General Practitioner, Dr C

Medical Centre

A Report by the

Health and Disability Commissioner

(Case 16HDC01215)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. Ms A was a patient of a medical centre. On 23 April 2015, she presented to locum doctor Dr C. During the consultation a laboratory form was provided for routine blood tests, which included HbA1c (a test for diabetes).

2. The tests were carried out later that day, and the HbA1c result was 53mmol/mol. A result of 53 in an asymptomatic person raises the possibility of a diagnosis of type 2 diabetes. The laboratory results form stated that to confirm the result, the test needed to be repeated in three months' time.

3. On 24 April 2015, Dr C saw and noted the result and the "task" of reporting the results to the patient was noted as being "completed".

4. Dr C printed a results template letter from the medical centre's IT system and saved it electronically in Ms A's clinical notes. The saved electronic letter had not been amended to remove the options that did not apply to Ms A, and did not include any typed advice or instructions.

5. It is not known whether Dr C made an indication on the form such as ticking one statement, whether several statements were crossed out, whether she handwrote a personal message on the form, or whether nothing was carried out once printed and therefore nothing sent. Because a paper copy was not scanned back into Ms A's patient notes, it is now not possible to identify from the outbox record or from Ms A's medical notes, what Dr C reported via the form, if anything.

6. Ms A did not receive any information about her HbA1c test.

7. In addition, Dr C did not enter a follow-up reminder into the system regarding Ms A's test needing to be repeated in three months' time.

8. The usual practice at the medical centre was that doctors added a "task" in the patient's task list on Medtech if they needed to follow up a patient's abnormal result. The "task" would remain until the doctor marked the "task" as having been completed. Usually the action taken was also recorded by the doctor.

9. The medical centre has since changed the process of how patients are advised of their results. Telephoning and text messaging the patient are used as the first method of contact, and a letter is sent only if those options are not available. If a letter is used, the system now requires that an electronic entry is made and saved in the system with the changes that have been made to the template to reflect the particular patient's circumstances. The change in process means that a blank template letter cannot be saved against a patient on the system.

Findings

10. On receipt of the test results, Dr C had the responsibility to ensure that appropriate management of that result (which was elevated) was facilitated. Dr C failed to ensure that the systems already in place were followed to ensure that the test was repeated. Without entering into the system any follow-up reminder regarding the test needing to be repeated in three months' time, there was no way for this to occur. It was found that Dr C's clinical

management of Ms A's elevated HbA1c result was deficient and, accordingly she was found to have breached Right 4(1) of the Code[1].

Complaint and investigation

11. The Commissioner received a complaint from Ms B about the services provided to her mother, Ms A, by general practitioner (GP) Dr C at the medical centre. The following issues were identified for investigation:

- *Whether Dr C provided Ms A with an appropriate standard of care between April 2015 and June 2015.*
- *Whether the medical centre provided Ms A with an appropriate standard of care between April 2015 and August 2016.*

12. This report is the Opinion of Kevin Allan, Deputy Commissioner, and is made in accordance with the power delegated to him by the Commissioner.

13. The parties directly involved in the investigation were:

Ms A	Consumer
Ms B	Complainant
Dr C	Provider/GP
The medical centre	Provider/medical practice

14. In-house clinical advice was obtained from general practitioner Dr David Maplesden (**Appendix A**).

Information gathered during investigation

Background

15. Ms A was a patient of the medical centre. She had a history of hypertension (high blood pressure), for which she was receiving medication and monitoring.

16. Dr C was working as a locum doctor at the medical centre at the time of these events. Previously she had trained and worked overseas, and had commenced work at the medical centre in 2013. She is no longer resident in New Zealand, and currently is practising overseas.

17. The medical centre told HDC that patients are not enrolled with a specific GP, but rather are enrolled with the clinic. However, it said that normally patients would be seen by the same

[1] Right 4(1) of the Code states: "Every consumer has the right to have services provided with reasonable care and skill."

doctor, but that because of staff shortages, up until recently often patients were seen by different doctors.

