products with Medsafe and CARM directly.

40. In forming my opinion on the care provided by Dr B, I have considered responses from all relevant parties and the advice of my in-house clinical advisor, GP Dr David Maplesden, whose advice is incorporated below where relevant. I have focused this report on the one aspect of care that Dr Maplesden indicated did not conform with accepted practice — Dr B's follow-up management of Ms A's ECG. Dr Maplesden also advised:

[10] https://www.medsafe.govt.nz/safety/Alerts/COVID-19-vaccine-blood-clots.asp

> '[The urgent care clinic's] response indicates [that] this incident and the complaint have been thoroughly reviewed and I believe the response, including proposed remedial actions, is appropriate. I have no further recommendations in this regard. This has been a tragic event and I pass my condolences on to [Ms A's] whānau at their loss.'

Opinion: Dr B — breach

41. As noted in his statement to the Coroner, Dr B arrived at the hospital at around 4.30pm and took over clinical management for the overnight call period. He said that at that time, Ms A was one of two patients awaiting review by a doctor.

42. Ms A was reviewed by Dr B at around 5.40pm[11] following a nursing triage approximately 90 minutes previously.

43. Ms A's mother and sister attended the review with Ms A. Dr B said that he was given a handwritten note that summarised Ms A's presentation and observations taken at the medical centre. He was also given a printout of the ECG taken at the hospital, timestamped 4.01pm. Dr B said that he reviewed Ms A's medical history and noted that she had a rare genetic condition. He said that he also reviewed Ms A's clinical notes and saw that she was under the care of a cardiologist.

44. Dr B told HDC:

> 'When I initially reviewed her ECG, I could see that it was abnormal … although I did not appreciate at the time that it was "markedly" abnormal. When I reviewed [Ms A's] medical history, I saw there was an explanation for the abnormal ECG — her previous surgery and cardiac issues, which would mean an abnormal ECG was expected.'

45. Dr B stated that in the ED environment he was 'focused on [Ms A's] presenting problem — of a potential adverse reaction to the covid vaccine'. He said that he planned to consider the ECG further during his in-person assessment of Ms A to see if it was relevant to her presenting problem.

46. In the clinical notes for the review, Dr B documented: 'A note from the Covid vaccination centre today says that she felt heavy and weak after the vaccine and had a pulse of 130.' Clinical notes state that further observations taken during Dr B's review included a blood pressure of 112/68mmHg, a pulse of 143 beats per minute, and an oxygen saturation of 98%. Dr B recalled that Ms A did not appear in distress or short of breath, and did not report any pain, nausea, or light-headedness. He also recalled that she had good blood circulation and was able to give a clear account of what happened that day.

[11] The urgent care clinic acknowledged that a delay of approximately an hour and a half between the nurse's triage and the doctor's review 'falls below [its] usual expected standard of care'. Dr Maplesden advised that given the clinical circumstances of review, he did not think such a wait 'would be unusual in a busy primary care urgent care clinic or secondary care ED' and, as such, he was not critical of the wait time in the circumstances. I acknowledge that the clinic has utilised these events to make improvements in its triage system and wait times.

47. Dr B said that with this additional information, he reached the view that Ms A was not acutely unwell or suffering an acute allergic reaction to the COVID-19 vaccination and sought to reassure Ms A and her whānau to that effect. He stated: '[O]ver the consultation [Ms A] clearly became more relaxed and calm, which led me to conclude that this was an anxiety reaction.'

48. In relation to Dr B's review, Ms A's whānau stated:

> 'His attitude and approach was very casual. When we entered the room with him, I [Mrs C] placed the notes from the clinic, and the ECG taken by [the registered nurse], on the doctor's desk. I did not see [Dr B] refer to these during our short time with him. He did not make any effort to assess [Ms A] himself by listening to her heart, or taking her temperature, or blood pressure, etc. Instead he made a quick and seemingly superficial judgement that took a total of less than ten minutes. … He ignored her change in colour, cold hands, racing heart, shortness of breath and her inability to move her left arm. He wrote "anxiety" on his notes without discussing that with [Ms A], myself or [Ms A's sister], another of my daughters who had joined us at the hospital.'

49. The complaint also said that Dr B advised that what Ms A was experiencing did not meet the criteria for filing a report to CARM. Dr B confirmed that at the time he did not consider a CARM report was necessary based on his assessment, and so did not complete one. I discuss this matter briefly at the end of this report.

50. I note the discrepancy between the contemporaneous clinical records of Dr B's review and the whānau's recollection regarding whether Dr B took additional observations during the review. Based on the clinical record, I am satisfied that observations were taken. I also note that Ms A's whānau did not see Dr B referring to the ECG printout. Dr B's recollection is that he did review the ECG, and, although he did not document such a review in the clinical notes, I leave open the possibility that he did so. I do not consider it necessary to make a definitive finding as to whether or not he did review the ECG, as the more material issue of concern is whether the action taken by Dr B to follow up on the abnormal ECG was appropriate. This is discussed below.

