HEALTH & DISABILITY COMMISSIONER
TE TOIHAU HAUORA, HAUĀTANGA

A Decision by the Deputy Health and Disability Commissioner

(Case 21HDC02898)

Introduction

1. This report is the opinion of Carolyn Cooper, Deputy Health and Disability Commissioner, and is made in accordance with the power delegated to her by the Commissioner. The report discusses the care provided to the late Mr A by a pharmacy and Mr B. My deepest condolences go to Mrs A for the loss of her husband.

2. The following issues were identified for investigation:

- *Whether [the pharmacy] provided [Mr A] with an appropriate standard of care from August 2021 to September 2021 (inclusive).*
- *Whether [Mr B] provided [Mr A] with an appropriate standard of care from August 2021 to September 2021 (inclusive).*

3. The parties directly involved in the investigation were:

Mr A (dec)	Consumer
Mrs A	Complainant/wife
Mr B	Pharmacist
Mr C	Pharmacist and pharmacy owner
The pharmacy	

4. Further information was received from:

Dr D	General practitioner (GP)
Dr E	CPAMS[1] member
Software system provider	

5. Independent clinical advice was obtained from pharmacist Mrs Julie Kilkelly (Appendix A).

[1] Community Pharmacy Anticoagulation Management Service.

Facts gathered during investigation

Background

6. On 19 November 2021 this Office received a complaint from Mrs A about the care provided to her late husband, Mr A. Immediately prior to Mr A's passing, Mr A suffered a brain bleed. Mrs A is concerned about the management of Mr A's warfarin[2] regimen and believes it was directly related to his death.

7. In her letter to HDC, Mrs A also expressed her dissatisfaction with the pharmacy's complaints management approach following her husband's passing.

8. Mr A had been prescribed warfarin by his GP, Dr D. The INR[3] monitoring and management of his warfarin dose was undertaken by the pharmacy under the CPAMS[4] programme.

9. Mrs A told HDC that Mr A had been a client of the pharmacy for over six years. The pharmacy records note Mr A's registration and consent to CPAMS on 30 December 2016 and that he was having INR tested at least monthly. In response to my provisional decision, Mrs A clarified that testing occurred more frequently when the INR result was outside the normal range. Mr A had started taking warfarin on 21 June 2011. Prior to registration with CPAMS, his warfarin had been managed by his GP.

10. The pharmacy told HDC that it tests INR at the pharmacy and, based on the reading, the pharmacist recommends the appropriate warfarin dose for the consumer. When informing the consumer of the dose to be taken, the pharmacist also provides the consumer with a calendar that shows the dates and dosage to be taken each day, and the date when the next test is due. This service is provided under a standing order (see Appendix B).[5] The pharmacy provided HDC with the most up-to-date version of the standing order, which was dated 24 October 2013. However, it is stated in the standing order that '[t]he issuer will review the [s]tanding [o]rder at least once a year' and '[p]harmacies must also annually review they are operating according to this [s]tanding [o]rder'.

11. Alongside the physical INR test, the process is managed through software that automatically generates a recommended dose based on an algorithm.

[2] Warfarin is an anticoagulant (often known as 'blood thinner'), commonly used to treat and prevent blood clots. It can have serious side effects, including excessive bleeding.

[3] The INR (international normalised ratio) test is used to monitor blood clotting times and adjust warfarin medication dose to within an acceptable therapeutic range.

[4] The overall objective of CPAMS is the provision of INR point-of-care testing by a community pharmacy and adjustment of warafin doses within a defined range with the aid of an approved decision-support system. Suitably qualified (accredited) pharamacists complete a CPAMS training programme and must re-certify every two years.

[5] A written instruction issued by a medical practitioner or nurse practitioner to authorise a specified person to administer or supply a particular medicine in certain situations. The standing order for CPAMS is included as Appendix B.

Software system provider

12. The software system provider explained to HDC the CPAMS programme and information technology that supports this service. The provider took over management of the CPAMS service in April 2021. Following INR testing, the system sends the result to the patient's GP through HealthLink[6] HL7 messaging, which uses an 'EDI'[7] to identify the medical practice or individual GP to whom the message is sent. All HealthLink messages for Mr A's GP practice are sent to one central EDI.

Procedure for results outside specified safe range

13. The standing order specifies that an upper and lower INR limit where a pharmacist can accept the dose recommendation from the system must be set for each patient. A default limit between 1.5 and 4.0 is used unless an alternative range is specified by the patient's doctor. The standing order states that 'INR values outside the upper and lower limits will be referred for review by the doctor'. The standing order notes that the normal procedure for any INR results outside the upper and lower INR default ranges of between 1.5–4.0 is that 'the [software system] will automatically set the result for review'. The pharmacist can accept the recommended dose and advise the patient that the result has been sent to the doctor for review. The standing order also notes that the supervising doctor will be informed by email and provides an outline of the information that is included in the email.

14. The software system provider stated that a result and dosage recommendation can be put into review to be checked by the GP if required. This is sent via HealthLink messaging and, if an email address for the GP is registered in the system, the review notification is also sent via email. Not all GPs have an email registered in the system. The provider told HDC that an email was optional and the main form of communication of results is via HealthLink HL7 secure messaging. The standing order notes under 'Record keeping' that the test result will be automatically sent to the doctor's patient management system via HealthLink. The review box can be 'ticked' by either the prescribing doctor or the pharmacist.

15. A flow chart included in the standing order notes that the GP will receive a notification stating that the INR result is outside the safe range and the notification would include information on the result, recommended dose, recent results, and a link to the review page. The flow chart does not note whether the notification is sent by email, HealthLink, or both.

16. Pharmacy owner Mr C told HDC that at the time of the incident, he contacted the software provider to make sure that Dr D was receiving notification of results outside the acceptable range, and this is when he discovered that the email address recorded for Dr D in the system was incorrect.[8] The email contact information has now been corrected.

[6] A messaging system that exchanges electronic messages between health providers' computer systems.
[7] Unique identifier for electronic messages.
[8] The software system provider told HDC that it depended on the pharmacy to provide correct details for the patient's GP. The provider stated that it did not have a regular audit in place for checking whether the details of the doctors in the system are correct. The details are updated at the request of pharmacies and medical centres. An 'invalid' report for failed HealthLink HL7 messages occurs weekly, and these are investigated to ensure that the test results are delivered.

Timeline of events

17. Between 17 August 2021 and 7 September 2021, Mr A's INR testing was managed by pharmacist Mr B. Mr B had completed accreditation training in the CPAMS programme in January 2020 (which was valid for two years following course completion). Training is managed nationally by the Pharmaceutical Society of New Zealand.

18. The pharmacy records note that prior to 17 August 2021, Mr A was taking 2mg of warfarin each day for four days and then 1mg for one day (an average of 1.86mg daily). On this regimen, his INR test results were predominantly within the normal target range of 2–3. Mrs A told HDC that Mr A always took his warfarin in the morning.

19. On 17 August 2021 Mr A went to the pharmacy for an INR test and to collect his regular medication, which included a month's supply of doxycycline.[9] Mr A's INR had dropped to 1.2. An INR reading below the target range increases the risk of the consumer having a blood clot, which may lead to medical conditions such as a stroke or heart attack. In response, Mr B instructed Mr A to increase his warfarin dose to an average of 2.33mg and come back for a further test on 19 August 2021. The pharmacy told HDC that the average dose of 2.33mg is achieved by the consumer alternating daily doses of 3mg and then 2mg. The pharmacy provided a printout of the record, which recommended taking 3mg on Tuesday and 2mg on Wednesday (17 and 18 August 2021).

20. The clinical record provided by Dr D notes that a different staff member at the pharmacy contacted the GP practice on 17 August 2021 to query a dose of another of Mr A's medications. However, there is no record of any discussion or information being provided by the pharmacy on Mr A's low INR result, nor is there any record of a request for GP review.

21. The software provider told HDC that the system automatically sends INR results to the patient's medical practice via secure messaging, and the result for 17 August 2021 was sent. Dr D confirmed that the test result was in Mr A's clinical record. The result was marked with an 'L' indicating low.

22. Mr A returned to the pharmacy on 19 August 2021 for the scheduled follow-up INR test. The result showed a slight rise to 1.4, but it remained under the lower limit specified in the standing order. Mr B did not change the dose and rescheduled a further test for five days later, on Tuesday 24 August 2021. Mr A's GP records do not contain any documented contact with the pharmacy on 19 August 2021. Dr D confirmed that the INR result marked as low was included in Mr A's medical record.

23. On 24 August 2021 Mr A's INR test result was 2.9, which was within the specified therapeutic range of 2–3. The software system records for the day documented that the dose changed to 2mg. A further test was scheduled for 7 September 2021. Mrs A provided HDC with a copy of the dose calendar, which notes, 'Take 2mg each day' with x2 tablets crossed out in pen and replaced with a '3' on 26 and 30 August 2021, and 3 and 6 September 2021. Mrs A told HDC that these changes in dose were made by the pharmacist, and in hindsight she

[9] An antibiotic that has the potential to interact with warfarin metabolism.

questioned why the dose was increased when the INR was 2.9. Mrs A also told HDC that it was common practice for the pharmacist to change the calendar printout, and that 'many printouts [were] changed over the years'.

24. The pharmacy provided HDC with a spreadsheet of Mr A's test results and dose recommendations. The result for 24 August 2021 was 2.9. The column labelled 'given_dose' recorded '2'. The calculated dose was 2.243680601mg and the rounded dose was recorded as 2.33mg. The software system incident report notes that the dose was edited and reduced from the recommended 2.33 to 2mg.

7 September 2021

25. On 7 September 2021 Mr A's INR reading was 5.6. This is well above the upper limit specified in the standing order. INR readings above the therapeutic range increase the risk of serious side effects such as excessive bleeding.

26. The pharmacy provided HDC with undated notes, written by Mr B, on his recollection of events that occurred following the high INR test result.[10] There is no documentation of a discussion with Mr A in the software system. Mr B wrote that he asked Mr A whether he had had any medicine changes or alcohol to cause the abnormally high INR, to which Mr A responded 'no'. Mr A had been prescribed the antibiotic doxycycline, which can interact with warfarin. However, Dr D told HDC that Mr A had been taking doxycycline for several years and a stable INR level had been established since commencement.

27. Mr B recorded that he then enquired whether Mr A felt unwell or if he could think of anything that might have changed his INR, to which Mr A also responded 'no'. Mrs A told HDC that Mr A had quite a bad headache and that he had been headachy for at least three days and felt tired.

28. Mr B recorded that he informed Mr A that the result was concerning because his INR results were normally quite consistent, and Mr B advised Mr A to be very careful of any bleeding or unusual symptoms, to omit taking warfarin for two days, and to come back for a retest in one week. Mrs A told HDC that when she enquired about the INR result when Mr A returned from the pharmacy, he told her that Mr B had said that 'it was only a worry re[garding] a low reading' and 'just watch out for bleeding'.

29. Mr B also wrote that his recommendation was based on 'successful past experience with patients who like Mr A, had consistent INR results overall, and their INR corrected well after the two missed doses'. Dr D told HDC that he has no recollection of being contacted by the pharmacy about a high INR result on 7 September 2021. He said that the verbally agreed protocol, from when the recording commenced on the system, was that the pharmacy would call if there was concern about a result that was significantly outside therapeutic range.

