

A Decision by the Deputy Health and Disability Commissioner (Case 21HDC02883)

Information gathered during investigation	2
Opinion: Dr A — breach	7
Recommendations	13
Follow-up actions	14
Appendix A: In-house clinical advice to Commissioner	15
Appendix B: In-house clinical advice to Commissioner	23

- 1. This report is the opinion of Deborah James, Deputy Health and Disability Commissioner, and is made in accordance with the power delegated to her by the Commissioner. It relates to a complaint about care provided by Dr A, a general practitioner (GP).
- A businessperson complained to HDC that Dr A inappropriately issued medical certificates to three of their employees, first for COVID-19 vaccine exemption and then for stress leave. The businessperson submitted that Dr A misled their employees to think the medical certificates would help them avoid the vaccine mandate.¹
- 3. The following issue was identified for investigation:
 - Whether Dr A provided Employee 1, Employee 2 and Employee 3 with an appropriate standard of care in November 2021.
- 4. This report sets out the Deputy Commissioner's opinion on the complaint about Dr A's actions.
- In-house clinical advice was obtained from Dr Fiona Whitworth, a general practitioner (GP) (Appendix A) and Dr David Maplesden, a GP (Appendix B).

12 September 2024

¹ See paragraph 7.

Information gathered during investigation

Background

or A is the only GP at a small general practice. The three people to whom Dr A issued documents (the employees of the businessperson) were not enrolled at his practice when the employees first saw him in November 2021, during the COVID-19 pandemic. They are referred to as Employee 1, Employee 2, and Employee 3 to protect their privacy.

Relevant legislation and guidance

- At that time, the COVID-19 Public Health Response (Vaccinations) Order 2021 (the Order) set out that 'affected persons' (certain workers defined in Schedule 2 of the Order)³ could not carry out certain work unless they were vaccinated (referred to as a vaccine mandate). Employees 1, 2, and 3 were affected persons who were required to be vaccinated by a certain date in order to work.
- From 14 July 2021, health practitioners such as Dr A were able to issue vaccine exemptions to affected persons pursuant to section 7A of the Order. However, at 11.59pm on 7 November 2021 section 7A was revoked, and a new exemption application process was introduced. An affected person could only be granted a vaccine exemption on medical grounds by the Director-General of Health, on application from a suitably qualified medical or nurse practitioner. Affected persons who were exempt prior to the law change would remain exempt for a transitional period until 21 November 2021 or the date on which they were notified that an exemption had not been granted to them under the new process, whichever was earlier.
- The Ministry of Health (the Ministry) published clinical criteria for vaccine exemption on 6 November 2021. The criteria document stated: '[T]here are very few situations where a vaccine is contraindicated and, as such, a medical exemption is expected to be rarely required.' The following were criteria for exemption:
 - 1. All COVID-19 vaccines: a) confirmed COVID-19 infection; b) a serious adverse event to a previous dose of the same COVID-19 vaccine; c) inability to tolerate administration due to risk to self or others (for instance, a severe neurodevelopmental condition).
 - 2. Pfizer vaccine: a) anaphylaxis (allergic reaction) to the first dose of the vaccine or known severe allergy to the excipients of the vaccine (inactive substances used in formulation of the vaccine); b) myocarditis/pericarditis following the first dose of the vaccine;⁸

12 September 2024 HX

² At the time of events (and currently), Dr A was a registered GP with an annual practising certificate from the Medical Council of New Zealand and a fellow of the Royal New Zealand College of General Practitioners (RNZCGP).

³ The affected workers defined in Schedule 2 changed over time.

⁴ Pursuant to section 9B of the Order.

⁵ Pursuant to schedule 1, clause 10 of the Order.

⁶ Ministry of Health, Vaccine Temporary Medical Exemption Clinical Criteria, Clinical Guidance and Resources, 6 November 2021.

⁷ The formal criteria also included a third category for any person who had been confirmed as having received the trial vaccine in any COVID-19 vaccine trial in New Zealand.

⁸ Respectively, inflammation of the heart muscle and inflammation of the lining around the heart.

c) inflammatory cardiac illness within the past six months; d) acute decompensated heart failure.

Documents issued

- Dr A issued each of the three patients a letter entitled 'Reference: Exemption from vaccine' (Employee 1 on 10 November 2021, Employee 2 on 8 November 2021, and Employee 3 on 11 November 2021).
- The 'exemption letters' stated: 'This letter certifies that the above named [patient] has been examined by me and I have determined that it would be inappropriate for [the patient] to be vaccinated against Sars-Cov-2.' Dr A told HDC that, in hindsight, 'the word "exemption" in the reference field of the letters was not the best word to use', and 'COVID vaccine' or something similar could have been used instead.
- The letter issued to Employee 3 also stated: 'This determination is made pursuant to clause 7A, COVID-19 Public Health Response (Vaccinations) Amendment Order 2021 by me as a suitably qualified health practitioner.' Dr A told HDC that reference to section 7A in this letter was an 'honest mistake' caused by using an old template letter. Dr A confirmed that he was aware that section 7A was revoked on 7 November 2021.
- Dr A also issued each patient with a medical certificate for stress leave (a medical certificate). The certificates, which were worded very similarly, stated that the patient was advised to be off work due to either 'duress at work' or 'stress related to duress at work' and was expected to be able to return to work by 13 December 2021 'pending review' (a leave period of four weeks).
- Dr A told HDC that he did not charge the three patients for their consultations related to the letters and the certificates or any follow-up telephone calls relating to the mandate.

Patient consultations

15. The clinical records of Dr A's consultations with the three patients are summarised below, alongside Dr A's response to HDC about each consultation and the statements each patient provided to Dr A.