Diabetes test and result

18. On 23 April 2015, Ms A presented to Dr C at the medical centre, primarily for a repeat prescription of her usual blood pressure medications. In addition, multiple issues were addressed during the consultation, including a history of low impact fractures and the possibility of osteoporosis; blood pressure control; and issues with weight. A laboratory form was provided for routine blood tests, which included HbA1c (a test for diabetes).

19. The tests were carried out later that day, and the HbA1c result was 53mmol/mol. A result of 53 in an asymptomatic person without a history of diabetes raises the possibility of a diagnosis of type 2 diabetes, but requires further testing for confirmation. The laboratory results form stated that to confirm the result, the test needed to be repeated in three months' time.

20. An audit trail shows that on 24 April 2015, Dr C saw and noted the result, which she annotated at the time in the system as "53". The medical centre said that the "task" of reporting the results was noted as being "completed" on 24 April 2015.

21. The medical centre told HDC that on 24 April 2015, the template letter (below) was printed from the medical centre's IT system and saved electronically by Dr C in Ms A's electronic clinical notes. The saved electronic letter had not been amended to remove the options that did not apply to Ms A, and did not include any typed advice or instruction.

Dear

We have received your lab results.

___ Your results are within normal tolerances.

___ Please phone the surgery.

___ Please make an appointment to see the nurse.

___ Please make an appointment to see the doctor.

If any concerns please make a GP appointment to discuss your results.

Kind regards

22. On 25 April 2015, Ms A's test results were filed electronically in the medical centre's patient management system (Medtech).

23. Ms A said that she did not receive any information about her HbA1c test, and therefore assumed that everything was normal. Ms A's daughter, Ms B, told HDC that the address where Ms A was living during this time was different from the address on the medical centre's records for this date.

24. At the time of these events, the medical centre had a "Test Results and Tracking Policy" and a policy and procedure document "Test Results Policy and Procedure". The Test Results and Tracking Policy's stated aims were:

> "To ensure that all test results have been sighted by the Medical staff and appropriate follow up, and filing of result, has occurred.
>
> To ensure that all patients are recalled as appropriate, in regard to abnormal results.
>
> To ensure that all patients are notified of test results where this is appropriate.
>
> To ensure that recall and screening information is initiated/updated where appropriate."

25. The Test Results and Tracking Policy outlined that all laboratory results were downloaded into the doctor's inbox. The doctor was then to "action" the results in the medical centre's patient management system (Medtech). This included notifying the patient. The results and the action taken were to be recorded, and the doctor was then to file the laboratory results into Medtech. There was also a comment box, in which doctors were to state what advice they had given to the patient (regarding the test results), so that this was entered into the record.

26. The usual practice at the medical centre was that doctors added a "task" in the patient's task list on Medtech if they needed to follow up a patient's abnormal result. The "task" would remain until the doctor marked the "task" as having been completed. Usually the action taken was also recorded by the doctor.

27. The medical centre told HDC that when Dr C requested Ms A's laboratory tests on 23 April 2015, she made an entry on the "completed tasks list" showing that the tests were carried out on 23 April 2015, and added a task in Medtech to ensure that she verified that the results were reported to Ms A.

28. The Test Results and Tracking Policy documented that clinicians were to advise their patients of their results via either telephone or letter. The medical centre told HDC that the usual process in place at the time for notifying patients of results consisted of a template letter (a copy of which is above). The clinician was to use the template by removing the options that did not apply to the patient's results prior to printing, signing and sending.

29. Often a personal message particular to the patient was also entered on this letter electronically prior to printing. An electronic copy of what was sent was to be retained on the file.

30. Dr C told HDC that usually she would delete the options provided on the template and type her own instructions/results in the letter for patients.