[10] HDC understands that the notes were written after Mrs A's contact in September 2021 as they refer to Mrs A's phone call on that day.

30. Mrs A told HDC that on 7 September 2021 she was very worried about the high reading as she knew Mr A 'was a bleeder' and asked Mr A to seek medical care. She said that Mr A told her that Mr B had said not to worry, and that his INR levels would drop quite quickly. Mrs A stated that Mr A took Panadol and ibuprofen later that day, but his headache symptoms did not improve. Ibuprofen is not recommended to be taken concurrently with warfarin. There is no documented discussion on whether Mr A had taken any ibuprofen prior to going to the pharmacy that day. In response to my provisional decision, Mrs A confirmed that Mr A had not taken any ibuprofen prior to having his INR tested.

31. Mrs A told HDC that she remained concerned and again tried to get Mr A to go to the hospital. She told HDC that '[h]e was very irritable and repeated what [Mr B had] told him'. Mr A was nauseous that evening and had a restless night, taking more Panadol during the night.

8 September 2021

32. Mrs A told HDC that on 8 September 2021 Mr A's headache was worse, and he was extremely irritable. He went to bed at approximately 3pm but had to get up twice to vomit. Mrs A encouraged him to go to the hospital, but he refused, although he told her that his head pain was extreme, and he kept hearing swishing noises in his ears. At approximately 5.30pm, Mrs A asked if she could telephone an ambulance, but Mr A said 'no' and shook his head.

33. Just prior to 6pm, Mrs A found Mr A half out of bed and sliding to the floor. She attempted to assist him to stand as he had got out of bed to go to the toilet and to get some water. Mr A was unable to stand so Mrs A gave him some water and called an ambulance.

34. The ambulance took Mr A to a public hospital's Emergency Department, where he was assessed and thought to have had a stroke. A short time later he was transferred by helicopter to a second public hospital. During the transfer Mr A's level of consciousness deteriorated to the point where he was unresponsive. On arrival he underwent a CT scan of his brain, which showed a large area of bleeding on the right side and extensive swelling.

35. Mr A's case was discussed with the neurosurgeon on call, who reviewed the CT scan and advised that given the extensive bleeding and Mr A's condition, surgery would be ineffective. Mr A was transferred to a medical ward for palliative care and subsequently, he passed away.

36. Mr A's Medical Certificate of Cause of Death notes in antecedent causes: 'On warfarin for [atrial fibrillation],[11] over anticoagulated.'

Further information

37. The software system and HealthLink do not retain messages for longer than three months and were therefore unable to provide any detailed information on what was sent to Mr A's GP via the system. The system's incident report recorded, 'Result sent to doctor's PMS[12]' on

[11] Heart condition where the heart rhythm is abnormally rapid and irregular.
[12] Patient management system.

17 August, 19 August, 24 August, and 7 September 2021. There is no documentation of a high or low result alert notification being sent through HealthLink to the PMS.

38. Dr D provided HDC with the INR records for Mr A received into the inbox for the practice EDI covering August and September 2021. The clinical records included the INR test results for 17 and 19 August 2021. The results included an 'L' in red next to the result indicating that it was low. However, there was no record of a specific notification or indicator that urgent attention was required. There was no record of the INR test for 24 August 2021 or 7 September 2021.

39. Mr B did not mention in his retrospective notes any action taken to contact Mr A's GP, and there is no record of contact in Mr A's GP clinical notes.

40. The pharmacy believed that Dr D would automatically receive notifications, and as they had not been contacted to change the dose of warfarin for Mr A, they concluded that Dr D had approved the dose recommendation.

41. The software system's incident report notes that the data for 19 August 2021 and 7 September 2021 shows the 'review request' marked as 'reviewed but not changed' and that this implies one of two scenarios. Either contact was established between the pharmacist and Dr D and the result was reviewed, or the pharmacist did not hear from Dr D and marked the result as reviewed without discussing it. In addition, the report notes that the result for 17 August 2021 had a result created, reviewed, and edited within five minutes, and that this would have occurred almost 30 minutes before an email would have been sent to the doctor. The system provided a spreadsheet of the data recorded against Mr A's test. The data indicates that changes were made under Mr B's account. Mr C said that where the INR is >4.5, the following process is expected:

a) The pharmacist would contact the doctor and discuss the treatment plan.

b) Once an agreed plan is reached with the prescribing doctor, the pharmacist informs the customer of the treatment plan and provides a dosing calendar for them to follow.

c) The usual recommendation would be to miss one dose and retest the next day. In some circumstances, the doctor would write a prescription for vitamin K.[13]

42. A Pharmacy Defence Association incident notification form completed by Mr B noted that the 'usual protocol' was followed, 'that is, that [Mr A] was to miss two days of warfarin in a row'. However, the instruction to omit two doses of warfarin and return for a further test in a week are not consistent with the standing orders for an INR above 5.0, which note:

'If the INR is >5.0

- The software system will provide advice for warfarin reversal in line with the Australasian Guidelines (Appendix 2).

[13] Warfarin acts by inhibiting the production of vitamin K. Giving vitamin K is the treatment for over-anticoagulation.

- All results should be discussed with the supervising doctor[.]
- If the guidelines recommend treatment with vitamin K, this must be discussed with the supervising doctor. Vitamin K can only be given with authorization from the supervising doctor.'

43. The guideline referred to, and included in the standing order as an appendix, a table listing the appropriate actions to take when the INR is elevated above the therapeutic range. The instructions for an INR between 5.0 and 9.0 where bleeding is absent are:

'— Cease warfarin therapy; consider reasons for elevated INR and patient specific factors.

— If bleeding risk is high, give vitamin K^2 (1.0–2.0mg orally or 0.5–1.0mg intravenously).

— Measure INR within 24 hours, resume warfarin at a reduced dose once INR is in therapeutic range.'

44. Mr C told HDC that the recommendation to miss two doses is not normal practice and not what he would do as a CPAMS qualified pharmacist.

45. Mr C told HDC that the expected process at the pharmacy is to follow the guidelines outlined in the standing order, and a qualified CPAMS pharmacist should not act outside those parameters.

Complaint management

Establishing consumer concerns

46. Mrs A told HDC that she telephoned the pharmacy in September 2021 to voice her concerns. She stated that she spoke to Mr C and that he was very defensive, constantly interrupting, and kept reading out Mr A's previous INR results. Mrs A said that Mr C delivered her medications early that evening and continued to be defensive, saying, 'I hope you aren't blaming us.' She told HDC that she was still in shock and grieving and that she felt intimidated and bullied during these interactions.

47. Mr C recalls receiving a phone call from Mrs A. He told HDC that the conversation was about 30–45 minutes long, and he found it difficult to determine Mrs A's exact concerns. Mr C told HDC that Mrs A requested delivery of her repeat medications, and he decided to deliver them personally as he had heard about Mr A's passing and wanted to understand her concerns further. Mr C said that during these two conversations Mrs A did not know what had caused Mr A's death.

48. In response to my provisional decision, Mrs A stated that she made it very clear what her concerns were and did not request delivery of her medications as she had arranged for a friend to drive her to collect them. Mrs A also stated that the phone call was under 30 minutes long as Mr C was unpleasant to talk to, and she knew that Mr A's death had been caused by a high INR and had made this clear to Mr C.

49. Mr C provided HDC with a copy of notes that he wrote following the phone call and visit. The notes contain the following information that is pertinent to this investigation:

- Mrs A telephoned the pharmacy after receiving a text message from Mr B asking Mr A to come in for a blood test. At the time, Mr B was unaware of Mr A's passing.
- Mrs A expressed concern that Mr A's death could have been related to his high INR reading. Mr C asked if this is what the doctors had said. Mrs A responded that they were unsure, and it could have been a stroke, fall or brain bleed. Mrs A explained that Mr A had shown weakness on the left side, and this is why he was in hospital. On this basis, Mr C believed Mr A may have had a stroke.
- Mrs A said that she expected the pharmacy not to take responsibility. Mr C responded saying that the pharmacy 'cannot take responsibility for something that is just based on possibility'.
- Mrs A expressed anger with herself for not calling for help earlier as she was concerned about Mr A's health during the day on 8 September 2021. Mr C attempted to comfort her.
- Mr C noted that throughout the conversation, he expressed empathy and said that he was sorry to hear the news.

50. In response to my provisional opinion, Mrs A disputed Mr C's account of events, including that a text message was sent by Mr B and or that a message was left on the landline. Mrs A further disputed that a fall or stroke could have caused Mr A's death and stated that she had received a phone call on 8 September 2021 from a doctor informing her of Mr A's right-sided brain bleed and the high INR reading. Mrs A stated that she requested the INR records as she believed this was the cause of Mr A's death.

51. In response to my provisional decision, Mrs A agreed that she was angry with herself for not having insisted that Mr A seek help. She explained that at the time she had felt nervous about how Mr A would react. Mrs A stated that she had talked to Mr B about this and had not discussed this with Mr C.

52. The Pharmacy Defence Association incident notification form completed by Mr B notes: 'Wife called to discuss issues surrounding the last days of husband's life. She wanted someone to talk to. Wife did not find fault with our service in any way!'

53. Mrs A told HDC that on 16 October 2021 she phoned the pharmacy to request a printout of Mr A's INR readings prior to 24 August 2021. Mrs A said that Mr C's response was again very defensive, and she was informed that the records could not be retrieved due to Mr A's death. She disagreed with this, stating that records could be retrieved for years prior, and Mr C agreed that this might be possible, but he would need to talk with the software company. Mrs A told HDC that Mr C then said: 'Are you making a complaint against us, if so I'm going to do something about it.' Mrs A said that she felt threatened, but she persevered and asked why Mr A had not been sent to the doctor or hospital for a vitamin K injection.

She stated that Mr C admitted that Mr B should have 'done that' but said that 'the [doctor] wouldn't have done anything'.

54. Mr C was surprised and upset to read of Mrs A's impression of him, particularly regarding her perspective of him being domineering and a bully. Mr C told HDC that he was under the impression that Mrs A felt comfortable during their interactions due to her openness and willingness to discuss a range of topics. Mr C said that he went to Mrs A's home to show empathy and listen to any concerns she had about the services provided by the pharmacy.

55. Mrs A stated that she phoned Mr B on 18 October 2021 as she had yet to receive a printout or hear of any progress. Mrs A said that Mr B was easier to talk to, and he said that he would print out the requested record. Mrs A told HDC that although Mr B was pleasant, he lied to her saying that he had informed Mr A of the warning signs. Mrs A is not convinced that this occurred, as she believes Mr A would have gone to hospital if he had been warned. Mrs A told HDC that the 'biggest lie' Mr B told her was that 'he had emailed [Dr D] to request a Vit[amin] K injection for [Mr A], but the [doctor] had refused and said [Mr A] didn't need it and he wouldn't see him'. Mrs A checked with Mr A's GP practice and spoke to the receptionist, who confirmed that she had checked all the records with a nurse and there was no email.

56. HDC has made extensive efforts to contact Mr B to obtain his view and provide him with an opportunity to comment. However, Mr B has relocated overseas, and these efforts have been unsuccessful.

Action taken following events

57. Mr C determined that Mrs A's main concern was Mr B's advice to Mr A regarding warfarin dosing. Mr C told HDC that the day after he spoke to Mrs A, he reviewed the INR readings and recommendations made by Mr B. He then contacted his professional body for advice.