8 November 2021 — Employee 2

- Dr A's consultation notes state, in full: 'So many close people has had side effects, 25 [year old] man had brain bleed 2 days after jab and died, another lost ability to play guitar, another had rash and genital swelling.'
- 17. Dr A told HDC that he consulted with Employee 2 by telephone regarding her request for a vaccine exemption. Dr A said he discussed Employee 2's medical history and rationale for not wanting the vaccine and 'agreed that [the vaccine] would not be an appropriate medical procedure for her'. As the law had just changed, Dr A said he advised Employee 2 that any letter he wrote would 'only be [his] opinion and not a formal exemption under the Order and would not carry weight in terms of ... being able to continue work under the mandate'. Dr A said that Employee 2 was not confused about the letter's '(in)ability to overcome the

mandate' and still wanted it to support a discussion with her employer about her concerns about the vaccine, as she hoped the employer would find a way for her to continue working. Dr A said that Employee 2 asked him if he could also speak to Employee 1 and Employee 3, which he agreed to do.

Employee 2 stated that she contacted Dr A as her own GP was fully booked for nearly two months. At a face-to-face appointment, Employee 2 told Dr A that she was not vaccinated due to 'personal health reasons, religious objections and concerns about a possible adverse reaction'. Employee 2 said she was stressed when the mandate was announced. She understood that the exemption Dr A provided was not valid but presented it to her employer.

10 November 2021 — Employee 1

- 19. Dr A's consultation notes state, in full: 'Really concerned about side effects.'
- 20. Dr A told HDC that he spoke to Employee 1 and explained that an exemption letter from him would carry no weight legally. He said that Employee 1 presented with what he felt were 'reasonable grounds for exemption' and therefore he issued an exemption letter. Dr A said he understood that Employee 1 decided against giving the certificate to her employer as she 'felt it would be pointless to do so having understood what [he] had discussed with [her]'.
- Employee 1 stated that she contacted Dr A as her own GP was fully booked for nearly two weeks. Employee 1 said she was 'under a great deal of stress due to the vaccine mandates ... had never been so stressed in [her] life and ... needed to speak with a doctor immediately'. Employee 1 said she did not present the exemption letter to her employer 'as Dr A had made it quite clear ... that it was not an exemption' and therefore it seemed to be 'worthless'.

11 November 2021 — Employee 3

- 22. Dr A's consultation notes state, in full: 'Anxious about side effects.'
- Dr A told HDC that he spoke to Employee 3 and explained that an exemption letter from him would carry no weight legally. He said that Employee 3 presented with what he felt were 'reasonable grounds for exemption' and therefore he issued an exemption letter. Dr A said he understood that Employee 3 decided against giving the certificate to her employer as she 'felt it would be pointless to do so having understood what [he] had discussed with [her]'.
- Employee 3 stated that she contacted Dr A as she did not have a GP. She provided no information about this consultation.

15 November 2021 — all employees

- On 15 November 2021, following telephone consultations, Dr A issued all three patients with medical certificates for stress leave. Dr A's notes for each consultation state, in full:
 - Employee 1: 'Really stressed with mandate, losing sleep, amenorrhoea⁹ for 10 weeks.'

HČ

⁹ The absence of menstruation.

- Employee 2: 'Massive stress at work, really not functioning well.'
- Employee 3: 'Very stressed at work.'
- 26. Dr A told HDC that he had a long consultation with Employee 2, who felt unsafe at work and requested a medical certificate for stress leave. Dr A said that this was appropriate in the circumstances. Dr A said that Employee 1 and Employee 3 'both described their circumstances and how it was affecting them' and he felt that stress leave was also appropriate for them. In terms of recommending four weeks' stress leave for each patient, Dr A said:

'My experience with leave due to stress has been that 2 weeks is never sufficient time for a person to properly decompress and that the current circumstances are beyond anything any of us have experienced before hence the extended time frame. As with any medical certificate for sick leave I explained that should they feel able to resume work they could do so either in consultation with me or without.'

- Employee 1 and Employee 3 stated that their consultations with Dr A lasted between 20 and 30 minutes. Employee 3 said she explained the stress and 'turmoil' she was feeling and that she had 'an emotional breakdown at work and had to take sick leave ... Dr A was very helpful and listened to [her]'.
- Employee 2 stated that as the date of the 'first dose of vaccine loomed, the stress increased. Things came to a head on 15 November 2021', at which time Employee 2 contacted Dr A and had a detailed telephone consultation.

Further information — Dr A

29. Dr A told HDC that the events occurred in 'an unusual situation not previously encountered in [his] career'. He said that 'the fundamental position of medical ethics is that it is the patient who determines what treatments he or she will take'. Further, Dr A said:

'[I]t is a fundamental human right to refuse medical treatment. A doctor has the freedom to write a letter recording the exercise of that right. This does not require a statutory power; it is simply a consequence of the freedom to impart information.'

30. Dr A rejected the claim that the documents he issued were fraudulent, saying:

'They were the result of careful consultation and consideration of the needs of the person being consulted. They were issued in good faith that the information provided was true ... I was approached by [the patients] for advice. It was because of care and concern for these deeply distressed individuals that I wrote these certificates.'

Dr A advised that he did not have access to the GP records of the three patients, but he did not consider that a problem. He said the patients 'were perfectly capable of reporting their medical history themselves', and there are many instances of people seeking medical care where GP records are unavailable.

6

Dr A told HDC that he did not charge the patients for his services. He stated:

'I was moved by the lack of compassion or interest from the medical profession generally and agencies whose purpose is to protect the rights of health consumers. The mandates adversely affected the mental wellbeing of many and eviscerated the right of informed consent and to refuse medical treatment. I felt that to charge them when they were facing the loss of employment would amount to adding insult to injury.'