31. Due to the system in place at the time, there was potential for the above letter to be printed and for the clinician to tick one of the options by hand. In such circumstances, if no copy of the original document were made, then only the above letter would be saved, without any indication of what had been entered by hand (as occurred in this case). The medical centre told HDC that this process, although possible, was contrary to usual practice and the guidelines in place at the time.

32. Dr C cannot recall these events, and does not recall what she did in relation to informing Ms A of her results. Dr C believes that she would not have sent a blank form (with nothing ticked) and would never knowingly have reported the result as normal. She told HDC:

> "I would have marked in one of the 4 spots indicating what the evaluation/recommendation was. That copy would also have been signed by me. Without a copy of the actual note sent to [Ms A] it is impossible for me to comment on what was or was not communicated."

33. It is not known whether Dr C made an indication on the form such as ticking one statement, whether several statements were crossed out, whether she handwrote a personal message on the form, or whether nothing was carried out once printed and therefore nothing sent. Because a paper copy was not scanned back into Ms A's patient notes, it is now not possible to identify from the outbox record or from Ms A's medical notes, what Dr C reported via the form, if anything.

34. The medical centre's Test Results Policy and Procedure document stated: "In cases where a GP suspects that the results will be clinically significant, additional safeguards in the form of patient alerts must be implemented to ensure that potentially clinically significant information does not get 'lost in the system'."

35. Dr C did not enter a follow-up reminder into the system regarding Ms A's test needing to be repeated in three months' time. In addition, as Dr C had marked the task list as having been completed (regarding informing the patient of her result), there was nothing to alert other clinicians of the need to review the outcome of the result notification.

36. Dr C told HDC that, as she left the medical centre shortly after these events, follow-up by other providers would have been expected. She told HDC that, following Ms A's visit, the majority of her time at the medical centre was "spent wrapping things up and arranging follow up for my patients with the different providers remaining at [the medical centre]".

Further visits to the medical centre

37. Ms A had further interactions with several nurses and doctors at the medical centre from 2 June 2015 to 25 May 2016. Ms A's HbA1c result from 24 April 2015 and the fact that a follow-up test had not been carried out was not known or discussed at these appointments.

38. There is no reference to any symptoms associated with diabetes in any of these consultations.

39. The medical centre told HDC that standard practice at any consultation is that the doctor would review the notes and address any outstanding issues.

40. The medical centre told HDC:

> "With respect to the presence in the notes of an elevated HbA1C, desirable management would be that at the next contact, that item would have been reviewed. This is unlikely to happen unless the item in some way had attention drawn to it. Good practice would be to bold an entry in the clinical notes. However, in this case it appears that the abnormality was overlooked, so there is nothing in the notes to indicate there

was an abnormal result. This would mean that a filed result would be relatively invisible unless the clinician specifically looked for it."

41. On 29 July 2016, Ms A had a walk-in consultation with a registered nurse (RN) with symptoms of a respiratory infection. Treatment was provided and, as part of this consultation, screening blood tests (including HbA1c) were undertaken. Ms A's HbA1c result was elevated at 73.

42. On 2 August 2016, Ms A was notified that her results showed that she had diabetes, and she was asked to make an appointment with a nurse urgently to discuss this.

43. On 3 August 2016, Ms A was seen by another RN for lifestyle advice regarding diabetes. It is documented that Ms A was upset at having been informed that she had diabetes, owing to having been tested previously and not having had anything said to her regarding the result.

44. The RN reviewed Ms A's notes and noted the previous result from April 2015. The RN apologised to Ms A that she had not been notified at the time that she had an elevated result.

45. The medical centre has since changed the process of how patients are advised of their results. Telephoning and text messaging the patient are used as the first method of contact, and a letter is sent only if those options are not available. If a letter is used, the system now requires that an electronic entry is made and saved in the system with the changes that have been made to the template to reflect the particular patient's circumstances. The change in process means that a blank template letter cannot be saved against a patient on the system.