58. Mr C directed Mr B to read and understand the information that was in the CPAMS training notes on how to manage high INRs. Mr C then monitored, in the system background, all INR tests completed by Mr B to make sure the correct procedures were being followed.

Guidance provided to staff

59. The pharmacy provided HDC with a standard operating procedure section on complaints management. The document appears to be adopted from the group provider and was implemented in 2016 and reviewed in 2024. It advises to refer complaints to the Charge Pharmacist and that the complaint should be attended to immediately, preferably in a private area. The document also notes:

> 'Allow the customer to express their concerns about a dispensing error or service, or explain, faulty products, poor quality etc. Listen in a sympathetic and calm manner and do not deny a problem. Ensure the problem is clearly identified …
>
> Where the problem appears to be complex or not easily resolved, your Pharmacy Defence Association (PDA) membership enables you to consult them for advice about

> how to proceed. The PDA strongly recommends consulting with their staff as soon as possible about ways to deal with a complex complaint issue …
>
> The client should be kept fully informed at regular intervals of progress in resolving their complaint.
>
> If the complaint is not resolved to the customers satisfaction withing 5 working days [t]hen it will be acknowledged in writing in accordance with Right 10 of the Code of Rights for Consumers of Health and Disability Services.'

60. In addition, the dispensing errors section of the pharmacy's SOPs provided to HDC in February 2022 contains similar guidance on communication with consumers, including the following:

> 'The Pharmacist will move to a quiet area of the pharmacy to talk to the customer or to make the phone call to the customer and will remain calm and in control and show recognition and understand the customers feelings. The Pharmacist will never make excuses or use a defensive tone of voice.'

61. The dispensing error section of the SOPs also includes instructions to acknowledge the mistake, explain to the consumer that they have the right to make a complaint to HDC, inform the consumer that the pharmacy is investigating to prevent a similar incident occurring in future, and follow up with a formal written apology.

Relevant legislation

62. Use of standing orders is supported by the Medicines (Standing Order) Regulations 2002. Clause 9 specifies the obligations of a person supplying or administering medicine under a standing order:

> 'A person who administers or supplies a medicine under a standing order must ensure that —
>
> (a) the medicine is supplied or administered in accordance with the standing order; and
>
> (b) he or she records or charts the assessment and treatment of the patient (including any adverse reactions) and any monitoring or follow-up of the patient's treatment, if necessary.'

63. Clause 7 covers the review of the standing order and states:

> 'Annual review of standing orders
>
> (1) A standing order may be reviewed at any time but must be reviewed by the issuer at least once a year.
>
> (2) When carrying out a review, the issuer must consider whether the standing order continues to be necessary and whether its terms are appropriate.

(3) Any material variations, deletions, or additions required to be made to a standing order as a result of a review must be dated and signed by the issuer.'

Responses to provisional opinion

Mrs A

64. Mrs A was provided with a copy of the 'Facts gathered during investigation' section of my provisional report and given an opportunity to comment. Mrs A said that her belief is that Mr C was not empathetic and from the outset was 'defiant and defensive', behaving in an extremely unprofessional manner. She would have liked Mr C and Mr B to have arranged a time to sit and listen to her, be kind, and explain everything in a quiet and peaceful way. Further comments have been incorporated into this report where relevant.

Mr B

65. A further attempt was made to contact Mr B to provide him with a copy of my provisional report and an opportunity to comment. No response was received from Mr B.

Pharmacy

66. Mr C was provided with a copy of my provisional report and given an opportunity to comment. Mr C highlighted that he has taken corrective actions since this incident (discussed further below). Further comments have been incorporated into this report where relevant.

Dr E

67. Dr E was provided with a copy of the relevant sections of my provisional report and given an opportunity to comment. Dr E's comments have been incorporated into this report where relevant.

Software system provider

68. The software system provider was provided with a copy of the relevant sections of my provisional report and given an opportunity to comment. The provider advised that it accepts the findings in the report and is considering options for strengthening the email alert feature.

Opinion: Mr B — breach

Background

69. Between 17 August and 7 September 2021 Mr B was the pharmacist testing Mr A's INR and advising him of the dose of warfarin to take in the interval between tests. The standing order specifically outlines a range of results, between 1.5–4.0, where a pharmacist can accept the dose recommendation generated by the software system without consulting with the prescribing GP. Results that fall outside this range require review by the prescribing doctor. My independent clinical advisor, Mrs Julie Kilkelly, advised that outside of this range, medical guidance must be sought, and the pharmacist must confirm that review has occurred and has been accepted.

Management of INR test results

70. On 17 August 2021 Mr A's test result was 1.2, which is below the acceptable range and requiring review by a doctor. Mrs Kilkelly noted that given that Mrs A advised that Mr A always took his warfarin in the morning, he would likely have already taken his warfarin at the time of the test. Mrs Kilkelly advised that the pharmacist doing the test would normally question patients as to when they take their warfarin, as the subsequent dose recommendation and the dose calendar provided to patients always starts from the day the test is done. If this is not allowed for, then subsequent dose recommendations may not be as accurate, as the system works on a mathematical algorithm.

71. Mrs Kilkelly noted that on 17 August 2021 Mr B edited and overrode the software system's recommendation of 2mg daily despite the possible interaction with the doxycycline and advised Mr A to increase his warfarin to an average of 2.33mg daily and return on 19 August 2021 for a further test. I am not critical that the possible interaction with doxycycline was apparently not discussed with Mr A, as I note that he had been taking this medication long term, and a stable INR had been established while he was on both warfarin and doxycycline. However, I accept Mrs Kilkelly's advice that the possible interaction between doxycycline and warfarin should have been considered when overriding the system's recommendation to increase the warfarin dose. In the absence of further evidence from Mr B, I am unable to determine whether Mr A was asked whether he had taken his warfarin that morning or whether the dose recommendation was adjusted accordingly.

72. The records indicate that the result of 17 August 2021 was reviewed, as the review tick box was completed. The software system records show that the result was created, reviewed and edited within five minutes, prior to any email being sent to the doctor (the software system provider told HDC that an email is generated approximately 30 minutes after the results are created). However, there is no record of Mr B consulting with Dr D about the dose change or low INR result prior to checking the review box.

73. Although not included in the main body of the standing order, there was verbal agreement between the pharmacy and Dr D that there would be phone contact if a consumer's INR fell outside the acceptable range. Dr D has no recollection of being contacted. There is a record of the pharmacy contacting Mr A's GP practice about another matter on 17 August 2021. If the pharmacy had discussed the low INR result and treatment plan with Dr D, it is reasonable to expect that this would have been recorded in Mr A's GP clinical record in a similar way that the telephone call from the pharmacy staff member has been recorded. From the information available it is clear that GP review of the INR result did not occur before Mr B accepted the treatment plan. Mrs Kilkelly advised that failure to ensure medical review is a severe departure from the accepted standard of care. I accept this advice and am highly critical that the review box was completed, and the dose recommendation overridden without consulting Dr D.

74. On 24 August 2021 Mr A's INR was at the upper end of the acceptable range at 2.9. This did not require medical review, and Mr B edited the recommendation of 2.33mg reducing it to 2mg. Mrs Kilkelly noted that this is higher than Mr A's usual maintenance dose of 1.86mg. The maintenance dose was established while Mr A was taking long-term doxycycline. With

the benefit of hindsight, it would have been better for the dose to have been reduced to the usual maintenance level. Mrs A provided HDC with a dose calendar that had been overwritten in pen and, if followed, would have increased the dose to 2.33mg for the period 26 August to 6 September 2021. I am unable to determine who changed the calendar printout, and as the INR recommendation was reduced in the system and the test result was within the acceptable range, I am not critical of the actions taken by Mr B on 24 August 2021. I would be concerned if Mr A had been given a dose calendar by someone at the pharmacy who had directed him to increase his dose to a level that was different to the dose set by Mr B in the system.

75. On two further occasions (19 August 2021 and 7 September 2021) the software system records show that Mr B ticked the review box, implying that the results had been reviewed by his GP. On these two occasions the dose recommendation was not changed.

Advice given on 7 September

76. On 7 September 2021, when Mr A had an INR result of 5.6, Mr B provided advice that was based on his past experience, and not in line with the specific instructions included in the standing order. Mrs Kilkelly advised that this was a severe departure from accepted practice by overriding guidelines in relation to high INRs (over 4.5) where the patient should miss one dose and return the next day for another test. In this case, Mr A was advised to miss two doses then resume warfarin and not return for a full week.

77. I note that the standing order includes further instruction for INR results above 5. In this situation the software system will provide advice for warfarin reversal in line with the Australasian Guidelines. These guidelines advise to cease warfarin therapy, retest in 24 hours, and contact the prescribing doctor to discuss whether vitamin K should be administered.

78. Mrs Kilkelly advised that Mr B, a CPAMS-accredited pharmacist, should have phoned Dr D for advice on all three occasions on which the INR fell outside the range acceptable for pharmacist management, particularly when the INR was 5.6. In this situation, discussion should have occurred between Mr B and Dr D about whether it was appropriate to give vitamin K. Mrs Kilkelly stated that failure to ensure that medical review was provided when the INR was outside the acceptable range for pharmacist management constitutes a severe departure from the accepted standard of care. I accept this advice and am highly critical of Mr B's decision to provide Mr A with instructions on warfarin management that were not consistent with the very clear instructions included in the standing order. Mr B took it upon himself to provide advice based on his own judgement and, in doing so, stepped outside his scope as a pharmacist working under a standing order. In my view, Mr B should have either received email confirmation of GP approval of the treatment plan, or contacted Mr A's GP by phone, prior to checking the review box.

Documentation

79. On 17 August 2021 Mr B edited and overrode the system's recommendation of 2mg daily and accepted the tick box alert indicating that a medical review had occurred. There is no

record of any review or rationale for editing in the notes section of the software system's programme.

80. Similarly, on 19 August 2021 Mr B edited and overrode the recommendation to recheck the INR in seven days, shortening the timeframe to recheck in five days, and accepted the review tick-box alert. Although this may be a reasonable adjustment, there is no documentation of a review or the rationale for the edit.

81. Mrs Kilkelly advised that not documenting in the notes box of the system the reasons for any deviations in dose or test interval constitutes a severe departure from accepted practice. I note that this requirement is specifically stated in the standing order, and I accept this advice.

Medication interactions

82. Mrs Kilkelly advised that doxycycline is a medication that can interfere with warfarin metabolism. As Mr A had been taking doxycycline long term, his usual maintenance dose and testing intervals had been adjusted to compensate for this. Mr A was therefore more complex than the usual patient taking warfarin. In my view, this increased the need for medical review to occur when Mr A's INR result was outside the acceptable range.

83. Mr A took ibuprofen for a headache on 7 September 2021. Ibuprofen is a non-steroidal anti-inflammatory drug that can be purchased over the counter and is not recommended to be taken concurrently with warfarin.

84. Mrs Kilkelly advised that new medications should be picked up when the safety questions outlined in the standing order are asked prior to testing. I note that Mr B questioned Mr A on possible reasons for his high INR on 7 September 2021, including whether he had taken any new medication. However, I am unable to determine whether the safety questions were asked prior to testing. Mrs A told HDC that Mr A took the ibuprofen after his INR test and confirmed that he had not taken any ibuprofen before this.