51. Following his assessment that Ms A was not acutely unwell, in that context Dr B believed the abnormal ECG 'seemed likely to be related to [Ms A's] other conditions' and not related to the presenting problem. He provided advice for Ms A to consult her usual GP or cardiologist, or to return to the hospital if she started to feel worse. I note that whānau do not recall any 'safety information' being given by Dr B; however, based on the contemporaneous notes of Dr B, I am satisfied that he did advise Ms A and her family to seek further medical advice if she deteriorated.

52. Dr B told the Coroner that notwithstanding the above assessment, he still planned to either discuss Ms A's ECG with the medical director or review it further himself in the context of any prior ECGs available from Ms A's clinical records. He said: 'If this raised any concerns we would be able to ask [Ms A] to come back in.'

53. Dr B stated that soon after his consultation with Ms A, he was called away to see another patient with a head injury, who subsequently was transferred to another hospital. Dr B reflected that this event caused him to forget about Ms A's ECG and therefore he did not follow up on it as planned.

Ms A's ECG

54. In relation to the ECG reading and findings ('sinus tachycardia … anteroseptal infarct[ion][12] … Heart rate: 143BPM … consider acute ischemia[13]. Abnormal ECG'), Dr Maplesden advised that it showed that Ms A had a rapid abnormal heartbeat that may have been putting strain on her heart. He further stated:

> 'I am confident my peers would recognise the tracing as being abnormal with some potentially significant abnormalities. While some of these features may be longstanding and not relevant to [Ms A's] eventual clinical course, I believe a majority of my peers … would seek specialist advice or at least an old ECG for comparison and would do this as a matter of urgency despite [Ms A's] apparent recovery from the earlier episode.'

55. I agree with Dr Maplesden's advice that the above actions should have been taken prior to Ms A's discharge, and that the failure to seek timely expert advice regarding the potential significance of the ECG was at least a moderate departure from accepted practice.

56. Dr B told HDC that broadly he accepted the above advice, and he explained that the reason why Ms A's ECG was not followed up at the time of her appointment was because it did not seem related to her presenting ED problem.[14] He had intended to discuss and review the ECG further after discharge, but this was forgotten owing to the arrival of the patient with a head injury, who required urgent attention.

57. The urgent care clinic was also in agreement with Dr Maplesden's advice and noted that it discussed the matter with Dr B, who 'expressed his sincere apology and sadness at this'.

58. Dr B stated:

> 'With the benefit of hindsight, it appears that while [Ms A's] ECG was not related to her presenting problem (of a potential adverse reaction to the vaccine), it may have indicated a worsening of her underlying cardiac condition — although this will need to be confirmed with a specialist.'

59. Dr B told HDC that his focus on the presenting problem may have obscured the wider importance of the ECG reading.

[12] A myocardial infarction (heart attack) affecting the front (anteroseptal) area of the heart. This indicates that the heart is not getting enough blood flow.
[13] Ischaemia means that part of the body is not receiving enough blood (and therefore oxygen). When this happens, the tissues become damaged. 'Acute' refers to a condition that is sudden and/or severe.
[14] In response to the provisional opinion, the clinic highlighted that the correct terminology for the facility that Ms A attended is an urgent care clinic.

60. Dr B further stated:

> 'I am truly sorry for any shortcomings in the care I provided [Ms A] … I had planned to follow up with the medical director, and it was certainly not my intent to overlook this step. This is not intended as an excuse, I just wish to explain my thinking and approach at the time I saw [Ms A].'

61. I acknowledge that Dr B had planned to follow up on the ECG later that day, and that unfortunately an incoming urgent patient derailed that plan. I also acknowledge Dr B's comment that given Ms A's pre-existing condition, an abnormal ECG was to be expected. However, given the potentially significant abnormalities on the ECG I am critical that Dr B did not obtain input from a specialist or the medical director regarding the ECG prior to discharging Ms A. While I accept, as Dr Maplesden has advised, that Ms A's presentation did not raise a particular suspicion for a diagnosis of pulmonary embolism, in my view Dr B needed to ensure that the ECG was reviewed to ascertain whether there could have been any concerning causes for the abnormalities it showed.

Conclusion

62. All parties agree that the omission to take the additional and appropriate follow-up actions on Ms A's ECG by discussing the ECG with the medical director or a relevant specialist, or compare it with any previous ECGs on Ms A's clinical record, was a departure from accepted practice. While I understand the circumstances that surrounded Dr B's failure to do so, that does not change my finding that the omission meant that Ms A did not receive an appropriate standard of care. Accordingly, I find that Dr B breached Right 4(1) of the Code.