Response to provisional opinion

- The provisional opinion was shared with Dr A for comment. Dr A made the following (summarised) remarks in response:
 - The vaccine mandate was a 'clear contraindication' to Dr A's professional obligation to uphold patients' rights to informed consent, and the need to apply to the Ministry for an exemption from the mandate is a contraindication to 'centuries of established medical ethics' and patient rights under the Code.
 - HDC's conclusion that there was mounting evidence regarding the overall safety of COVID-19 vaccines is flawed and not evidence-based. Dr A said that administration of the COVID-19 vaccine was 'experimental' as evidence was still accumulating. Even during the mandate, there was only weak evidence 'that the vaccine prevented any deaths at all', and there was 'a strong safety signal worldwide and in New Zealand that it was harmful'. Dr A stated that 'death by all causes in New Zealand spiked after the vaccine roll out'.
 - The criteria for vaccine exemption 'would not have given [the three employees] any
 grounds for an official exemption', but it was not relevant to the letters as they were
 not an application for an exemption under the Order.
 - HDC assumed 'that the three employees should take the vaccine. They did not want to take it. They did not consent. The vaccine did not prevent infection or transmission and [the three employees] were at extremely low risk from the virus.'
 - The MCNZ statement 'COVID-19 vaccination and professional responsibility' of 28 April 2021 was guidance only and was not binding. It did not form part of the Code of Ethics for the New Zealand Medical Profession, it falsely stated that the vaccine reduced the transmission of COVID-19, and it has since been revoked (in September 2023).
 - Dr A addressed the three employees' stress through his consultations with each of them for nearly an hour, which were therapeutic. Dr A is unsure what appropriate 'clinical management' or a 'management plan'¹⁰ would have comprised in the circumstances and said that the Kessler 10¹¹ and GAD-7¹² assessment tools would not have added any useful information. Dr A said that the stress 'was caused by the perceived loss of autonomy these patients were at the sharp end of. Had they relinquished their bodies

ΗČ

¹⁰ HDC's in-house clinical adviser, Dr Fiona Whitworth, stated that evidence of these was lacking.

¹¹ A 10-point questionnaire to measure psychological distress.

¹² A 7-point questionnaire to screen for, and measure, anxiety.

to the physical assault of the injection they would have suffered compounding emotional and spiritual harm as a result.'

- The clinical notes do not reflect the detail of the three consultations, the support each employee had, and the safety-netting information given, and 'nor could they hope to'. Dr A said that clinical notes may record the basic facts, but it is impossible for them to record all the facts and discussion. He said that the situation was urgent in this case, as the three employees were in 'extreme' distress. Dr A said that clinical records must reflect the interaction, and his records of the three consultations do that. He stated that 'full record keeping of the consultations would have been superfluous', and 'it is not the case that only contemporary records are reliable evidence'.
- Dr A made additional submissions about his objections to the vaccine mandate and the Ministry's clinical criteria for vaccine exemption. Those comments have not been included in this report as they are not directly relevant to whether he breached the Code.

Opinion: Dr A — breach

Having undertaken a thorough assessment of the information gathered, including Dr A's comments on my provisional decision, and guided by the in-house clinical advice I received from GP Dr Fiona Whitworth and GP Dr Maplesden, I am critical of aspects of Dr A's practice in this case. I have set out my opinion on these matters below.

Exemption letters

- A key part of assessing the adequacy of a doctor's care is review of the clinical records for the patient concerned. In this case, deficiencies in Dr A's record-keeping (which I will go on to discuss) meant that much of the information about his patient consultations was drawn from his statement to HDC and those of the three patients. I have taken into account that these statements are not contemporaneous and inevitably will be less reliable than full, clear, and accurate notes made at the time of the consultations, or as soon as possible afterwards.
- Medical certificates (and letters as in this case) are legal documents and must be based on appropriate evidence. The Medical Council of New Zealand (MCNZ) statement on medical certification states: ¹³

'Any statement you certify should be completed promptly, honestly, accurately, objectively and based on clear and relevant evidence ... The information disclosed should be accurate and based upon clinical observation, with patient comment clearly distinguished from clinical observation.'

In noting the standard, it is important to recognise that clinical letters and certification are usually relied upon by a patient to engage with, and potentially influence, a third party (for example, as in this case, an employer). That is, medical certification can carry significant weight with potentially serious implications and, given that the documentation is often used

ΗĊ

¹³ Refers to the MCNZ statement that was valid at the time of events.

for planning and decision-making, the receiving parties must be able to rely upon the doctor's statements as evidence based, accurate, and truthful.

- 39. In my view, Dr A's exemption letters did not meet this standard.
- The Ministry's official criteria for vaccine exemption was available when the letters were issued and should have been the basis for Dr A's decisions. The three letters did not accord with the criteria. In addition, the letters were based on a lack of information, which Dr Whitworth considered was a moderate departure from the accepted standard of care. Dr Whitworth noted that there was a lack of documentation to show that Dr A examined the three patients and, despite the letters stating that the patients 'had been examined', at least two of the consultations regarding vaccine exemption appear to have been by telephone. This statement was therefore misleading. There is also no indication that Dr A appropriately assessed the patients' underlying medical conditions, mental health issues, current therapeutics, previous allergies, and incidence of anaphylaxis. I consider this particularly relevant as these were new patients for whom he did not have any previous clinical information.
- Dr A knew the letters were invalid as vaccine exemptions. Dr A also recognised that the three patients would not be eligible for a valid vaccine exemption, as he told HDC that the Ministry's criteria for vaccine exemption 'would not have given [them] any grounds for an official exemption'. I am troubled by Dr A's decision to issue the letters in light of this knowledge, regardless of whether the patients were given that information.
- Dr A's decision to issue the three exemption letters also did little to support the public health response to the COVID-19 pandemic in accordance with guidance from the MCNZ. The MCNZ's expectations in that respect were communicated to doctors on 28 April 2021. The guidance statement, entitled 'COVID-19 vaccination and professional responsibility', ¹⁴ stated, in part:

'[Doctors] have an ethical and professional obligation to protect and promote the health of patients and the public, and to participate in broader based community health efforts. Vaccination will play a critical role in protecting the health of the New Zealand public by reducing the community risk of acquiring and further transmitting COVID-19.'