85. I have also considered that Mr B was reliant on Mr A self-reporting non-prescription medication and headache symptoms, and that Mr A may not have understood the significance of having a headache at the time of testing.

Conclusion

86. In my view, Mr B advised Mr A to take action that was based on his own opinion and not consistent with instructions specified in the standing order. In addition, Mr B did not ensure that medical review occurred when the INR result fell outside the range that was specified in the standing order as safe to be manged by a pharmacist.

87. By completing the review tick box, Mr B incorrectly documented that medical review had occurred. In addition, when he altered the dose and/or testing interval on three occasions (17 August, 19 August, and 7 September 2021), he failed to record the rationale for changes made to the recommendation generated by the software system.

88. By not supplying medication in accordance with the instructions set out in the CPAMS standing order and by failing to document the rationale for adjustments to the recommended dose or testing interval, I find that Mr B failed to provide services with reasonable care and skill. Accordingly, Mr B breached Right 4(1)[14] of the Code of Health and Disability Services Consumers' Rights (the Code).

Opinion: the pharmacy — adverse comment

Care provided — adverse comment

89. When considering whether the care provided to Mr A was of an appropriate standard, I must not only examine the care provided by the individual pharmacist, but also whether the systems in place at the pharmacy were sufficient to support an appropriate standard of care.

90. The pharmacy provided HDC with a current training certificate for Mr B certifying him as accredited in the standard required for the CPAMS programme. The pharmacy could reasonably expect that a pharmacist who had completed training and been credentialled as a CPAMS provider would follow the procedures and guidance outlined in the standing order. Accordingly, I do not consider that the pharmacy is responsible for Mr B's breach of the Code.

91. I now consider whether the pharmacy met its obligations as a pharmacy participating in the CPAMS programme. Mrs A stated that it was common for the pharmacist to routinely modify the recommendations produced by the software system. It is clear that Mr B modified recommendations without medical review and oversight. However, it is not clear whether this behaviour was indicative of the culture of the pharmacy. I am unable to make a finding on whether modifying results without medical review was widespread behaviour across the pharmacy, and I would be critical if this was occurring.

92. It is clear from this investigation that on more than one occasion, an assumption was made that because Dr D was receiving alerts from the system via email, he agreed with the treatment plan because he did not otherwise contact the pharmacy. Mrs A told HDC that Mr C admitted that Mr B should have contacted Dr D by phone, but Mr C believed that Dr D would not have done anything. I note that the pharmacy had an informal agreement to telephone the prescribing doctor when an INR was outside the acceptable range.

93. Mrs Kilkelly advised that after receiving no medical acknowledgement on the first occasion of a low INR, best practice would have been to check that the email was correct or ring the doctor directly rather than to assume that the doctor was happy. Mrs Kilkelly stated: 'As the owner of a business which is contracted to provide the CPAMS service you are responsible for ensuring your staff provide safe and appropriate services.' Mrs Kilkelly advised that failure to ensure review constituted a moderate to severe departure from accepted practice. While I accept Mrs Kilkelly's opinion that best practice is to contact the consumer's GP and not make assumptions, I consider that ultimately Mr B is responsible for failing to ensure that GP review occurred when the INR results were outside the acceptable range. I

[14] Every consumer has the right to have services provided with reasonable care and skill.

am critical of the pharmacy's failure to ensure that the informal agreement to contact the prescribing doctor by phone was not formalised and reinforced with staff.

94. The standing order requires the participating pharmacy to undertake an annual review to ensure that staff are operating according to the standing order. Mr C took action to monitor tests completed by Mr B after Mr A's passing. However, HDC has not been provided with any documentation of an annual audit or review of tests for compliance with the standing order. Mrs Kilkelly advised that failure to complete this review constitutes a moderate departure from the accepted standard. The review is an important avenue for identifying issues before they result in an adverse event, and I am critical of the pharmacy's failure to put in place a review programme.

Complaint management — adverse comment

95. Mrs A and Mr C have differing perspectives on their interaction following Mr A's passing. Mrs A felt bullied and intimidated at a time when she was grieving and still in shock following the sudden death of her husband. Mr C attempted to gather information on her concerns, determine the pharmacy's involvement, and express empathy.

96. The pharmacy's SOPs note that the pharmacist should listen to the consumer's concerns and not deny the problem or be defensive. Mrs A stated that Mr C was defensive, and Mr C's record of his meeting with Mrs A notes that when she expressed her opinion on the pharmacy's lack of accountability, he informed her that the pharmacy cannot take responsibility for something that is based on possibility.

97. Although I am unable to reconcile these differences, it is clear that Mrs A did not perceive Mr C's approach as empathetic. I trust that Mr C will reflect on his communication style and make adjustments when dealing with consumer complaints in future.

98. The pharmacy's SOP also notes that the client should be kept fully informed at regular intervals, and that the complaint will be acknowledged in writing if not resolved withing five working days. The dispensing error section of the SOPs advises to inform the consumer that the pharmacy is investigating to prevent a similar incident occurring in future, and to follow up with a formal written apology.

99. I am critical of the complaint process followed by the pharmacy. There was no written acknowledgement of Mrs A's concerns. There was also no follow-up communication addressing the concerns and outlining the outcome of the investigation, including any measures put in place to prevent a recurrence. Mrs A did not receive a written apology for the actions taken by Mr B that were contrary to the instructions specified in the standing order.

Opinion: Dr E — adverse comment

100. This investigation has identified that the standing order, which was last updated in October 2013 and is expected to be reviewed annually, is well overdue for review. The requirement for annual review is specified in the standing order and required under the Medicines

(Standing Order) Regulations 2002. I am critical of the extensive timeframe since the standing order was last reviewed. In my view, urgent compliance with relevant legislation is required.

101. In response to my provisional decision, Dr E acknowledged that he is listed as the issuer in the standing order in use at the time of these events and that the standing order specifies annual review, which did not occur. Dr E further stated that the following two concurrent areas of responsibility were not clear in the document and were open to ambiguity:

a) That Dr E was responsible for the review of the document, which in his opinion does not require regular review; and

b) That the annual review of the standing order process referred to in the Medicines (Standing Order) Regulation 2002 is the responsibility of the patient's GP and pharmacist.

102. Dr E stated that the standing order document incorrectly identifies him as the issuer, and it would be more correct to state that he prepared the standing order template. Dr E said that the GP is the issuer of the standing order, and steps have been taken to clarify this in a draft revised document currently under review by members of the Pharmaceutical Society.

103. I consider it essential that the CPAMS standing order is reviewed to ensure that it is compliant with the Medicines (Standing Order) Regulations 2002 and the broader health regulatory regimen. I acknowledge the unique structure of the CPAMS programme and the shared responsibility of roles that contribute to its success in practice. However, at its core, a standing order is a written instruction, and this document has been prepared at a central point for use in a national programme with some flexibility built in to adjust for individual patients. In my view, maintaining a central point for reporting adverse events and issuing the standing order has its benefits. I would be concerned if the core structure of the CPAMS programme was compromised by decentralising the role of the issuer, allowing the opportunity for inconsistencies to occur.

104. This investigation has also highlighted an over-reliance on automated systems leading to the assumption of prescriber oversight where it did not exist. Strengthening of the verbal agreement to contact the prescriber by telephone when an INR test falls outside the acceptable range for pharmacist management would be beneficial, and, in my view, should be formalised in the standing order.

105. In response to my provisional decision, Dr E stated that phone calls are the preference of some pharmacies, and others prefer email contact. Dr E has taken this into consideration when reviewing the standing order. I acknowledge that the key consideration is that the prescriber has been contacted. The method of contact is secondary.

Changes made since events

106. The pharmacy is limited in its ability to make system change as the CPAMS programme is a national programme managed by the software provider with training support provided by

the Pharmaceutical Society of New Zealand. Mr C told HDC that as a result of this incident, he has implemented the following changes:

- Reinforced the CPAMS training by verbally discussing with new pharmacists how to manage INR results less than 1.5 or higher than 4.5; and
- Reinforced the message that pharmacists must follow the parameters set out in the standing order.

107. In response to my provisional decision, Mr C provided further information on the corrective actions that were taken following this incident. As the pharmacy owner and manager, Mr C took steps to ensure that staff reflected on the incident and implemented training to ensure that all pharmacists, both new and existing, strictly adhered to the CPAMS Standing Order until provision of the service ceased in July 2024. Training included a particular focus on the management of high and low INR results and the requirement for direct communication with prescribers if results fell outside the accepted range.

108. The pharmacy decided not to continue to offer the CPAMS programme from July 2024. The pharmacy told HDC that the stress of HDC's investigation and the absence of the pharmacist involved led to its inability to provide the appropriate responses and affected Mr C and his team, forcing them to reconsider offering the service. Mr C stated: 'As an owner, I need to trust that qualified and accredited pharmacists are competent in the services they provide and practice safely.' Although I understand Mr C's decision, it is a disappointing outcome for the region's community.

109. In response to my provisional decision, Mrs A said that she is also sad that the INR testing has been discontinued at the pharmacy, and she hopes that the other local health providers will continue to offer the service.

Recommendations

110. Recommendations are designed to improve practice and systems with the aim of preventing similar situations occurring to other consumers. Although this investigation has identified individual failings of Mr B, the fact that he is no longer in New Zealand and is not practising as a pharmacist makes it impractical to recommend individual action to improve his practice. My recommendations are therefore targeted toward systems improvement.

Pharmacy

111. In accordance with the proposed recommendations in my provisional decision, the pharmacy provided HDC with a formal written apology to Mrs A for the deficiencies identified within the report, and evidence of staff having completed the HDC online training modules on the Code of Health and Disability Services Consumers' Rights and complaints management. I consider that these recommendations have been met.

112. I recommend that should the pharmacy decide to reoffer the CPAMS programme in future, before starting the programme, the pharmacy develop an annual audit schedule to ensure that the pharmacy is operating in compliance with the standing order.

Mr B

113. Should Mr B return to New Zealand and reapply for a practising certificate, I recommend that the Pharmacy Council of New Zealand consider whether a review of his competence is necessary.

Software system provider

114. I recommend that the software system provider:

a) Review the email contact details system and consider implementing a checking process similar to the weekly failure report in place for HealthLink HL7 messages. A report on the results of this review and any actions taken is to be provided to HDC within three months of the date of this report.

b) Consider changing the review tick box to ensure that the prescriber has reviewed the result or been consulted. A report on actions taken to improve the system is to be provided to HDC within three months of the date of this report.

CPAMS

115. I acknowledge that the standing order has been reviewed taking into consideration the findings of this report. The updated version of the standing order is to be provided to HDC within three months of the date of this report.

Follow-up actions

116. A copy of this report with details identifying the parties removed, except the clinical advisor on this case, will be sent to the Pharmacy Council of New Zealand, and it will be advised of Mr B's name. Due to the seriousness of this departure, I considered a referral to the Director of Proceedings. However, as Mr B is no longer residing in New Zealand, it would be impractical to proceed with this.

117. A copy of this report with details identifying the parties removed, except the independent advisor on this case, will be sent to the Pharmaceutical Society of New Zealand, the Pharmacy Defence Association, the Royal New Zealand College of General Practitioners, CPAMS, and the software system provider and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent clinical advice to Commissioner

The following independent advice was obtained from pharmacist Mrs Julie Kilkelly:

'I have been asked to provide clinical advice to HDC on case number C21HDC02898. I have read and agree to follow HDC's Guidelines for Independent Advisors.