63. In stating this, I wish to make clear that it is not HDC's role to make findings about whether Ms A's death could have been prevented if this failing had not occurred, and I acknowledge the post-mortem findings that there was a risk that sudden death could have occurred at any time. Once again, I extend my condolences to Ms A's whānau for their loss.

Further comments

CARM reporting

64. I note that Ms A's whānau did not agree with Dr B's decision not to complete a CARM report regarding their concern that Ms A may have experienced an adverse reaction to the vaccine. Although the earlier attempt to submit a report by staff at the medical centre was unsuccessful due to technical issues, I acknowledge that eventually a CARM report was submitted by the medical centre four days later.

65. It appears that the issue of a CARM report and/or whether Ms A may have had an adverse reaction to the vaccine was discussed to some extent in Ms A's appointment with Dr B. The urgent care clinic stated that the criteria for initiating a CARM report has a low threshold. The New Zealand Pharmacovigilance Centre website[15] states that '[a]ny serious suspected [adverse drug reactions] to any medicine, vaccine or complementary medicine should be

[15] https://nzphvc.otago.ac.nz/reporting/#what-to-report
The New Zealand Pharmacovigilance Centre consists of CARM and the Intensive Medicines Monitoring Programme.

reported [to CARM]' and that anyone may report a suspected adverse event to CARM. I accept that although Dr B assessed that Ms A was not suffering from an adverse reaction to the vaccination, it was open to him to encourage the whānau to do this if they had outstanding concerns. I consider this to be a learning opportunity for healthcare professionals to ensure that consumers are appropriately supported with completing a CARM report if they or their whānau remain of the view that an adverse drug reaction may have occurred.

Changes made since events

66. Dr B has undertaken professional supervision regarding his role in Ms A's care.

67. Dr B told HDC that currently he is not, and he does not have any intention to return to, practising in GP or urgent care practice, although he would not want to rule this out indefinitely. Dr B's current role does not include review of ECG readings, but he noted that there is a possibility that it may require him to undertake some more 'front-line' clinical work.

68. I note that Dr B has offered to attend a restorative hui with Ms A's whānau regarding the care he provided to Ms A.

69. The urgent care clinic undertook several actions in response to these events in order to improve services and address the issues raised by the whānau. I consider the changes appropriate, and these have been communicated to the whānau separately.

Recommendations

70. I acknowledge that Dr B has expressed his apologies to Ms A's whānau (in correspondence to third parties such as HDC, the Coroner, and via the urgent care clinic) for not following up on the ECG as he had intended, and the whānau has been forwarded copies of those communications. In my provisional opinion, I considered that it might also be beneficial for the whānau to receive a written apology from Dr B directly addressed to them, for the breach identified in this report. Dr B has provided HDC with a written apology, which has been forwarded to Ms A's whānau.

71. I am satisfied that Dr B has reflected appropriately on the care he provided to Ms A, and that no further recommendations are necessary.

Follow-up actions

72. A copy of this report with details identifying the parties removed, except the advisor on this case, will be sent to the Medical Council of New Zealand, and it will be advised of Dr B's name.

73. A copy of this report with details identifying the parties removed, except the advisor on this case, will be sent to Medsafe and CARM, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: In-house clinical advice to Commissioner

The following in-house advice was obtained from GP Dr David Maplesden:

'1. My name is David Maplesden. I am a graduate of Auckland University Medical School and I am a practising general practitioner. My qualifications are: MB ChB 1983, Dip Obs 1984, Certif Hyperbaric Med 1995, FRNZCGP 2003. Thank you for the request that I provide clinical advice in relation to the complaint from [Mrs C] about the care provided to her late daughter, [Ms A], by [Dr B] and [the urgent care clinic]. In preparing the advice on this case to the best of my knowledge I have no personal or professional conflict of interest. I agree to follow the Commissioner's Guidelines for Independent Advisors.

2. I have reviewed the following information:

- Complaint to [the urgent care clinic] from [Mrs C]
- Response from [the urgent care clinic] to [Mrs C]
- Response from [the urgent care clinic] to HDC including: relevant operating guidelines; clinical notes [the urgent care clinic] and [the public hospital]; statement to Coroner from [two GPs]; Coronial autopsy report.

3. [Ms A] … had a diagnosis of … a rare genetic disorder which can be complicated by cardiovascular disease including pulmonary stenosis, hypertension and valvular disease[1]. She had undergone mitral valve repair in 2001 and was under the care of [a cardiologist]. Regular medications were metoprolol and cilazapril for hypertension and Pulmicort and Bricanyl inhalers for asthma. [Ms A's] most recent echocardiogram was 2017 (normal left ventricular function) with most recent cardiology review March 2020 (asymptomatic, review in two years). She was not known to have ischaemic heart disease and there is no record of coagulopathy. [Ms A] had previously lived independently but was currently residing with her mother [Mrs C].