In his response to my provisional opinion, Dr A submitted that the above statement did not form part of the Code of Ethics for the New Zealand Medical Profession ¹⁵ and is misinterpreted in this report as 'binding' rather than as guidance. I do not accept this submission. Dr A was obliged to comply with the MCNZ guidance that was current at the

HČ

¹⁴ https://www.mcnz.org.nz/assets/standards/Guidelines/Guidance-statement-COVID-19-vaccine-and-your-professional-responsibility.pdf

¹⁵ The New Zealand Medical Association (NZMA) was a membership organisation that represented New Zealand doctors. It published, amongst other things, a 'Code of Ethics for the New Zealand Medical Profession'. The NZMA was liquidated in May 2022.

time of the events, including the professional responsibility guidance statement of 28 April 2021.

The statutory powers of the MCNZ to prescribe standards of professional practice and 44. conduct for doctors are set out in the Health Practitioners Competence Assurance Act 2003 (the Act). The MCNZ is the authority appointed in respect of the practice of medicine under section 114(1)(a) of the Act. It is a function of the MCNZ, under section 118, to set standards of clinical competence and ethical conduct to be observed by medical practitioners. MCNZ's standards for the medical profession set out its expectations for medical practitioners' conduct and practice, including how information and opinions are imparted to their patients. The MCNZ states that it developed *Good Medical Practice*¹⁶ to be the foundation document for these standards. Good Medical Practice states:

> 'Under Right 4 of the Code of Health and Disability Service[s] Consumers' Rights, patients also have "the right to have services provided that comply with legal, professional, ethical and other relevant standards" ... the standards set out in Good Medical Practice, and in other Council statements, are those which the public and the profession expect a competent doctor to meet ... the Health Practitioners Disciplinary Tribunal, the Council's Professional Conduct Committees and the Health and Disability Commissioner may use Good Medical Practice as a standard by which to measure [a doctor's] professional conduct and competence.'

Dr A was obliged to act in accordance with the MCNZ's medical certification statement and 45. guidance on professional responsibility and COVID-19 vaccination. In my view, Dr A failed to meet these standards in this case.

Information provided with exemption letters

- There is no evidence in Dr A's notes, his responses to HDC, or the statements of the three 46. patients to indicate that Dr A had an objective, evidence-based discussion with the patients about the vaccine. Dr Whitworth noted that there is also no mention of any educational information having been given in that respect.
- 47. The MCNZ guidance statement on COVID-19 vaccination and professional responsibility stated, in part:

'As a health practitioner, you have a role in providing evidence-based advice and information about the COVID-19 vaccination to others. You should be prepared to discuss evidence-based information about vaccination and its benefits to assist informed decision making.'

The guidance referred health practitioners to the Ministry's website for further information to support engagement with staff, colleagues, and patients who may be hesitant about vaccination.

¹⁶ The version of *Good Medical Practice* published on 3 November 2021 was current at the time of the events: https://www.mcnz.org.nz/assets/standards/b3ad8bfba4/Good-Medical-Practice.pdf.



In a previous HDC investigation, ¹⁷ Dr David Maplesden, a GP and HDC in-house clinical advisor, advised that GPs, which would include Dr A, had ready access to COVID-19 vaccine safety and efficacy information at the time of the events. ¹⁸ Dr Maplesden stated:

'There was mounting evidence regarding the overall safety and relative efficacy of the various vaccines in preventing severe Covid infection, and the morbidity and mortality associated with Covid infection far outweighed that associated with the vaccine. New Zealand GPs had access to Ministry of Health and IMAC [the Immunisation Advisory Centre] resources providing evidence-based advice on efficacy and safety of the vaccine.'

I have considered Dr A's comments in response to my provisional opinion about the body of evidence available at the time regarding COVID-19 vaccine safety and efficacy. I also sought further in-house advice from Dr Maplesden in this respect. Dr Maplesden stated:

'I remain of the view that there was sufficient evidence regarding the safety and efficacy of the mRNA Covid vaccine at the end of 2021, by way of meta-analyses of robust clinical trials, to provide patients querying these issues with a balanced view.

That view might justifiably have referred to the fact that no vaccine is either completely safe or completely effective but in the absence of factors known to increase the risk of a serious adverse reaction, some degree of reassurance could be offered to patients querying whether or not they should have the vaccine. I agree that such discussion might include the individual's risks of a severe outcome associated with contracting the disease — this being part of an informed discussion.'

- I accept Dr Maplesden's advice that by the time the events occurred at the end of 2021, there was sufficient evidence of the safety and efficacy of the mRNA COVID-19 vaccine to provide a balanced view to any patient who was concerned about those issues.
- Dr Maplesden advised that he expected that a responsible and ethical GP, when seeing a patient with concerns about the safety of the COVID-19 vaccine for their specific health issues, would acknowledge and empathise with the patient's specific concerns and provide them with an evidence-based and balanced perspective on the relative risks of the vaccine specific to their concerns. Dr Maplesden stated:

'I would expect the patient to be given objective, evidence-based advice relevant to their concerns and would be moderately critical if medical evidence was misrepresented or incorrect advice was provided.'

Dr A had an obligation to provide the three patients with objective information about the safety and efficacy of COVID-19 vaccination in line with the MCNZ guidance. As noted above, all three patients presented to Dr A for an exemption letter because of fears about possible

12 September 2024 10

¹⁷ 21HDC03172 available at www.hdc.org.nz

¹⁸ Dr Maplesden advised that by the end of October 2021 over 7 billion doses of COVID-19 vaccines had been administered worldwide, with 6.88 million doses having been administered in New Zealand.

side-effects of the vaccine. In that context, it was important that evidence-based vaccine information was shared to help to balance those concerns and ensure that the patients could make informed decisions about vaccination.

54. While Dr A has emphasised his professional obligation to uphold patients' rights to informed consent, I have seen no indication that he provided balanced information in any of the patient consultations. I am concerned that Dr A's own strongly held views about the ethics of the public health response to COVID-19 contributed to that failing. *Good Medical Practice* specifically states that a doctor's 'personal beliefs, including political, religious and moral beliefs, should not affect [that doctor's] advice or treatment'.