I am not aware of any personal or professional conflicts of interest with any of the parties involved in this complaint.

I am aware that my report should use simple and clear language and explain complex or technical medical terms.

Qualifications, training and experience relevant to the area of expertise involved:	NZ Registered Pharmacist 1990–current NZ Registered Pharmacist Prescriber Dec 2023–current Accredited CPAMS Provider 2012–2022 Co-owner of Unichem Olsens Pharmacy (2002) Ltd contracted by the West Coast District Health Board to provide CPAMS services from Pilot Scheme (2012) through till the pharmacy was sold in 2021
Documents provided by HDC:	1. Transcript of complaint letter 25 October 2021 2. Letter of complaint dated 29 October 2021 3. [The pharmacy] response dated 11 February 2022 4. Response notes from Pharmacist [Mr B] 5. Clinical records from [the pharmacy] covering the period 17 August 2021 to 9 September 2021 6. Pharmacy Defence Association Incident Notification Form dated 7. [The pharmacy] SOPs and CPAMS standing orders 8. [The software system's] incident report dated 21 January 2022 9. [The pharmacy's] response dated 8 September 2023
Referral instructions from HDC:	[The pharmacy] 1. Was the care provided to [Mr A] in line with the CPAMS standing orders and [the pharmacy's] SOPs? 2. Were the CPAMS standing orders and [the pharmacy's] SOPs adequate? 3. Whether [Mr B's] assessment of [Mr A] and actions taken when INR results were outside the therapeutic range was appropriate and if not, why not? 4. Whether the co-ordination of care and communication between [the pharmacy] and [Mr A's] GP regarding abnormal INR results was adequate? 5. Whether [the pharmacy's] remedial actions and response to the incident was appropriate? 6. Any other comments that you feel are relevant.

Factual summary of clinical care provided

Brief summary of clinical events:	**29 Oct 2021:** The complainant ([Mrs A]) lodges an official complaint with the HDC. She alleges in her complaint letter that the pharmacy responsible … for testing her late husband's ([Mr A's]) INR and subsequent recommended warfarin dosing via the CPAMS service may have failed in their duty of care and this may have been a factor in his death. Timeline of events leading up to and after the complaint was lodged: **Dec 2016–Aug 2021:** [The pharmacy] (formerly …) provide[d] Community Pharmacy Anti-Coagulation Service (CPAMS) which includes INR testing and subsequent warfarin dosing to [Mr A] without incident. This service is to be provided in line with a Standing Order developed in 2013 by [the software system provider]. Suitably qualified (accredited) pharmacists can check INRs and give dose recommendations independently when INRs are in the range 1.5–4. Outside of this range advice is to be sought from the patient's medical practitioner ([the software system] triggers a review process) to ensure safe dosing. **June 2020–17 Aug 2021:** [Mr A's] INR results and warfarin dosage are stable. Only one result (1.4 on 10 Nov 2020) would have triggered a medical review. Throughout this time [Mr A's] warfarin dose was unchanged from a daily average of 1.86mg (dosed as 2mg for 6 days per week and 1mg on 1 day per week) even when the INR result of 1.4 occurred. On 10 Nov 2020 his dose remained unchanged and one week later (17 Nov 2020) the INR result was back in range. **17 Aug 2021:** [Mr A] is dispensed his usual medications and one month's supply of Doxycycline, an antibiotic which when taken concurrently can interfere with warfarin metabolism (a potentially significant drug interaction). Records provided do not indicate whether [Mr A] has received this antibiotic before nor do we know what the indication was. The interaction was noted on the prescription provided and [Mr A] should have been counselled about the potential interaction with his warfarin and advised to have another INR test within 3 days of starting the Doxycycline (as per NZ Formulary guidelines). [Mr A's] INR was tested on this date and was found to be 1.2. He would likely have already taken his warfarin at the time of the test as it was noted in correspondence from [Mrs A] that he always took it in the morning. The pharmacist doing the test would normally question patients as to when they take their warfarin as the subsequent dose recommendation and the dose calendar provided to patients always starts from the day the test is done i.e. if [Mr A]

	came to the pharmacy at 2pm he may have already taken his warfarin dose for that day. If this was not allowed for then subsequent dose recommendations may not be as accurate as the system works on a mathematical algorithm. Dose recommendation was provided to [Mr A] to increase his warfarin to an average of 2.33mg daily (the pharmacist edited and overrode the [software system's] recommendation of 2mg daily despite the possible interaction with the Doxycycline) and return on the 19/8/23 for a further test. The calendar provided to [Mr A] would have indicated to take 3mg Tuesday 17/8/21 and 2mg 18/8/21 and retest 19/8/21. We do not know if [Mr A] was told to take more warfarin on 17/2/21 following his test (as he had likely already taken that day's dose) nor do we know whether the possibility of the interacting Doxycycline was discussed or when/if [Mr A] actually took any of the Doxycycline. The [software system's] records indicate that the result (1.2) was sent to the Dr's PMS (Patient Management System) and a review result email sent to the doctor. The records also indicate that the result was reviewed (this is a tick box alert that the pharmacist is supposed to accept once the outside of 1.5–4 range result has been reviewed by a medical practitioner). We do not know whether the pharmacist ([Mr B]) spoke to the doctor about this low result but no mention of this was noted in the notes section of the [software system's] programme. **19 Aug 2021:** [Mr A] returns for another INR test as instructed. Once again we do not know if he had already taken his warfarin prior to the test or if he had started taking the Doxycycline dispensed on the 17/8/21. INR result was 1.4 (still low and still requiring a medical review as under 1.5). The dose algorithm suggested continue with an average daily dose of 2.33mg (2mg 4 days per week and 3mg 2 days per week) and recheck INR in 7 days (26/8/23) which the pharmacist edited and overrode to recheck in 5 days (24/8/23). It is not known whether [Mr A] had taken any Doxycycline) but this should have been picked up in the 4 safety questions that should be asked at every INR test as per the CPAMS standing order i.e. 1) Have you noticed any unusual bleeding or bruising since your last INR test? 2) Have you missed any warfarin doses since your last INR test? 3) Have you started, stopped or changed any medicines (including OTC) since your last INR test? 4) Have you been admitted to hospital since your last INR test?

Once again the [software system's] records indicate that a review email was sent to the doctor and the result was sent to his PMS. The [system's] log also indicates that the result was reviewed.

24 Aug 2021: [Mr A] returns for a further INR test. We do not know if he has already taken his warfarin for the day. INR is measured at 2.9 and system suggested dose of 2mg daily with retest in 2 weeks is reviewed but not changed. At this point we do not know if [Mr A] is taking the Doxycycline but standard safety questions should pick up. INR has risen and is back in range (top end). Dose of 2mg daily is higher than usual maintenance dose of 1.86 (as per previous results) and potential for interacting medicine.

7 Sep 2021: [Mr A] returns for INR test. INR is 5.6 (high result and outside of 1.5–4 range that pharmacist can manage without medical practitioner input). [The software system's] suggestion is MISS one dose for that day i.e. 7/9/21 (we do not know whether [Mr A] has already taken 2mg by the time the test is done but the pharmacist doing the test should question for this as part of safety questions) and retest the following day i.e. 8/9/23.

The pharmacist ([Mr B]) edits/overrides both the dose and retest suggestions and suggests MISS 2 doses then resume usual maintenance dose of 1.86mg per day average and retest in 1 week.

Calendar provided would have read:

Tue 7/9	Wed 8/9	Thu 9/9	Fri 10/9	Sat 11/9	Sun 12/9	Mon 13/9	Tue 14/9
MISS dose	MISS dose	1mg	2mg	2mg	2mg	2mg	Recheck INR

This dose may have already been taken at the time of the test if [Mr A] took his warfarin in the morning prior to the test and may have been 2mg as per the previous dose instruction. [Mrs A] notes in her letter of 25 Oct 2021 that [Mr A] had already taken his warfarin prior to the INR test on 7 Sep.

This is a direct contraindication to CPAMS Standing orders and [Mr B] suggests (in his response provided of unknown date) that recommendation was based on "successful past experience with patients who like [Mr A], had consistent INR results overall, and their INR corrected well after the two missed doses". There is no mention as to whether one of the suggested "Miss doses" may have already been taken by [Mr A] or of a potentially interacting medicine (Doxycycline) being taken concomitantly.

As per Mrs A's letter (25 Oct 21) it is noted that [Mr A] took Ibuprofen (not a dispensed medicine from the pharmacy according

	to the records provided) for a headache on 7/9/21, along with Panadol. Ibuprofen is a non-steroidal anti-inflammatory drug (NSAID) that can be purchased over the counter and is not recommended to be taken concurrently with warfarin. Ibuprofen does not alter the anticoagulant effect of warfarin but does reduce platelet aggregation and can prolong bleeding (NZ Formulary). Any patients taking warfarin are usually advised not to take NSAIDs except on medical advice. We do not know how much he took on this day or how frequently [Mr A] took this medication. … **Sep 2021:** [Mrs A] phones [Mr C] to voice her concerns in relation to her late husband's care. [The pharmacy] pharmacist [Mr B] reports incident to Pharmacy Defence Association (PDA), incident form included in correspondence. [Mr C] visits [Mrs A] at her home. **16 Oct 2021:** [Mrs A] phones [Mr C] at [the pharmacy] requesting [the software system's] printouts prior to 24 August 2021 but was told they were not able to be provided as the patient was deceased. **29 Oct 2021:** The complainant ([Mrs A]) lodges an official complaint with the HDC regarding the care provided to her late husband by [the pharmacy] pharmacists and subsequent requests for information following his death. **19 Nov 2021:** [Mr C] contacts … requesting information provided and visible to doctors from the [software] system. **21 Jan 2022:** [Mr C] requests paper trail of INR results sent to [Dr D] in relation to [Mr A]. It is noted in this correspondence that the email address of [Dr D] was incorrect (as created in Jan 2016, last updated in February 2016) thus any emails (including the request review emails) sent from the [software] system to this Dr's email address would not have been received by [Dr D] (information provided in Incident Report INR NZ HDC and [the pharmacy]). The doctor's name was spelt incorrectly … This date is written in the letter supplied as 21 Jan 21 (possibly a typo). **11 Feb 2022:** [Mr C] from [the pharmacy] provided written response to HDC. I note the letter is addressed to … and that [Dr D's] name is still incorrectly spelt in the letter as … despite this being identified as one of the problems with the email communication of the requested INR reviews.