4. On [date] [Ms A] received her first dose of the Pfizer mRNA Covid vaccine Comirnaty at [the medical centre]. [The cardiologist] had given specific advice that vaccination could proceed. [Mrs C] states [Ms A] had an immediate reaction to the vaccine with her becoming pale, cold hands, breathing faster and rapid pulse (statements provided from others accompanying [Ms A]). There was prompt nursing attention but some difficulty obtaining [Ms A's] blood pressure and oxygen levels and an issue with computer software prevented documenting of observations. The observations were eventually handwritten and provided to [Mrs C] to take to [the public hospital] with [Ms A] for review by a doctor. [Mrs C] describes a wait of an hour at [the hospital] before nursing staff took further tests including an ECG. She states [Ms A] was still complaining of dizziness and was pale with rapid pulse during this time. There was a further wait of almost two hours before [Ms A] was eventually reviewed by [Dr B]. [Mrs C] is concerned that [Dr B] took a casual attitude to [Ms A's] condition, not seeking additional information from her about [Ms A's] pre-existing condition and not examining [Ms A]

[1] [Reference]

himself. [Mrs C] states [Dr B] made a diagnosis of anxiety without discussing this with [Ms A] or her whānau who were present, and he stated [Ms A] did not meet the criteria for filing an adverse reaction with CARM. [Ms A] was discharged with advice she could get her second vaccine at the appropriate time. Over the next three days [Ms A] remained lethargic and cold and was apparently more short of breath than usual particularly on exertion. Tragically she was found deceased in her bed [four days later]. [Mrs C] has questions regarding the clinical care provided to [Ms A] which will be the focus of this advice. She has further issues regarding the Covid vaccination programme in general which might be best addressed by the Ministry of Health. Issues regarding the computer software have been addressed by [the medical centre].

5. [Ms A's] death was referred to the Coroner and she underwent an autopsy on [date]. Extracts from the report include:

- *The most significant post mortem findings were of pulmonary thromboembolism (clot in the left lung) and severe atherosclerosis (narrowing) of the left anterior descending coronary artery. The source of the thromboembolism was not established however may have arisen from a deep vein thrombosis.*
- *The degree of coronary atherosclerosis was such that a sudden death could have occurred at any time as a result of myocardial ischaemia causing a fatal cardiac arrhythmia. There was no evidence of acute myocardial infarction. Death most likely arose from the combined effects of pulmonary thromboembolism, severe coronary atherosclerosis, hypertensive heart disease and mitral valve disease in association with [the rare genetic disorder].*
- *A blood sample showed a normal serum tryptase level (a raised level may be an indication of anaphylaxis).*
- *There was no indication that the deceased had suffered an acute reaction to Covid 19 vaccination. Given the pre-existing conditions present, there was a risk of sudden death which could have occurred at any time.*

6. [Dr B's] statement includes the following points:

(i) [Dr B] commenced his overnight call shift at [the urgent care clinic] around 1630hrs on [date]. [Ms A] presented to [the clinic] that afternoon. Her history was *of feeling heavy and weak while sitting in the recovery room after receiving her first Covid 19 vaccine that morning.*[2] *Immediately following the vaccination she had been observed to have a low blood pressure and elevated pulse, which were unusual observations for her.* [Dr B] was provided with a written note from [the medical centre] staff and an ECG which was timed 1401hrs.[3] He accessed [Ms A's] medical file and noted her diagnosis of [a rare genetic disorder] and reviewed her most recent cardiology clinic notes. He noted the ED nurse observations and comments (see section 7).

[2] Ms A received her vaccine in the afternoon.
[3] The correct time recorded on the ECG report is 1601hrs.

(ii) [Dr B] reviewed the ECG noting features (not otherwise specified) which he was unsure represented a normal finding for [Ms A] given her medical history. [Dr B] states: *My plan at that stage was to consider the ECG further in the context of my assessment of [Ms A].* [Dr B] spoke with [Ms A] who appeared *well perfused and able to give me a good account of the events that had unfolded during the day.* In the consulting room observations were BP 112/68, O2 sats 98% on air and pulse 130. [Dr B] states: *From the examination, my assessment was that [Ms A] was not suffering an acute allergic reaction to the Covid vaccination. She did not appear in distress or short of breath. Nor did she report any pain, nausea or light-headedness etc.* [Dr B] sought to reassure [Ms A] and attending whānau that it appeared unlikely she had suffered a physical reaction to the vaccine. [Mrs C] mentioned [Ms A] had been somewhat short of breath in the two days preceding the vaccination and he advised that should the symptom continue [Ms A] should consult her usual GP and, if required, seek advice from her cardiologist. [Dr B] perceived [Ms A] to become more relaxed following the explanation and although he did not recheck her pulse, he concluded she most likely had an anxiety reaction.