46. Ms A is now on appropriate diabetes management, and her HbA1c has improved.

Other information

47. The medical centre told HDC that, at the time of these events, locums were provided with an "orientation to the practice" package when they started work at the clinic. The medical centre said that Dr C received peer orientation on commencement, and that review of policies is an expectation for all clinicians. This is outlined with the employer/employee agreements as a standard obligation. In addition, a weekly peer review process was in place with an independent senior GP, who provided peer review of cases and clinical management while Dr C settled in.

48. Other examples of Dr C's usual process around reporting of abnormal results (prior to Ms A's) were provided to HDC. Detailed and appropriate reporting was identified, with the correct retention of an electronic version. In line with what Dr C said was her usual practice, these contained a personal message saved electronically on the records. The medical centre told HDC that there are no other instances where a results letter has been saved with no indication as to what was recorded on the form.

49. Following these events, the medical centre performed an audit of all patients with an HbA1c over 50 to ensure that no other results had been overlooked. In addition, it now checks on an annual basis to ensure that no patient with an abnormal result has been overlooked. It also reviewed its processes regarding the management of results, and has now instituted a double-check system for locum doctors.

50. The medical centre has also changed its system so that the "choose an option" type of template letter can no longer be used. In addition, each day, a clinical staff member will filter all abnormal inbox laboratory results and check that they have all been actioned. If not, the person responsible for the result will be advised. The medical centre said that it has tested the system and found it feasible to add it into routine clinical tasks. It also said that this system would have identified Ms A's case as an unmanaged HbA1c result, had the system been in place at the time.

Responses to provisional opinion

51. The parties were all given the opportunity to respond to relevant sections of my provisional opinion. They had no comments to make.

Opinion: Dr C — breach

Communication with Ms A — adverse comment

52. This opinion highlights the importance of the effective and prompt communication of test results by providers to consumers. The primary responsibility for following up abnormal results rests with the clinician who ordered the tests, in this case Dr C.

53. At the time at the medical centre, the usual process in place for notifying patients of results consisted of a pre-formatted letter, which required the doctor to remove all of the statements that were not relevant to the individual patient prior to printing, signing and then sending the letter to the patient. The medical centre said that the intention was for the advice given to the patient to be entered into the Medtech record in the results outbox. The results form in the outbox required a recorded message; it was not meant to be printed with additional handwriting then added to the hard copy.

54. On 24 April 2015, Dr C printed one of the template letters for Ms A. However, when printed, it still contained all the options/statements, and it is not known whether one statement was ticked, whether several statements were crossed out via hand, or whether Dr C took any action at all once the letter was printed.

55. Dr C told HDC that she has no recollection of these events and does not know what she did at the time. She thinks that she would have "marked in one of the 4 spots indicating what the evaluation/recommendation was". She acknowledged that "without a copy of the actual note sent to [Ms A] it is impossible for [her] to comment on what was or was not communicated".

56. I note that there was a deficiency in the medical centre's process at the time, in that the letter could be completed by hand, and thereby result in no electronic record of the advice provided being kept. However, this was contrary to the medical centre's, and Dr C's, usual practice. Other examples of Dr C's usual process around reporting of abnormal results (prior to Ms A's) were provided to HDC, and these examples all showed detailed and appropriate reporting, with the correct retention of an electronic version on the file. I note that the previous option of being able to complete the letter by hand (and therefore not

saving electronically what was sent) is no longer available, and that the system now requires an option to be selected and the amended version of the letter saved.

57. Ms A did not receive any information about her HbA1c test at that time, and told HDC that, as a result, she assumed that everything was normal. If Dr C did send a letter to Ms A, a copy of what was sent was not recorded in the system, contrary to usual practice.

58. As part of this investigation, I obtained clinical advice from HDC's in-house clinical advisor, GP Dr David Maplesden. Dr Maplesden noted that Dr C's "usual" results letters depicted accurate and informative results reporting, and were consistent with expected standards of clinical documentation and communication.