	[Mr C] also notes in this response that he received a call from [Mrs A] in December of 30–45 minutes duration. I think this may also be a typo and should read September 2021 based on other records provided. [Mr C] notes in his response that the pharmacist ([Mr B]) should have contacted [Dr D] directly, rather than just relying on email for reviewing results (which is in line with CPAMS Standing Order recommendation). **8 Sep 2023:** [Mr C] … from [the pharmacy] provided second written response to HDC further clarifying points raised. **8 Feb 2024:** HDC office seeks independent clinical advice from myself.
Question 1: Was the care provided to [Mr A] in line with the CPAMS standing orders and [the pharmacy] SOPs?	
List any sources of information reviewed other than the documents provided by HDC:	Nil
Advisor's opinion:	From information provided, care departed from CPAMS standing order guidelines on 17/8/21 (INR=1.2), 19/8/21 (INR=1.4) and 7/9/21 (INR=5.6) at which times INR results were outside the range at which accredited CPAMS pharmacists can provide dosing guidance without review of a medical practitioner. On 17/8/21 [Mr B] acknowledged online on the [software] system at 14.49 (2.49pm) that a result had been reviewed and changed (result would have been INR of 1.2). The review did not occur but the acceptance was acknowledged. On 24/8/21 at 0938 (9.38am) [Mr B] acknowledged online on the [software] system that a result had been reviewed but not changed (result would have been INR of 1.4 on 19/8/21 that would have triggered a review). The review did not occur but the acceptance was acknowledged. [Mr A's] test was not conducted that day till 12.54 (12.54pm) and his INR at this test was 2.9 and did not require a doctor's review. On 8/9/21 [Mr B] also departed from an acceptable standard of care when at 11.16 (11.16am) on the [software] system he acknowledged that a result had been

	reviewed (the INR of 5.6 from the 7/9/21) but not changed. This review did not occur. Care provided in relation to [the pharmacy's] Assessing/Processing a prescription, Dispensing/Checking a prescription and dispensing errors SOPs was likely adequate. It was noted on the Doxycycline prescription (likely by the assessor/processor) that there was a potential drug interaction between the Doxycycline and Warfarin.
What was the standard of care/accepted practice at the time of events? Please refer to relevant standards/material.	In line with CPAMS Standing Orders INRs can be managed by an accredited CPAMS pharmacist between the range of 1.5–4.0. Outside of this range medical guidance must be sought and the pharmacist must confirm that review has occurred and been accepted. This acceptance is noted in [the software system's] records by the pharmacist indicating that the review has been accepted by the medical practitioner.
Was there a departure from the standard of care or accepted practice? No departure; Mild departure; Moderate departure; or Severe departure.	Yes, a severe departure from accepted practice by overriding guidelines in relation to high INRs (over 4.5) where the patient should miss one dose and return the next day for another test. In this case the patient was advised to miss 2 doses then resume warfarin (at a previously stable dose) and not return for a full week. A severe departure by not ensuring that medical review was provided when the INRs were outside the acceptable range for pharmacist management. The CPAMS accredited pharmacist ([Mr B] in this case) should have phoned [Dr D] for advice at all 3 times, particularly when the INR was 5.6 and a discussion should have occurred between the doctor and pharmacist about whether it was appropriate to give Vitamin K. A severe departure by not documenting in the notes box of [the software system] the reasons for any deviations in dose or test interval recommendations. A moderate departure by the pharmacy not reviewing annually that they are operating according to the CPAMS standing order.
How would the care provided be viewed by your peers? Please reference the views of any peers who were consulted.	I consulted the advice of a colleague and former pharmacy owner who offered the CPAMS programme (…) and she was of the same opinion as myself in relation to the management of low and high INRs in this case, noting that

	no identifying information was provided just INR values and actions taken in response to these.
Please outline any factors that may limit your assessment of the events.	We do not know whether the CPAMS standing order essential 4 safety questions were asked at each INR test nor whether the pharmacist doing the INR testing was aware of the potential drug interaction between warfarin and doxycycline. We do not know whether the potential drug interaction noted on the prescription dispensed on 17 Aug 21 was followed up via patient counselling at the time of prescription collection.
Recommendations for improvement that may help to prevent a similar occurrence in future.	Include in annual check of operation in accordance to CPAMS standing orders an audit of email addresses for medical practitioners so that any incorrect email addresses can be amended. Include in [the software system] training what to do if warfarin has already been taken on the day of INR testing (as was likely the case for [Mr A] if he took his warfarin in the morning) i.e. how you can account for this in the subsequent dose recommendation.
Question 2: Were the CPAMS standing orders and [the pharmacy's] SOPs adequate?	
List any sources of information reviewed other than the documents provided by HDC:	Nil
Advisor's opinion:	Yes though annual check of operation in accordance with CPAMS standing order guidelines was not done by [the pharmacy]. [The pharmacy's] Assessing/Processing a prescription, Dispensing/Checking a prescription and dispensing errors SOPs appear adequate.
What was the standard of care/accepted practice at the time of events? Please refer to relevant standards/material.	Operation of CPAMS programme in accordance with CPAMS Standing Order.
Was there a departure from the standard of care or accepted practice? No departure; Mild departure; Moderate departure; or Severe departure.	No, the CPAMS standing order and [the pharmacy's] SOPs were of an acceptable standard.
How would the care provided be viewed by your peers?	The CPAMS standing order and [the pharmacy's] SOPs would be acceptable to peers. The CPAMS standing order

Please reference the views of any peers who were consulted.	is a generic document that all pharmacies offering CPAMS services operate under.
Please outline any factors that may limit your assessment of the events.	N/A
Recommendations for improvement that may help to prevent a similar occurrence in future.	Highlighting the section in the CPAMS Standing order that states that pharmacies must also annually review that they are operating according to this Standing Order and also highlighting this as part of the [software system] accredited pharmacist training.
Question 3: Whether [Mr B's] assessment of [Mr A] and actions taken when INR results were outside the therapeutic range was appropriate and if not, why not?	
List any sources of information reviewed other than the documents provided by HDC:	New Zealand Formulary — NZF v141 — 01 Mar 2024
Advisor's opinion:	[Mr B] did not follow accepted guidelines i.e. the CPAMS standing order when making dose recommendations for INRs outside of the 1.5–4 range for the following reasons: • He did not directly contact the doctor involved in [Mr A's] care ([Dr D]) • He made dose and frequency alterations without appropriate medical oversight • He overrode guidelines for accepted practice for a high INR (above 4.5) where the INR should be checked again within 24 hours • He acknowledged in the [software system] doctor reviews for dosages outside of the accepted range that had not occurred (as noted in Question 1 above) [Mr B] provided advice that he had managed the high INR based on "successful past experience with patients who like [Mr A], had consistent INR results overall, and their INR corrected well after the two missed doses". What was the basis for this "successful past experience" that was a direct contraindication with guideline management? [Mr B] made mention (on more than one occasion in the correspondence provided) that he had asked about whether [Mr A] had been drinking alcohol as a cause for the high INR. No mention was made about the concurrent doxycycline or the medical condition that [Mr A] had as reason to need antibiotics potentially contributing to the high INR.
What was the standard of care/accepted practice at the	Following CPAMS Standing Order Guidelines.

time of events? Please refer to relevant standards/material.	
Was there a departure from the standard of care or accepted practice? No departure; Mild departure; Moderate departure; or Severe departure.	Yes, a severe departure from the accepted practice.
How would the care provided be viewed by your peers? Please reference the views of any peers who were consulted.	I consulted the advice of a colleague and former pharmacy owner who offered the CPAMS programme (…) and she was of the same opinion as myself in relation to the actions of [Mr B] in assessing [Mr A] and providing advice outside of an accepted protocol noting that no identifying information was provided to [the former pharmacy owner].
Please outline any factors that may limit your assessment of the events.	It is unclear whether all 4 safety questions were asked by [Mr B] at each INR test to ensure [Mr B] was aware of dose times, other possible interacting medicines or [Mr A] being clinically unwell. We do not know for sure what recommendation (if any was made) to warfarin dose adjustments when warfarin dose may have been taken prior to the INR test.
Recommendations for improvement that may help to prevent a similar occurrence in future.	A system for ensuring "in house" that a possible drug interaction between a medicine and warfarin in a CPAMS patient is brought to the attention of all pharmacists offering CPAMS services within the pharmacy. Improved pharmacist training in the [software system] programme that focuses on understanding the messaging features of [the software system] and what to do when a doctor hasn't responded to a review request.
Question 4: Whether the co-ordination of care and communication between [the pharmacy] and [Mr A's] GP regarding abnormal INR results was adequate?	
List any sources of information reviewed other than the documents provided by HDC:	Nil
Advisor's opinion:	No the co-ordination of care and communication between [the pharmacy] and [Dr D] was not adequate. The pharmacist concerned ([Mr B]) did not contact the doctor directly and was relying on reply to an email (that it was subsequently discovered was going to an incorrect email address).

What was the standard of care/accepted practice at the time of events? Please refer to relevant standards/material.	Contact the doctor directly if the INR is outside the accepted range of 1.5–4, do not rely on reply to an email i.e. phone them and if not able to speak to them directly get a message for them to phone back urgently regarding "named patient".
Was there a departure from the standard of care or accepted practice? No departure; Mild departure; Moderate departure; or Severe departure.	Yes, severe departure on more than one occasion.
How would the care provided be viewed by your peers? Please reference the views of any peers who were consulted.	I consulted the advice of a colleague and former pharmacy owner who offered the CPAMS programme (…) and she was of the same opinion as myself in relation to significant departure from acceptable practice with regard to care co-ordination and communication between parties involved.
Please outline any factors that may limit your assessment of the events.	Nil
Recommendations for improvement that may help to prevent a similar occurrence in future.	Whether an email back into [the software system] software advising that an email was not delivered e.g. because of an incorrect email address is possible. Whether a warning could be put on the … software that when a pharmacist overrides a recommendation when the INR is above 4.5 the warning flashes stating you are working outside recommended guidelines and do you wish to continue and you have to acknowledge this warning.
Question 5: Whether [the pharmacy's] remedial actions and response to the incident was appropriate?	
List any sources of information reviewed other than the documents provided by HDC:	Nil
Advisor's opinion:	First response dated 11 February 2022 … Lack of attention to detail where the addressee's name is spelt incorrectly in the salutation "Dear Mrs …" when the name is … Still incorrectly spelling the [first] name of the doctor involved i.e. … rather than … when this had previously been identified as one of the problems of communicating with the doctor for alert warnings as the email was not delivered because of this spelling error. Factually incorrect where it states that "to achieve a dose of 2.33mg the dosing regimen included alternating daily

	doses of 3mg (three 2mg tablets) with 2mg (two 1mg tablets) to create an average dose of 2.33mg". This would achieve an average dose of 2.6mg. To achieve 2.33mg the patient would be instructed to take 2mg/3mg/2mg/2mg/3mg/2mg/2mg i.e. 16mg in a week. The review process as set out in the CPAMS standing order will only work if the email address is correct. After no acknowledgement on the first occasion of a low INR (17/8) best practice would be to check that the email was correct or ring the doctor directly rather than just assuming/concluding that the doctor was happy on 2 separate occasions (17/8 and 19/8). The response implies that the doctor was at fault when in fact the pharmacy was sending emails (via the … software) to an incorrect email address. Acknowledgement is provided in response 11Feb22 that [Mr B] should have contacted [Dr D] directly and spoken with him as per the CPAMS Standing Order. Acknowledgement is provided that the email address the pharmacy was using was incorrect at the time the review warnings were being sent thus [Dr D] would not have received the messages but the test results would still have gone into his PMS. Date stated in response letter of December when a call was received from [Mrs A] is inconsistent with timelines — likely a typo and should read September. Actions taken included making the pharmacist read and understand how to manage high INRs from CPAMS training notes and monitoring (in the background) all INR tests done by [Mr B] to make sure correct procedures were being followed — how was this monitored in the background and how did the pharmacy owner ensure [Mr B] knew how to manage high (or low) INRs safely? What was documented in relation to this? Were any notes made in [Mr B's] employment records? Was an error documented and the outcome discussed at a staff meeting to avoid future mistakes like this? Second response letter dated 8 September 2023 … 1. c) Not a correct response to the question as on 10 Nov 2020 the INR result was 1.4 (outside of accepted range). The average daily dose was not changed and one week later (17 Nov 2020) the INR