(iii) [Dr B] states: *Having reached the view that [Ms A] was not acutely unwell, my plan was to either discuss the ECG with the medical director or review it further myself in the context of any prior ECGs available from [Ms A's] clinical records. If this raised any concerns we would be able to ask her to come back in.* [Dr B] recalls providing his usual safety netting advice for [Ms A] to return for review if there were any ongoing concerns. He states he then had to attend a patient with an acute head injury who required evacuation to [another hospital] and this distracted him from the need to review [Ms A's] ECGs which he omitted to do and was not reminded until he was informed of [Ms A's] death. In removing copies of confidential patient information [Dr B] had accumulated during his locum at [the urgent care clinic] [Dr B] tore up the copy of [Ms A's] ECG without realizing this had not been incorporated into her electronic file. He subsequently reassembled the document so it could be placed on [Ms A's] file. I could not find a copy of the reassembled ECG in the documentation provided to me.

7. Clinical notes review

(i) Notes are consistent with the provider responses. It appears standard pre-vaccine related documentation was completed and expected processes were followed in this regard. It is noted the cardiologist had requested [Ms A] be vaccinated against Covid and there were no apparent contraindications (per IMAC guidance[4]) to administration of the vaccine. I am unable to comment on the vaccine pre-administration process but assume this was undertaken in line with IMAC guidance and local operating guidelines. I could see no indication to administer [Ms A] other than the standard adult dose of Comirnaty. A vaccine reaction such as [Ms A] exhibited should be recorded contemporaneously in the electronic vaccine register (CIR) and notified to CARM but I understand there were technical issues with the software at the time of the events in

[4] https://covid.immune.org.nz/covid-19-vaccines-nz/covid-19-vaccines/comirnaty-vaccine-overview Accessed 20 April 2022

question although the provider response indicates efforts were made to complete this notification.

(ii) Nursing notes from [the medical centre] record that [Ms A] *felt heavy and weak after Covid vaccine.* She was brought to an observation room and laid flat then transferred to a quieter room to facilitate recording of vital signs. Notes include: *[Ms A] feeling ok … BP 112/98 L arm, unable to auscultate BP in R arm, pulse = 130 auscultated, cold hands — pulse oximetry not picking up a pulse …* Subsequent notes refer to [Ms A's] condition improving but a decision to transfer her to [the hospital] for review (contact made with [hospital] nursing staff regarding transfer). There is reference to observations not saving in the PMS and these were apparently provided in a handwritten handover note to [the hospital]. I have not been provided with a copy of this note and am unable to determine what additional observations were recorded prior to transfer (eg O2 sats, respiratory rate).

(iii) The provider response indicates ambulance transfer was considered but given [Ms A] was feeling better and it was felt she had most likely suffered a vaso-vagal reaction to the injection, this was not felt necessary. It is also noted, in hindsight, that the limited availability of ambulances at that time meant that even had ambulance transfer been arranged, this would not necessarily have resulted in any significant difference to the timing of [Ms A's] subsequent reviews. [Ms A] arrived at [the hospital] about 1530hrs and was triaged by a nurse around 20 minutes later. Notes include:

Sent in from [medical centre]. Feeling weak after covid vaccine. Mum mentioned that she has been short of breath in the past 2 days when she goes and carry firewood. She also has to stop a couple of times to catch her breath when walking uphills. On metoprolol and cilazapril.

Exam: Temp= 37.3, Pulse= 115, 02sat=97% RA, BP= 110/80, Tongue appears to be coated ECG rate 140 JVP < 4cm Clear lung fields Heart rate dual and regular Ambulatory and Independent. Passing and BM OK. Denies chest pain or tightness, diarrhea or vomiting

Action: ECG done

Action: Duty doctor to review

(iv) [Dr B] reviewed [Ms A] at 1720hrs. The provider response indicates the approximately 90 minute wait is outside their expected wait time but *[the hospital's] urgent care clinic was busy in terms of demand and capacity* on the day in question. [Dr B's] notes read as follows:

History: Seen following Covid vaccine today. Has [a rare genetic disorder] and is under the care of [a cardiologist] who is due to see her again in March of next year. Lives with her mother. A note from the Covid vaccination centre today says that she felt heavy and weak after the vaccine and had a pulse of 130. There is a background story of decreasing exercise tolerance and shortness of breath.

Exam: On exam today she is settled and has a pulse of 130 per minute BP= 112/68, Pulse= 143 , SpO2= 98

Anxiety
P: reassure — review again as required

If exercise tolerance drops further for re-referral to [the cardiologist]

8. Comments

(i) As far as I can determine, [medical centre] staff followed accepted practice in relation to the administration of the Comirnaty vaccine to [Ms A] … However, as evident from the Vaccine Operating Guidelines there are significant requirements covering all aspects of vaccine preparation and administration and the environment in which it occurs and I am unable to comment on every aspect. I have assumed the clinic had staff and equipment available to deal appropriately with an anaphylactic reaction should one occur.