Medical certificates

- As with Dr A's exemption letters, the medical certificates he issued are not supported by full, clear records of the associated patient consultations. Dr Whitworth has advised that Dr A's decision to issue the three patients with medical certificates for stress leave was reasonable, given that all three confirmed that they were suffering with stress at the time. In their statements, the three patients described their stress (at 15 November) as follows:
 - Employee 1 stated that she 'had never been so stressed in [her] life'.
 - Employee 2 said that her stress was increasing day by day until 'things came to a head'.
 - Employee 3 said that she had 'an emotional breakdown at work and had to take sick leave'.
- Dr A accepted the three patients' accounts of their stress, and he described them as 'deeply distressed'. It is therefore concerning that Dr A did not take any action to address their stress, aside from providing the patients with a medical certificate. While the medical certificates implied a follow-up review at the end of the leave period, rather than during it, as Dr Whitworth advised would 'often' occur, there is no evidence that Dr A undertook any such reviews.
- 57. Dr Whitworth considered that Dr A's clinical management to address the stress was 'completely lacking' and represented a mild to moderate departure from the accepted standard of care. I agree. While I accept that Dr A's consultations with the three employees were therapeutic in themselves to an extent, that did not negate the need for a documented and more detailed management plan. The specific elements of care that were omitted by Dr A were significant. Dr Whitworth advised:

'The entries [in the notes] are very brief. They contain no record of any mental health assessment, no documentation of assessment of anxiety or stress levels — I would commonly see a GP complete a Kessler 10 or GAD-7 assessment. There is no documentation of the functional impact of the stress, other than loss of sleep and lack of menstruation. There is no management plan stated. I am moderately concerned that no interventions to help ... mental health are stated eg referral to counsellor, mindfulness, discussion re medication. There is no assessment of suicidal risk/ideation. There is no follow-up plan or safety netting stated.'

I acknowledge Dr Whitworth's remarks about the pressure some GPs were experiencing at this time from patients seeking exemptions. However, I am not persuaded that this was a factor or any mitigation in this case. Dr A certified the three patients to be off work for a significant period of stress leave (one month). The patients' records should reflect a sound assessment and plan in relation to their stress, but they do not. It is notable that Dr A does not accept that there were any omissions or shortcomings in his management of the patients' reported extreme stress and distress. Whether Dr A's lack of clinical management in this respect was inadvertent or otherwise, it was inconsistent with his stated 'care and concern' for the three patients, and the accepted standard of care.

Clinical record-keeping

Good quality clinical records are crucial to ensuring safe, effective, and timely health care. They reflect a doctor's reasoning and are an important source of information about a patient's current and previous care. The MCNZ's record-keeping standards are detailed in its statement on managing patient records:¹⁹

'[Doctors] must maintain clear and accurate patient records that note: a) clinical history including allergies; b) relevant clinical findings; c) results of tests and investigations ordered; d) information given to, and options discussed with, patients (and their family or whānau where appropriate); e) decisions made and the reasons for them; f) consent given; g) requests or concerns discussed during the consultation; h) the proposed management plan including any follow-up; [and] i) medication or treatment prescribed including adverse reactions.'

- In my view, Dr A's documentation did not adhere to any element of this standard. As already noted, Dr A's records of all six patient consultations were minimal. The notes of five of the consultations comprise less than a sentence, the longest being only ten words. Although Employee 2's first consultation notes contain a little more information, it comprises anecdotal accounts of vaccine side effects, with no information relating to Employee 2. Dr Whitworth considers that the standard of Dr A's notes represents a mild to moderate departure from the accepted standard. I agree.
- In his response to my provisional opinion, Dr A submitted that 'full record keeping of [these] consultations would have been superfluous', and the 'urgent' circumstances and 'extreme distress' of the three employees mitigated his brief clinical records. I do not accept this explanation. The MCNZ's record-keeping statement does not provide for brief record-keeping in urgent situations, in that it specifies that 'records must be completed at the time of the events you are recording, or as soon as possible afterwards'. In addition, a GP consultation with any person who presents in 'extreme distress' is plainly a situation that should be documented fully, rather than one where keeping a full record is 'superfluous'.
- As a result of Dr A's extremely brief consultation notes, this investigation has had to rely on other, less contemporaneous evidence, leading to some questions about what occurred at the consultations. In addition, very little information is available in the practice's records for

¹⁹ Version dated December 2020, which was valid at the time of the events.



continuity of care or for patients themselves. It is notable that Dr A has not recognised, in any of his responses to this investigation, that his record-keeping fell far short of the standard required by the MCNZ.

Conclusion

- Right 4(2) of the Code states that every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards. I have found that Dr A did not meet these standards for the following reasons:
 - a) The exemption letters he issued were based on insufficient information and in the knowledge that the letters were invalid as exemptions and the three patients were not eligible for valid exemptions from the Ministry.
 - b) There is no evidence that the three patients received any objective information about the safety and efficacy of the vaccine, alongside their exemption letters.
 - c) The quality of his clinical record-keeping fell far short of the accepted standard.
- As noted above, I am concerned that Dr A's own strongly held views about the ethics of the public health response to COVID-19 motivated some of the failings I have identified. While I respect a health practitioner's right to their private opinions, professional health practice demands that practitioners behave in accordance with the law, standards, and guidance that apply to their profession. I am critical that Dr A's response to the three patients' fears and concerns about the COVID-19 vaccine did not adhere to the applicable law, standards, and guidance.
- Right 4(1) of the Code states that every consumer has the right to have services provided with reasonable care and skill. I have also found that Dr A did not meet this standard, as he failed to clinically manage the three patients' stress, despite certifying that they each required one month of leave due to workplace stress, and his own stated concerns about their welfare.
- 66. Accordingly, I find Dr A in breach of Right 4(1) and Right 4(2) of the Code.