	was 2.8. This example could have been used to base the recommendation of 17 Aug 2021 and 19 Aug 2021 on rather than increasing the average daily dose to 2.33 on both occasions. 2. Advice provided is inconsistent with previous advice letter where owner/pharmacist [Mr C] had said after this event he monitored ALL tests done by [Mr B] in the background. 3. Positive change implemented on how to manage INRs outside of range. Is this documented in the orientation package of new Pharmacists who offer CPAMS?
What was the standard of care/accepted practice at the time of events? Please refer to relevant standards/material.	I do not believe so. As the owner of a business which is contracted to provide the CPAMS service you are responsible for ensuring your staff provide safe and appropriate services. Deflecting responsibility is not an accepted practice.
Was there a departure from the standard of care or accepted practice? No departure; Mild departure; Moderate departure; or Severe departure.	Yes, moderate–severe departure. Acceptance of departure from standard is acknowledged for high INR and email being incorrect is acknowledged as being part of the problem. The response should, however, include actions taken to avoid a mistake like this occurring in the future and should be documented. Deflecting responsibility is not accepted practice. How will this pharmacy ensure this does not happen in the future with any other pharmacists? What processes have changed?
How would the care provided be viewed by your peers? Please reference the views of any peers who were consulted.	Outside of accepted practice.
Please outline any factors that may limit your assessment of the events.	I do not know what was documented at the time in the pharmacy in regard to remedial actions/advice. [Mr B] was an accredited CPAMS provider according to the owner of [the pharmacy]. Was he the only one on site? How experienced was he with the CPAMS service? Report mentioned in 8 Sep 23 response showing who did INRs and what was reviewed/edited/sent only shows 9Jun21–17Sep21 What systems are in place at [the pharmacy] to ensure a similar event does not happen again?

Recommendations for improvement that may help to prevent a similar occurrence in future.	Annual check on email addresses for CPAMS referring doctors to ensure they are correct. Buddy system to ensure out of range INRs are seen by more than one pharmacist noting that [Mr B] seemed to be the only pharmacist involved in [Mr A's] INR management over 17 August 2021–7 September 2021 when 3 tests fell outside of accepted guideline management.
Name: Julie Kilkelly Date of Advice: 15 March 2024'	

Appendix B: CPAMS Standing Order

STANDING ORDERS FOR THE MANAGEMENT OF WARFARIN
Dose adjustment and INR testing frequency

Applicable to: Pharmacists Standing Order used for the Community Pharmacy Anticoagulant Management (CPAM) Service **24 October 2013**	Issued by: Medical Advisor, Community Pharmacy Anticoagulation Management Service Contact: [redacted]

Purpose

To improve the safety of warfarin management by providing anticoagulant control through a pharmacist led service using point of care testing (CoaguChek XS Plus) and online computer decision support (INR Online Ltd).

The standing order is required to enable pharmacists to supervise anticoagulant management, and must be signed by the general practice prior to commencing services.

Scope

Accredited pharmacists who are participating in the Community Pharmacy Anticoagulation Management (CPAM) Service.

Medicine

Name of Medicine
Warfarin

Indications
Anticoagulation therapy initiated or confirmed by a doctor for:

1. Atrial Fibrillation
2. Deep vein thrombosis
3. Pulmonary Embolus
4. Tissue Heart valve
5. Mechanical Heart valve
6. Mural thrombus
7. Transient ischaemic attack
8. Post myocardial infarction

Method of Administration: Oral
Dosage : see below

Contraindications

1. High risk of haemorrhage: active ulceration, overt bleeding of gastrointestinal, genitourinary or respiratory tracts, cerebrovascular haemorrhage, cerebral aneurysm.
2. Pregnancy.

Side effects

- High incidence of drug interactions
- Haemorrhage; GI upset; fever; dermatitis; urticaria; alopecia. hypersensitivity.

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Test Procedure	**Consent** All patients must be referred to the pharmacist anticoagulant management service by the prescribing doctor. All patients must give informed consent. **Safety** All patients are to be asked about signs and symptoms of bleeding (haematuria, blood in bowel motions, severe bruising, mucosal haemorrhage etc). - If there is minor bleeding the doctor should be informed and the patient reviewed if necessary. - If the patient has significant bleeding the doctor should be informed immediately. All patients are to be asked about new medication including OTC medications and/or other complementary medicines since the previous INR test. - If a significant interaction is identified the doctor should be informed and the patient reviewed if necessary. All patients are to be asked about warfarin compliance. - If a significant number of doses have been omitted the doctor should be informed. All patients are to be asked if they have been admitted to hospital since their previous INR test. Details of the reason for admission will be recorded.
Referral criteria for new patients	**Referral criteria for new patients** Referral to the service is at the discretion of the General Practitioner. If the doctor believes a specific patient requires close supervision, the doctor should indicate this to the pharmacist and arrange a process of individualised "shared care". This could involve more frequent consultation with the doctor during the period of instability.
Criteria for discontinuing services	**Criteria for discontinuing services and referral back to general practice** Once a patient is referred to the CPAM service it is best practice that they remain with pharmacist management unless the doctor or pharmacist elects to remove them, or the patient chooses an alternative service, or the medication is discontinued or replaced. The patient should only be referred back to the GP after consultation between the GP and pharmacist. The reasons for referral back to the GP care are most likely to relate to poor control or poor compliance. Where possible, a shared care arrangement with close supervision should be considered.
Dose Adjustment	**Dose recommendation** Dose recommendation and interval to next INR test to be determined using INR Online software at the time an INR result is entered from the point of care device (CoaguChek XS Plus with direct data connection).

The recommended dose can be accepted by the supervising pharmacists if the INR is within a specified range.

Parameters for warfarin adjustment

- All patients must have a specified target INR and treatment range
- An upper and lower INR value that will trigger a REVIEW must be set for each patient.
- The default values: lower INR – 1.5 upper INR – 4.0 will be used unless otherwise specified by the doctor.
- The pharmacist can accept the dose recommendation made by INR Online for INR values between the lower and upper limits.
- INR values outside the upper and lower limits will be referred for review by the doctor.
- An INR >4.5 will automatically advise the patient to miss 1 dose of warfarin and recommend a test the following day.
- The pharmacist can contact the supervising doctor and discuss any dose recommendation if he or she believes that the dose recommendation is inappropriate for the patient.
- The pharmacist must document in the notes box in INR Online the reasons for any deviation in dose recommendation

Test interval

- A maximum test interval must be set for each patient. **The default value of 28 days will be used unless otherwise specified by the doctor**. For patients with stable control the maximum interval can be increased to 42 days after consultation with the doctor.
- The test interval varies depending on the patient's anticoagulant control.
- The system automatically reduces the test interval when the INR is outside the treatment range. The test interval increases in a step wise manner if the INR remains in range up to the maximum (42 days).
- The pharmacist can recommend a shorter test interval at anytime if he or she believes an earlier test is appropriate.
- The pharmacist must document in the notes box in INR Online the reasons for any deviation in the test interval recommendation.

The pharmacist will provide the patient with advice about the warfarin dose and the date of the next INR test, and provide a printed dosing calendar.

Starting warfarin

The INR Online software provides a protocol to assist with warfarin loading and initial stabilisation.

This stage of treatment can be supervised by the pharmacist, but close consultation with the supervising doctor is recommended.

Review process

Where the INR is outside the specified range, the INR-Online software will automatically set the result for review:

- The pharmacist can accept the recommended dose from INR Online and advise the patient that the result has been sent for review by their doctor.

The patient is advised to continue on the recommended dose unless they are informed otherwise. If their doctor wishes to modify the dose they will be informed of the change either by e-mail or by telephone by the pharmacist.

Medical Review

Medical review

If a patient has an INR result outside the specified safe range, the supervising doctor will be informed by e-mail. The contents of the message will include:

- The latest INR result
- The recommended dose
- The date of the next test
- A graph showing recent warfarin control
- A list of previous results to enable the doctor to appropriately review the new dose.
- A link to open INR Online on the appropriate page to enable the doctor to edit the dose or date of the next test.

The doctor has two options on reviewing the result:

1. Acknowledge result
   - If the doctor agrees with the recommendation made by the INR Online software or the pharmacists, the doctor will need to acknowledge that the result has been seen by clicking on a link in the notification. No further action will need to be taken. The patient will have been informed of the dose and the date of the next test.
2. Modify the recommendation
   - If the doctor wishes to modify the dose or date of next test a web-page link is provided in the review message to take the doctor directly to the review page.
   - The doctor can then change the dose or date of the next test and confirm the change.
   - The pharmacist who entered the result will automatically be notified by e-mail that the dose or date has been changed. If the patient has e-mail the patient will also be informed.
   - The doctor does not need to take any further action.
   - The responsibility to inform the patient rests with the pharmacist.

The review must be completed within 24 hours of the INR test.

Warfarin Reversal

Managing High INR Results

- All INR results >4.0 will trigger a review message to the doctor
- If the INR is >4.5 INR Online will recommend missing a dose and repeating a test the following day
- If the INR is >5.0
  - INR Online will provide advice for warfarin reversal in line with the Australasian Guidelines (Appendix 2).
  - All results should be discussed with the supervising doctor
  - If the guidelines recommend treatment with vitamin K, this must be discussed with the supervising doctor. Vitamin K can only be given

with authorization from the supervising doctor.

- IF A PATIENT HAS SIGNIFICANT BLEEDING
  - Refer to the hospital immediately.
  - Inform the supervising doctor.
  - Consider giving 10mg oral vitamin K if there is significant travel time to the nearest hospital. Vitamin K can only be given with authorisation from the supervising doctor.

NB: Significant bleeds include: Blood in the urine, Blood in the bowel motions, A prolonged nose bleed, large bruises (bigger than 4cm in diameter).

Many patients on warfarin have minor bleeds, such as gum bleeding, spotting from the nose, or easy bruising. These do not need urgent attention.

Record keeping

Recording results
The INR result, dosage of warfarin and testing interval are to be recorded in the INR-Online software and the same information will be sent automatically to the doctor's patient management system and the Laboratory Test Repository, if available, via HealthLink.

INR Online automatically records the date, time and user, when results are entered or any changes made.

Adverse events are recorded during the assessment prior to each test and additional information can be recorded in a notes field with each INR test.

Countersign period

The Doctor initiating anti-coagulation therapy will sign off treatment. Sign off will take place every 3 months at the time a new warfarin prescription is provided.

Training and Competency Assessment

Prior to administering Warfarin dose titration under this Standing Order, Accredited pharmacists are required to have:

- Attended a Standing Order education session
- Completed the INR-Online training session
- Completed CoaguChek XS Plus Competency Training

Process for audit and review

The issuer will review the Standing Order at least **once a year**.

Pharmacies must also **annually** review they are operating according to this Standing Order.

Programme data will be monitored, and adverse events related to the Service will be reported to CARM or other relevant body by the Clinical Director.

Responsibility for Review

[redacted] is responsible for review of this Standing Order.

Time period for which the Standing Order is valid

This Standing Order is valid until it is replaced by a new Standing Order or cancelled by the issuer.