(ii) Based on the description of [Ms A's] reaction to vaccination, and without the benefit of hindsight, it appears she most likely suffered a vasovagal reaction (pre-syncope) to the vaccination process. However, given her cardiac history it was appropriate to advise medical review even when [Ms A] apparently reported feeling better. The symptoms described are not characteristic of an anaphylactic reaction. My comments on the adequacy of [Ms A's] assessment at [the medical centre] are limited by the apparent absence of some of the reported observations undertaken at the time. I would expect a comment on any signs of respiratory distress (respiratory rate, increased work of breathing) and (if technically possible) recording of oxygen saturations. If [Ms A] appeared to be objectively stable and subjectively improving following a period of observation at [the medical centre], and given the likely diagnosis of vasovagal reaction, I believe it was reasonable to arrange transport to [the hospital] by private car given it was reasonable to have low expectation of any deterioration en-route, and the referral was being undertaken as a precaution given [Ms A's] complex medical history rather than because she was suspected to be significantly unwell.

(iii) The apparent 20 minute wait for triage nurse assessment at [the hospital] is outside what I would expect for a hospital emergency department but I understand the clinic in question was functioning more as a primary care urgent care facility rather than an ED, and it could be argued the assessment at [the medical centre] represents the initial nurse triage. Noting [Ms A] did not appear as acutely unwell, the wait, while not representing best practice, was probably acceptable. I believe the provider intent to provide additional training around the Australasian Triage Scale is an appropriate quality improvement measure. Once the triage occurred, nursing assessment was reasonable although measurement of respiratory rate might have been expected given the history obtained of recent effort-related shortness of breath. The most significant finding was a persistent tachycardia but this in itself did not necessitate urgent clinician review. Oxygen saturations were satisfactory and the absence of any complaint of chest pain or tightness is of some relevance with respect to [Ms A's] eventual diagnosis. It was

appropriate to perform an ECG and if it [is] possible to obtain a copy of the tracing, this should be done.

(iv) The provider has noted the 90 minute wait for [Ms A] to be seen by a clinician was longer than desirable but, given the circumstances of review (precautionary assessment following likely vasovagal reaction to a vaccine, stable patient), I would not say such a wait would be unusual in a busy primary care urgent care clinic or secondary care ED.

(v) The care provided by [Dr B] must be examined in the context of the referral and without the benefit of hindsight. While it is possible [Ms A's] recent increase in shortness of breath on exertion (which preceded her vaccination) may have been due to pulmonary thromboemboli, the breathing history was presented as incidental to the primary reason for her presentation which was the potential vaccine reaction. [Ms A's] presentation was not typical for ischaemic heart disease in terms of her age, circumstances of the presentation and symptoms presented. I am currently unable to comment on whether the ECG findings might have raised concerns regarding underlying ischaemia. With respect to diagnosis of pulmonary embolism (PE), a review article on this topic[5] notes: *the clinical presentation of PE is variable and often nonspecific making the diagnosis challenging … Pulmonary embolism (PE) has a wide variety of presenting features, ranging from no symptoms to shock or sudden death. The most common presenting symptom is dyspnoea (73%) followed by chest pain (classically pleuritic in nature, but not always — 66%), cough (37%), and symptoms of deep venous thrombosis (44%). With severe PE, patients can present with shock, arrhythmia, or syncope. Many patients, including some with large PE, are asymptomatic or have mild or nonspecific symptoms. Thus, it is critical that a high level of suspicion be maintained such that clinically relevant cases are not missed.* Common presenting signs on examination include: tachypnoea (54 percent); calf or thigh swelling, erythema, oedema, tenderness, suspicious for DVT (47 percent); tachycardia (24 percent). While [Ms A] did have a persistent tachycardia, this is a very non-specific finding and was reasonably attributed by [Dr B] to a degree of anxiety. ECG abnormalities, although common in patients with suspected PE, are nonspecific. The most common findings are tachycardia and nonspecific ST-segment and T-wave changes (70 percent). Abnormalities historically considered to be suggestive of PE (S1Q3T3 pattern, right ventricular strain, new incomplete right bundle branch block) are uncommon (less than 10 percent).

(vi) The scenario with which [Dr B] was presented was of a [woman] with a rare genetic syndrome which involved cardiovascular pathology (hypertension and previous valve repair) which appeared, on review of recent specialist reports, to be stable and of no specific concern. Nursing notes suggested a likely vasovagal reaction to the Comirnaty vaccine with there being no particular suspicion the reaction was anaphylactoid in nature. While there had been previous publicity regarding increased incidence of thromboembolic complications associated with some Covid vaccines, this was not felt