Recommendations

- 67. I recommend that Dr A:
 - a) Undertake refresher training on clinical record-keeping. The training should be in conjunction with, or endorsed by, a relevant professional association or authority. Evidence of completion of the training should be provided to HDC within three months of the date of this report.
 - b) Undertake an audit of the notes of 20 patients seen within the previous three months, using a relevant professional audit tool (such as module 2 of the RNZCGP clinical record review self-audit checklist, including the 'Report and Plan template').
 - c) Arrange for his clinical record audit report to be peer-reviewed by a relevant professional body or a suitable professional mentor, and a plan established to address

any necessary improvements. Dr A's audit report and the peer review should be provided to HDC within three months of the date of this report.

I also recommend that the Medical Council of New Zealand consider whether a review of Dr A's competence is warranted.

Follow-up actions

- 69. A copy of this report with details identifying the parties removed, except Dr A and the advisors on this case, will be sent to the Medical Council of New Zealand.
- 70. A copy of this report with details identifying the parties removed, except the advisors on this case, will be sent to Health New Zealand|Te Whatu Ora, the Medical Council of New Zealand and the Royal New Zealand College of General Practitioners, 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 Dr Fiona Whitworth, a GP, on 27 November 2023:

'1. My name is Fiona Whitworth. I am a graduate of Oxford University Medical School and I am a practising general practitioner. My qualifications are: MA 1991, BM BCh 1994, DCH 1996, DCRCOG 1996, MRCGP 1999, PGCMed Ed 2011, FRNZCGP 2013, PGDip GP 2016, FAEG 2020. Thank you for the request that I provide clinical advice in relation to the complaint from [a businessperson] about the care provided by [Dr A]. 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. Documents reviewed

18/11/2021 Complaint

22/2/2022 S14 Response [Dr A]

29/9/2023 GP records and patient statements

3. Complaint

[Dr A] provided one staff member [Employee 2] a vaccine exemption certificate on 8/11/2021 despite this not being the correct process.

[Dr A] provided long term medical certificates (15/11/2021–25/12/2021) to 3 members of staff.

The complainant feels that [Dr A's] behaviour caused unnecessary stress by misleading them about exemptions and conditions to get around the Ministry of Education and Ministry of Health Order.

Provider response(s)

In the response [Dr A] acknowledges that he issued medical certificates stating that the patients concerned had a medical reason to be exempt from the COVID 19 vaccination Mandate.

He also states he fully informed the patients that these were not legally binding — the clause 7A exemption in the COVID-19 Public Health Response (Vaccinations) Order 2021 had been revoked.

The MOH had brought in legislation that required application to the MOH and Director General for vaccine exemption. He states he gave the certificates and explained that "any certificate that I wrote would only be my opinion and not a formal exemption under the Order and would not carry weight in terms of her being able to continue work under the mandate".

It is stated that [Employee 2] "She understood that the certificate was not an exemption but wanted one anyway to support her in her dialogue with her employer about her genuine concerns about the vaccine."

He acknowledges that on 10/11/2021 he spoke to [Employee 1] and [Employee 3] and he issues exemption certificates. He again states "I explained that an exemption would carry no weight legally."

He states that there were then telephone consultations with all three individuals and that due to their underlying stress that "I felt that stress leave would be appropriate for each of them as well."

He comments on the length of time given — "My experience with leave due to stress has been that 2 weeks is never sufficient time for a person to properly decompress and that the current circumstances are beyond anything any of us have experienced before hence the extended time frame."

5. Review of clinical information/records

[Employee 3] statement — this patient states she did not have a GP and had 2 telephone conversations with [Dr A] (11 and 15th Nov 2021). She states she explained "the extreme stress she was under".

[Employee 2] statement — she was unable to see her usual GP for 2 months. She states she therefore had an in-person consultation on 8/11/2021 — "[Dr A] gave me a doctor's letter dated 8 November 2021 stating that it would be inappropriate for me to be vaccinated against SARS-CoV-2. Prior to giving me this letter, he explained to me that the law had changed and that doctors could no longer give exemptions from a governmental requirement to be vaccinated. All such exemptions had to now go through the Ministry of Health. I understood that the doctor's letter was not a valid exemption." In a subsequent telephone consultation on 15/11/2021 she states, "the stress increased" and "contacted [Dr A] and had a detailed phone consultation with him. [Dr A] provided me with a medical certificate which I presented to my employer."

[Employee 1] statement — She was unable to get a timely appointment with her own GP. She therefore has a telephone consultation with [Dr A] on 15/11/2021. She states she discussed her current health and was given a medical certificate and "a letter saying that it would be inappropriate for me to get vaccinated.' She states that 'I did not present that letter to my employer, as [Dr A] had made it quite clear to me that it was not an exemption. He said that the law had changed and that exemptions were only given by the Ministry of Health now. I felt that this second piece of paper was worthless and so did not hand it in to my employer."

Comment

In all 3 patient statements it is clear that the patients felt they had a medical problem that would justify a medical certificate being issued at that time. They all clearly state that [Dr A] had clearly informed them that exemptions could only be given by the

Ministry of Health. They understood that the letter provided by [Dr A] was not a valid exemption.

Review of Clinical Notes

Employee [1]

10/11/2021 GP consultation

"really concerned about side effects"

The Exemption from vaccine statement — This letter certifies that the above named has been examined by me and I have determined that it would be inappropriate for her to be vaccinated against Sars-Cov-2.

15/11/2021 GP consultation

"really stressed with mandate, losing sleep, amenorrhea for 10 weeks"

The medical certificate states stress that is related to duress at work. It implies a planned review on 13/12/2021. There is no evidence that this review occurred.

Comment

I am mild to moderately concerned re the brevity of these notes. It is not clear if these are in person or telephone consultations. It is standard GP practice to state the mode of delivery of healthcare. This is alleged by the patient and [Dr A] to have been a telephone consultation — it is unclear how he could have examined her.