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Limitations	This standing order only applies to Pharmacists who are accredited to provide community pharmacy-based anticoagulant management services and who have a current agreement with the DHB to provide community pharmacy services.

Standing order prepared by

[redacted]

In collaboration with

[redacted]

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

Consent

By signing this standing order you are consenting to allowing patients at this practice to continue management of their warfarin using a Pharmacy based anticoagulant management service.

I confirm I have read these Standing Orders, and consent to referring selected patients in the practice to _____Pharmacy for Community Pharmacy Anticoagulation Management Services.

NB – this Standing Order may be signed by the practice Clinical Director on behalf of all medical practitioners in the practice, or alternately signed by each GP.

GENERAL PRACTICE: _____

Name of doctor:.....

Signed:.....Date:.....

Name of doctor:.....

Signed:.....Date:.....

Name of doctor:.....

Signed:.....Date:.....

Name of doctor:.....

Signed:.....Date:.....

Name of doctor:.....

Signed:.....Date:.....

Annual Review[1] of the Standing Order by the Issuer

Date	Person reviewing the Standing Order on behalf of the General Practice	Signature

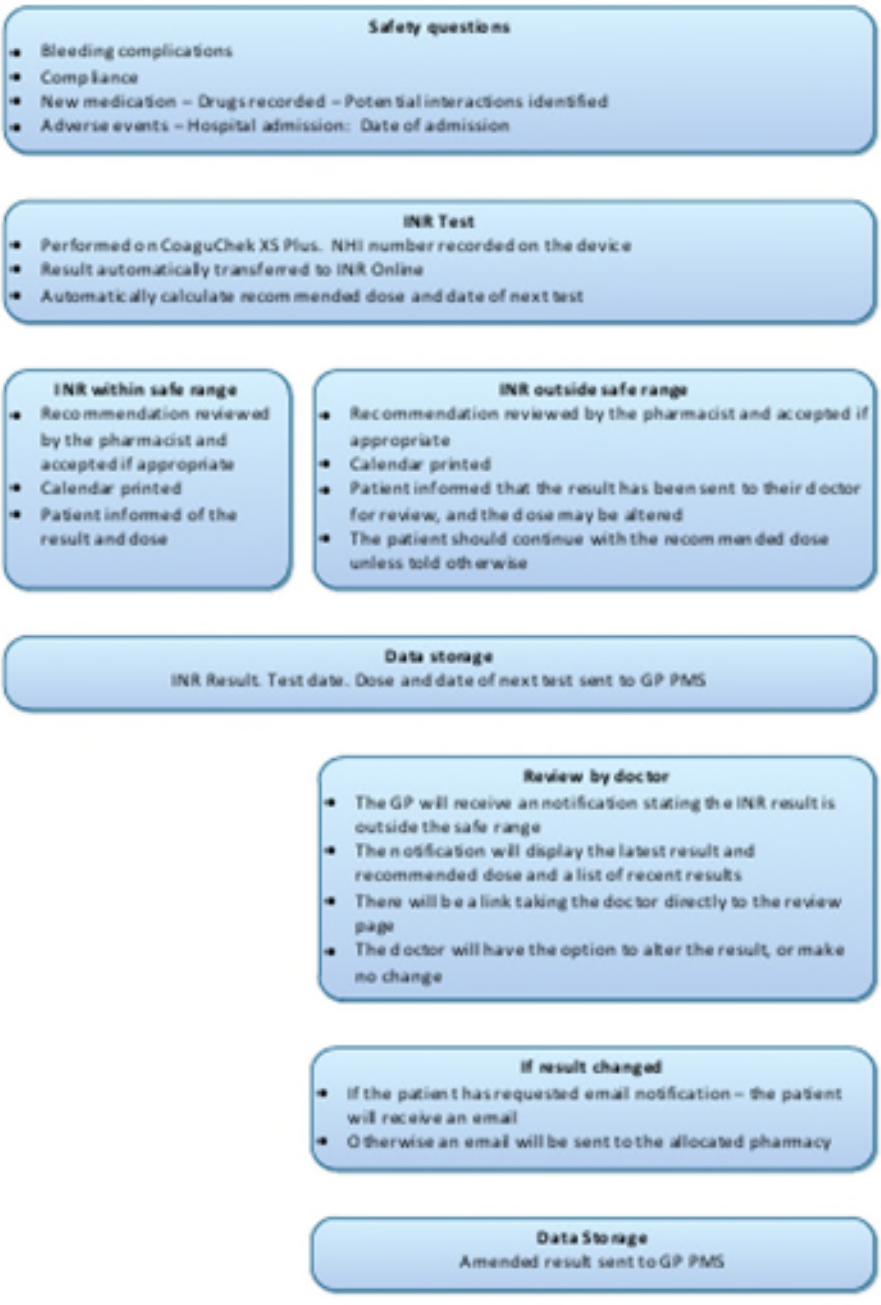
[1] Annual review of the Standing Order by the Issuer is a requirement in the *Medicines (Standing Order) Regulations 2002*.

Appendix 1

Summary of the testing process

The patient attends their allocated pharmacy.
The patient is interviewed by the pharmacist.
The patient is identified on INR Online (search by NHI or name)

CPAMS – Overview of the Test Process



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Appendix 2

Guidelines for the management of an elevated international normalized (INR) in adult patients with or without bleeding

Clinical Setting	Action
INR higher than the therapeutic range, but <5.0; bleeding absent	- Lower the dose or omit the next dose of warfarin. Resume therapy at a lower dose when the INR approaches the therapeutic range. - If the INR is only minimally above the therapeutic range (up to 10%), dose reduction may not be necessary.
INR 5.0-9.0[1]; bleeding absent	- Cease warfarin therapy; consider reasons for elevated INR and patient-specific factors. - If bleeding risk is high, give vitamin K[2] (1.0-2.0mg orally or 0.5-1.0mg intravenously). - Measure INR within 24 hours, resume warfarin at a reduced dose once INR is in therapeutic range.
INR >9.0; bleeding absent	- Where there is a low risk of bleeding, cease warfarin therapy, give 2.5-5.0mg vitamin K[2] orally or 1.0mg intravenously. Measure INR in 6-12 hours, resume warfarin therapy at a reduced dose once INR <5.0. - Where there is a high risk of bleeding[3], cease warfarin therapy, give 1.0mg vitamin K[2] intravenously. Consider Prothrombinex-HT (25-50IU/kg) and fresh frozen plasma (150-300mL), measure INR in 6-12 hours, resume warfarin therapy at a reduced dose once INR <5.0.
Any clinically significant bleeding where warfarin-induced coagulopathy is considered a contributing factor	- Cease warfarin therapy, give 5.0-10.0mg vitamin K[2] intravenously, as well as Prothrombinex-HT (25-50IU/kg) and fresh frozen plasma (150-300mL), assess patient continuously until INR <5.0, and bleeding stops[4]. OR - If fresh frozen plasma is unavailable, cease warfarin therapy, give 5.0-10.0mg vitamin K[2] intravenously, and Prothrombinex-HT (25-50IU/kg), assess patient continuously until INR <5.0, and bleeding stops[4]. OR - If Prothrombinex-HT is unavailable, cease warfarin therapy, give 5.0-10.0mg vitamin K[2] intravenously, and 10-15ML/kg of fresh frozen plasma, assess patient continuously until INR <5.0, and bleeding stops[4].

1. Bleeding risk increases exponentially from INR 5 to 9. INR greater or equal to 6 should be monitored closely.
2. Vitamin K effect on INR can be expected within 6-12 hours.
3. Examples of patients in whom the bleeding risk would be expected to be high include those with active gastrointestinal disorders (such as peptic ulcer or inflammatory bowel disease), those receiving concomitant antiplatelet therapy, those who underwent a major surgical procedure within the preceding two weeks, and those with a low platelet count.
4. In all situations carefully reassess the need for ongoing warfarin therapy.

Ref: R I Baker, P B Coughlin, Al S Gallus, P L Harper, H H Salem and E M Wood. The Warfarin Reversal Consensus Group. Warfarin reversal: consensus guidelines, on behalf of the Australasian Society of Thrombosis and Haemostasis. MJA 2004; 181: 492–497

Appendix 3

Procedure to manage patients when unable to communicate with INR Online

The following procedure should be followed if access to INR Online is interrupted due to local computer problems, lost internet connection, problems with the INR Online server, or the INR Online program stops running.

1. Interview patient and record as a hard copy any missed medication, history of bleeding since the last visit, new medication since the last visit and any hospital admissions.

2. Perform the INR test as usual on the CoaguChek XS Plus. Enter the NHI number if known. If the patient does not know their NHI Number perform the INR test without a reference number.
3. Record the following information as a hard copy
   - Patient's name,
   - NHI number (if known) or date of birth
   - Present warfarin dose
   - INR result
   - Patient's GP details

INR within the therapeutic range

If the INR is within the therapeutic range, advise the patient to continue on the same dose and recommend a dose interval the same as the previous interval.
Record the dose recommended and the date of the next test

If the INR Is outside the therapeutic range
Warfarin dosing is the responsibility of the patient's general practitioner. You should therefore contact the GP practice, advise them that you are unable to contact INR Online and require dosing advice.
The dose recommendation from the doctor and the date of the next test should recorded and the patient should be contacted with this information.

If the INR is >4.5, advise the patient to miss a warfarin dose and repeat the INR the next day.

When access is resumed
The missing results should be entered into INR online.

Enter the results by using the *add result* tab on the top of the left-hand column on the overview page.
This will ensure that the results are sent to the doctor's PMS and an e-mail will be sent to the patient.

When you enter a result the computer will recommend a new dose. Edit this to the dose you gave and edit the recommended date of the next test to the date you recommended. Then confirm the result.

DO NOT ENTER THE MISSING RESULT USING THE *EDIT RESULT* TAB. If you do, the result will not be sent to the doctor's PMS and the patient will not receive an e-mail.

Appendix 4

Procedure for the management of non-compliant patients

Note: The responsibility for the patient's warfarin management rests with the supervising doctor.

It is important that the supervising doctor is informed if a patient is a regular poor complier. It may be appropriate for the doctor to reassess the risks and benefits of warfarin in such cases and may recommend discontinuing warfarin if the risk of poor compliance is assessed to be potentially dangerous.

The following is a recommended procedure for managing non-attenders. Where possible we suggest this is followed but individual patient circumstances must be considered with these recommendations. It is important to document all deviations from the procedure and to maintain good communication with the supervising doctor.

Procedure if patient fails to attend for INR testing on the specified date

- As a general rule the patient should go no more than 6 weeks between tests.
- If the patient fails to attend within 3 days of the specified test date, the patient should be contacted by phone to remind the patient that the test is due.
- If the patient fails to attend within 4 to 6 days of the first reminder, a second call should be made to the patient.
- If the patient fails to attend within 1 week of the second reminder, the patient should be contacted a third time and the patient's doctor should be informed that the test is 2 weeks over due and a maximum of 6 weeks since the last test and you will only send further reminders at the doctor's request. Further follow up of the patient is the responsibility of the doctor.
- Each contact with the patient and the doctor should be documented in INR Online.
- If a patient presents for a test more than 2 weeks after the expected date of the test, the test should be performed and the doctor should be informed.
- If a patient regularly fails to attend on time, discuss management with the supervising doctor.