[5] Thompson T, Kabrhel C, Pena C. Clinical presentation, evaluation, and diagnosis of the nonpregnant adult with suspected acute pulmonary embolism. Uptodate. Literature review current through March 2022. www.uptodate.com Accessed 23 April 2022

to be a particular issue with Comirnaty and certainly a vaccine-related thromboembolic complication would not occur in the time frame relevant to [Ms A's] witnessed reaction. There was no history provided of leg pain or swelling suggestive of deep vein thrombosis (DVT) and [Ms A] did not appear to be at increased risk of venous thromboembolic disease. Incidental history of some shortness of breath in the two days prior to the vaccine was obtained but this was not the primary reason for the assessment and had not resulted in [Ms A] seeking medical attention specifically for this symptom. In addition, [Ms A] was known to be asthmatic which could cause such a symptom. There was no history of cough or chest pain. Although respiratory rate has not been recorded, it appears [Ms A's] oxygen saturations were normal and I would expect significant tachypnoea at rest to have been obvious and noted if it was present. It appears the only abnormal physical finding was a persisting tachycardia which is a very non-specific observation. ECG findings remain unconfirmed at this point. Taking all of these factors into account, I do not believe [Ms A's] presentation raised particular suspicion for a diagnosis of PE and I am not critical [Dr B] failed to consider this diagnosis. Even had he considered the diagnosis and applied a validated risk tool (Wells criteria for PE)[6], on the basis of the findings recorded [Ms A] would have fallen into a low risk group for the diagnosis.

(vi) Taking into account the nursing observations available to [Dr B] (including heart and lung auscultation findings), I believe it was reasonable for him to recheck [Ms A's] observations with no particular need to perform cardiorespiratory auscultation again, although some of my colleagues might have repeated the examination. I believe the clinical scenario was suggestive of a vaso-vagal reaction to the vaccination process with some persisting anxiety, with [Ms A] apparently recovering and not requiring any specific treatment. In that context, I believe it was reasonable for [Dr B] to reassure [Ms A] and her whānau regarding the assumed nature of the reaction and to discharge her with standard safety-netting advice although I believe some of my colleagues might have repeated observations prior to discharge to ensure [Ms A's] tachycardia was settling. These comments are subject to my review of the ECG tracing which, if there were abnormalities which might have suggested significant cardiac pathology, places [Dr B's] review into a different context. If there were obvious and potentially significant ECG changes present but [Dr B] was unsure of their significance, I believe accepted practice would be to have sought cardiology advice or a previous ECG for comparison prior to discharging [Ms A], particularly given [Ms A's] history of cardiac disease and cardiologist involvement. If the changes were more subtle and appeared unlikely to be of significance, [Dr B's] intended plan to further review the ECG in more detail as time allowed, might have been acceptable. [Dr B] might reflect on strategies he can use in the future to ensure intended clinical actions (in this case broader review of [Ms A's] ECG) are completed in a timely manner.

(vii) The provider response indicates this incident and the complaint have been thoroughly reviewed and I believe the response, including proposed remedial actions,

[6] https://www.mdcalc.com/wells-criteria-pulmonary-embolism Accessed 23 April 2022

is appropriate. I have no further recommendations in this regard. This has been a tragic event and I pass my condolences on to [Ms A's] whānau at their loss.

9. Addendum 13 June 2022

I have been provided with a copy of the reassembled ECG dated [2021]. The ECG (Appendix 1) is markedly abnormal but accepted practice, noting [Ms A's] cardiac history, would be to compare the ECG with a previous ECG to determine whether the abnormalities were longstanding or acute, and/or to seek specialist advice. Notable features in the ECG include: narrow complex tachycardia 143 bpm suggestive of a supraventricular tachycardia; left axis deviation; difficult to define P waves with sawtooth baseline in some leads suggestive of atrial flutter; possible pathological Q waves in V2 and V3; machine reporting of possible left anterior fascicular block, anteroseptal infarct and possible inferior and left-precordial acute ischaemic changes.[7] A cardiologist will be able to provide a more detailed interpretation of the tracing, but I am confident my peers would recognise the tracing as being abnormal with some potentially significant abnormalities. While some of these features may be longstanding and not relevant to [Ms A's] eventual clinical course, I believe a majority of my peers, when faced with this ECG result in the context of a patient with a known cardiac history who has suffered a likely syncopal or similar event and has a persisting tachycardia, would seek specialist advice or at least an old ECG for comparison and would do this as a matter of urgency[8] despite [Ms A's] apparent recovery from the earlier episode. Viewing the ECG places the comments made earlier in this report in a different clinical context and I am now of the view that the failure by [Dr B] to seek timely expert advice in regard to the potential significance of the ECG changes observed represents at least a moderate departure from accepted practice. However, I am unable to state whether or how the changes might relate to [Ms A's] subsequent clinical course. I realise [Ms A's] whānau may now question whether/how the ECG findings relate to her death and this might be best answered by seeking the opinion of [Ms A's] cardiologist who would have access to her previous records, although it may be difficult to provide a definitive answer in this regard.'