In GP I would commonly see durations of 1 month being given off work in regard to workplace stress to allow a patient to fully make changes/recover however this would often be punctuated by a review after 1–2 weeks from the initial presentation. This did not occur in this case. Please see below.

Employee [3]

10/11/2021 GP consultation

"anxious about side effects"

The Exemption from vaccine statement — "This letter certifies that the above named has been examined by me and I have determined that it would be inappropriate for her to be vaccinated against Sars-Cov-2."

15/11/2021 GP consultation

"very stressed at work"

The medical certificate states stress that is related to duress at work. It implies a planned review on 13/12/2021. There is no evidence that this review occurred.

Comment

I am mild to moderately concerned re the brevity of these notes. Please see below.

Employee [2]

8/11/2021 GP consultation

The notes document facts about other individuals but there is no documentation regarding her health.

The Exemption from vaccine statement from 11/11/2021 — "This letter certifies that the above named has been examined by me and I have determined that it would be inappropriate for her to be vaccinated against Sars-Cov-2. This determination is made pursuant to clause 7A, COVID-19 Public Health Response (Vaccinations) Amendment Order 2021 by me as a suitably qualified health practitioner."

15/11/2021 GP consultation

"massive stress at work, really not functioning well."

The medical certificate states stress that is related to duress at work. It implies a planned review on 13/12/2021. There is no evidence that this review occurred.

Comment

I am mild to moderately concerned re the brevity of these notes. There is no documentation of any examination (as stated on the vaccine exemption statement). [Dr A] would have been aware that clause 7A had ceased on 8/11/2021. Please see below.

6. Comments on clinical care

The entries are very brief. They contain no record of any mental health assessment, no documentation of assessment of anxiety or stress levels — I would commonly see a GP complete a Kessler 10¹ or GAD-7² assessment. There is no documentation of the functional impact of the stress other than loss of sleep and lack of menstruation. There is no management plan stated. I am moderately concerned that no interventions to help her mental health are stated eg referral to counsellor, mindfulness, discussion re medication.³ There is no assessment of suicidal risk/ideation.⁴ There is no follow up plan or safety netting stated.

The notes do not state the time frame off work given (stated on certificates).

There is no documentation of any discussion regarding the safety and efficacy of the vaccine. No statement of any educational resources given. There is no documentation of the change in provision of Vaccine exemptions (i.e. now from MOH).

It should be noted at this point in 2021 that there were incredible degrees of distress and misinformation circulating in both medical circles and for the public.

Of note [Dr A] was not the usual GP for any of these patients however he chose to write both medical exemption letters and medical certificates. (See advice below that

12 September 2024

¹ https://healthify.nz/tools/d/distress-scale-kessler-10/

² https://healthify.nz/tools/g/general-anxiety-scale-gad-7/

³ https://bpac.org.nz/BPJ/2009/December/anxiety.aspx

⁴ https://bpac.org.nz/bpj/2009/adultdep/management.aspx

applications for exemptions to MOH should be from a GP with an existing relationship with the patient.)

I would commonly see a GP in this situation to write a short certificate and advise the patient to see their own GP. (I note one patient states she did not have a regular GP.)

Below summarises some of the key information released in a timeframe.

21 October 2021. RNZCGP update to members⁵ includes: The College is being asked to clarify who can receive a vaccine exemption as patients are requesting them. The College has been working with IMAC on a statement about vaccine exemptions however the Ministry of Health has asked us to pause this work until they provide further clarification. In the meantime, our advice is not to write vaccine exemption certificates until we receive the Ministry's guidance.

28 October 2021. RNZCGP update to members⁶ includes: The College and IMAC have been working with the Ministry of Health to establish both criteria for exemptions and a process to make this standardised and secure for practitioners, patients and employers. This is taking some time and we have heard from our members that there are many requests for these exemption certificates. While the formalised process and criteria are agreed and set up, we suggest that members can state that from what we know so far the following are the likely criteria that are exempt:

- Anaphylaxis to the first dose of the vaccine
- Known severe allergy to the excipients of the vaccine
- Acute decompensated heart failure
- Inflammatory cardiac illness within the past 6 months
- Myocarditis
- Pericarditis
- Endocarditis
- Acute rheumatic fever
- Acute rheumatic heart disease.

This has not been confirmed by the advisory group yet and may change. We expect a more formal process to be available in the next week that will allow members to produce the validated certificate. Any documents produced in the meantime may give confidence to the patient but will need to be reproduced with the validated process.

7 November 2021: COVID-19 Public Health Response (Vaccinations) Amendment Order (No 4) 2021. Clause 7(A) revoked by Clause 9(B) *Director-General may grant COVID-19 vaccination exemption*

⁶https://rnzcgp.informz.net/informzdataservice/onlineversion/pub/bWFpbGluZ0luc3RhbmNlSWQ9MjM3MjE 4MQ==



⁵https://rnzcgp.informz.net/informzdataservice/onlineversion/pub/bWFpbGluZ0luc3RhbmNlSWQ9MjM2ODI wMQ==

- (1) A suitably qualified medical practitioner or nurse practitioner (the applicant) may apply to the Director-General for a COVID-19 vaccination exemption on behalf of a person who—
 - (a) belongs to a group specified in Part 6, 7, 8, or 9 of the table in Schedule 2 and—
 - (i) is not vaccinated:
 - (ii) has not received a booster dose; or
 - (b) belongs to a group specified in Part 10 of the table in <u>Schedule 2</u> and is not vaccinated.
- (2) An application may be made only on the ground that the person on whose behalf the application is made (the person) meets the specified COVID-19 vaccination exemption criteria.
- (3) The person must—
 - (a) certify that the information that they have provided to the applicant for the purposes of making the application is accurate; and
 - (b) sign the application.
- (4) An application must be accompanied by a certificate signed by the applicant certifying that they—
 - (a) have reviewed the person's medical history and assessed the person's state of health; and
 - (b) have reasonable grounds for believing that the person meets the specified COVID-19 vaccination exemption criteria.
- (5) The applicant must state their grounds for believing that the person meets the specified COVID-19 vaccination exemption criteria.
- (6) On receiving an application, the Director-General may ask the applicant or person to provide any evidence or further information that the Director-General reasonably requires for the purposes of deciding whether to grant the application.
- (7) The Director-General may grant the application if the Director-General is satisfied, on the basis of the evidence or other information provided, that the person meets the specified COVID-19 vaccination exemption criteria.
- (8) A COVID-19 vaccination exemption is valid for the period that the Director-General determines, which must be no longer than 6 months.

- (9) The Director-General must notify the applicant and the person of the outcome of the application.
- (10) If the application is granted, the Director-General must provide a copy of the COVID-19 vaccination exemption in written or electronic form to the applicant and person that states the date on which the exemption expires.
- (11) At any time before or after a COVID-19 vaccination exemption expires, a new application for a further exemption may be made under this clause by any medical practitioner or nurse practitioner on behalf of the person in respect of whom an exemption was granted.
- 8 November 2021. Ministry of Health formalises process and criteria for vaccine exemption for mandated workers. Final version of process and criteria published 30 November 2021⁷. As well as listing the specific exemption criteria, the Ministry outlined the principles of temporary medical exemption which included:
- There are very few situations where a vaccine is contraindicated and, as such, a medical exemption is expected to be rarely required.
- Exemptions should be limited to situations where a suitable alternative COVID19 vaccine is not readily available for the individual.
- Exemptions should be for a specified time, reflecting, for example, recovery from clinical conditions or the availability of alternate vaccines.
- Vaccination should be completed as soon as clinically safe within the exemption timeframe. This is particularly relevant for criteria 1C where it is unlikely that a full six months is required.
- It is likely that most people who are not medically exempt can be safely vaccinated, with some requiring extra precautions.
- The practitioner completing the application form should have an existing clinical relationship with the consumer and will support them for completing their vaccinations going forward.

19 November 2021. RNZCGP update to members⁸ includes: *The issues that arose over* the issuing of vaccine exemption certificates, and who would be eligible for an exemption, were particularly difficult. The fact the exemption was announced with no formal process in place meant that GPs were put straight in the firing line across many parts of the country with verbal, and at time[s] physical abuse, and threats. On top of the other demands already on frontline GPs in the COVID response, the way this was rolled out and the unintended consequence was unacceptable.

⁷ https://www.health.govt.nz/system/files/documents/pages/vaccine-temporary-medical-exemption-30nov21.pdf

⁸ https://rnzcgp.informz.net/informzdataservice/onlineversion/pub/bWFpbGluZ0luc3RhbmNlSWQ9MjM4ND g3Mw==

7. Clinical advice

I would advise that although the notes are very short, the provider response from [Dr A] and letters from the patients identify that all three patients stated they had stress. As such the issuing of a medical certificate would have been appropriate.

However, I am mild to moderately critical that the standard of the notes is poor and the clinical management to address the stress is completely lacking.

I note the mitigating circumstances at the time as noted by the statement from RNZCGP on 19/11/2021.

Regarding the issuing of letters that state his opinion that it would be "inappropriate for her to be vaccinated against Sars-Cov-2". (It is noted that these were not legally binding.) There is very minimal documentation of appropriate assessment of the patients' underlying medical conditions/mental health issues/current therapeutics/ previous allergies/occurrence of anaphylaxis. I am moderately critical of the lack of information used to issue these certificates. I acknowledge that there potentially may have been significant distress/pressure from the patients concerned to issue the letters.'

Follow-up advice to Commissioner

The following in-house advice was obtained from Dr Fiona Whitworth on 6 August 2024:

'I have been asked to comment on [Dr A's] comments received by the HDC to the initial provisional report [attachments to email to HDC of 24 May 2024].

I note that [Dr A] has stated that the 1-hour long telephone contacts with the patients in question was a therapeutic intervention in itself. I agree that as clinicians we can use our clinical skills in this way. However, I would note that it would be common practice to record more detailed documentation around this approach and to also state a more complete management plan including follow up review.

I would note that as an experienced GP and medical educator I am fully aware of the clinical models of care including Te Whare Tapa Wha and more recently the Hui process — including the Meihana model.

It is still my opinion that the clinical documentation was brief and that the management plan and follow up were not clearly documented.

I do note the mitigating factors of GP provision in [the region] and the very challenging period of time that this was in New Zealand for provision of healthcare.'

Appendix B: In-house clinical advice to Commissioner

The following in-house advice was obtained from Dr David Maplesden, a GP, on 6 August 2024:

'I have reviewed [Dr A's] comments [attachments to email to HDC of 24 May 2024]. You ask:

- 1. whether the clinical issues raised change your original advice in any way; and
- 2. provide additional advice/comments to address the issues raised.

I remain of the view that there was sufficient evidence regarding the safety and efficacy of the mRNA Covid vaccine at the end of 2021, by way of meta-analyses of robust clinical trials, to provide patients querying these issues with a balanced view.

That view might justifiably have referred to the fact that no vaccine is either completely safe or completely effective but in the absence of factors known to increase the risk of a serious adverse reaction, some degree of reassurance could be offered to patients querying whether or not they should have the vaccine. I agree that such discussion might include the individual's risks of a severe outcome associated with contracting the disease — this being part of an informed discussion.

I do not believe it would have been reasonable at this time to present the vaccine as being overtly dangerous, or to downplay the potential for Covid infection to have a serious outcome, or to actively discourage any patient (other than those with recognised contraindications) from receiving the vaccine although I am not saying [Dr A] undertook such actions.

I agree it is the right of any patient to refuse medical treatment and for them to base that decision on appropriate and balanced clinical information. I acknowledge that a minority of my colleagues may share [Dr A's] views regarding the safety and efficacy of the mRNA Covid vaccine, but I believe a majority of my colleagues would accept that Covid vaccination greatly reduced the health burden in New Zealand during the height of the pandemic.'