Further in-house advice was obtained from GP Dr David Maplesden on 13 November 2023:

'I have reviewed the information provided by [Ms A's] family members in response to the PO. Once again, I would like to express my condolences at their tragic loss. I can empathise with the family's frustration at there being no specific cause found for the pulmonary embolism (PE) that contributed to [Ms A's] death and acknowledge their strongly held belief that [Ms A's] death was directly related to the Comirnaty vaccine. However, it is outside my remit to make a conclusion as to the cause of the PE and I

[7] When requested to convey these findings in non-clinical/layman terms, Dr Maplesden advised that the ECG showed 'rapid abnormal heartbeat that may have been putting strain on [Ms A's] heart'.

[8] When requested to clarify how urgently he meant, Dr Maplesden further advised: 'My feeling is that some effort was required [by Dr B] at the time of the presentation and prior to discharge … to confirm whether the abnormalities in the ECG warranted further action (such as immediate referral to [a main centre hospital] for cardiology input or further assessment) or whether the changes were not new in which case the approach he adopted (of discharging the patient) might have been appropriate.'

have no further comments in this regard. The response refers to dissatisfaction with the coroner and the coronial process which is again outside the scope of my advice or role. I note the comments from family members regarding aspects of [Ms A's] presentation both immediately following the vaccine and prior to her discharge from [the hospital] and that observations noted in the provider records and responses differ from the family's recollections in some respects. I have considered such discrepancies in my original advice and remain of the view that medical review of [Ms A] was required following her vaccine reaction and note that such a review was undertaken. I remain of the view there was a deficiency in that review by [Dr B], mainly in relation to consideration of ECG findings, and there is no new information provided that alters my view in this regard. However, I am unable to state that had [Dr B] sought further advice in relation to [Ms A's] ECG findings, this would necessarily have altered the tragic outcome for her. I note the concern of the family that there has been no cardiologist input into the review of her death but it is not appropriate to seek such advice in regard to comment on [Dr B's] management of [Ms A] (a cardiologist not being a peer of [Dr B]) and it is not the role of HDC to determine the cause of death or the relationship between the Comirnaty vaccine and [Ms A's] death — those issues being the concern of the coroner. It is not clear if [Ms A's] family have pursued a Treatment Injury claim with ACC in regard to their belief [Ms A's] death was vaccine-related, but such a claim is likely to involve input from relevant specialist clinicians which may or may not assist with determining the likelihood of her death being vaccine-related.'

Appendix B: Medsafe letter

MEDSAFE

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W www.medsafe.govt.nz

17/02/2023

Health & Disability Commissioner
Level 11, TechnologyOne House, 86 Victoria Street
Wellington 6011

HDC information request: Comirnaty (Pfizer COVID-19 vaccine) and risk of thrombosis with thrombocytopenia syndrome (TTS) and other thrombotic complications.

Medsafe continues to monitor the safety of COVID-19 vaccines available in New Zealand. At this current time, Comirnaty has not been found to be associated with a risk of TTS or other thrombotic complications in New Zealand or internationally. This reflects the information provided in the Medsafe monitoring communication published 27 April 2021 (COVID-19 vaccines and rare cases of blood clots with bleeding: no current risk with Comirnaty Pfizer/BioNTech vaccine).

The Comirnaty data sheet is available on the Medsafe website [1]. The data sheet is maintained and regularly updated by the sponsor that markets the product in New Zealand (Pfizer). Section 4.8 of the data sheet lists the known adverse events associated with the product, TTS and other thrombotic events are not listed as adverse events for Comirnaty. The data sheet was last updated 5 January 2023.

In a recently published New Zealand study, authors evaluated the risk of specific adverse thrombotic events following vaccination with Comirnaty[2]. The authors did not find an association with thrombosis adverse events following administration of the Comirnaty vaccine in the general population or within different ethnic groups across New Zealand.

A second study (available as preprint) by the same authors analysed adverse events following the Comirnaty vaccine in New Zealand[3]. The authors did not find a statistically significant difference in the observed versus expected rate for arterial thrombosis, cerebral venous thrombosis, splanchnic thrombosis, venous thromboembolism, and thrombocytopenia in a 21-day risk period following vaccination with Comirnaty.

I hope you find this information helpful.

1. Pfizer New Zealand, 2023. Comirnaty New Zealand data sheet. Available at: https://www.medsafe.govt.nz/profs/datasheet/c/comirnatyinj.pdf
2. Walton et al, 2022. Thrombotic events following the BNT162b2 mRNA COVID-19 vaccine (Pfizer-BioNTech) in Aotearoa New Zealand: a self-controlled case series study. Available at: https://www.sciencedirect.com/science/article/pii/S0049384822004893
3. Walton et al, 2022. Adverse events following the BNT162b2 mRNA COVID-19 vaccine (Pfizer BioNTech) in Aotearoa New Zealand. Available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4329970

Nāku noa, nā

Chris James
Group Manager
Medsafe

Names have been removed (except the advisor) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.