59. I accept that Dr C had an intention to notify Ms A of her abnormal test result and of the need for follow-up, as Dr C generated a template results letter. However, either this was completed by hand and sent (to the wrong address), not completed and not sent, or it was completed by hand and not sent. In addition, there is no electronic record to show what, if anything, was sent to Ms A. After considering all of the information available, I am unable to make a finding about what did or did not happen once the template letter was generated.

60. As the clinician who ordered the test, Dr C had the responsibility to communicate the results and their implications to Ms A. Provision of this information is crucial to enable patients to be partners in their own treatment. While I have been unable to ascertain what occurred, I am concerned that Ms A was not informed of her abnormal result.

Clinical management/recall — breach

61. On 23 April 2015, Ms A presented to Dr C at the medical centre. During the above consultation on 23 April, a laboratory form was provided to Ms A for routine blood tests. One of these was to test Ms A's HbA1c (a test for diabetes). The tests were carried out later that day.

62. On 24 April 2015, Dr C saw and noted the result for the diabetes test, which was "53". The result raised a possibility that Ms A might have diabetes. The laboratory results form stated that to confirm the result, the test needed to be repeated in three months' time.

63. At the time of these events, Dr C had been a locum at the medical centre for nearly a year and a half. Dr C received peer orientation to the medical centre when she first started, and her employer/employee agreement stated that review of policies was an expectation for all clinicians.

64. At the time of the incident, the medical centre had in place policies and procedures regarding the procedure to be followed upon receipt of an abnormal test. Under these policies, follow-up of an abnormal result was to be added to the patient's Medtech task list until completed, and the action that had been taken was to be recorded. In addition, an alert should have been implemented to ensure that follow-up occurred. Dr C marked the action taken as "completed" on 24 April 2015 without recording what action she took, and she also did not enter a follow-up reminder into the system regarding the test needing to be repeated in three months' time.

65. Dr Maplesden advised that "once the 'Task completed' had been ticked (as Dr C evidently did) there was no prompt to further review the outcome of the result notification". Dr Maplesden also advised: "[T]he management of [Ms A's] HbA1c result from April 2015 departed from expected standards of care to a moderate degree despite the relevant written policies [the medical centre] had in place at the time being robust and consistent with accepted standards."

66. While I have been unable to ascertain exactly what action, if any, Dr C took regarding Ms A's results on 24 April 2015, it is clear that, contrary to the medical centre's policies and procedures, Dr C failed to place a follow-up reminder in the practice's Medtech system to ensure that the required repeat testing was requested.

67. On receipt of the test results, Dr C had the responsibility to ensure that appropriate management of that result (which was elevated) was facilitated. Dr C failed to ensure that the systems already in place were followed to ensure that the test was repeated. Without entering into the system any follow-up reminder regarding the test needing to be repeated in three months' time, there was no way for this to occur. In my view, Dr C's clinical management of Ms A's elevated HbA1c result was deficient and, accordingly, I find that Dr C failed to provide services to Ms A with reasonable care and skill, and breached Right 4(1) of the Code.

Opinion: Medical centre — no breach

68. As a healthcare provider, the medical centre is responsible for providing services in accordance with the Code.

69. As set out above, the medical centre had policies outlining how to manage test results. Dr Maplesden advised that the medical centre's relevant policies and procedures, including the policies in place at the time of these events, were robust and consistent with accepted standards.

70. I also considered whether the other clinicians who saw Ms A following her abnormal result should have identified Ms A's requirement for a repeat test, or noted that her abnormal result may not have been reported. After Ms A's diabetes test on 23 April 2015, she had further interactions with several nurses and doctors at the medical centre from 2 June 2015 to 25 May 2016. Ms A's HbA1c result from 24 April 2015 and the fact that a follow-up test had not been carried out was missed at each of these appointments.

71. The medical centre told HDC that there is an expectation at any consultation that standard practice would include a review and update of the patient's notes, and for any outstanding issues to be addressed. In addition to this, the patient dashboard is to be updated to ensure that health target and population health items are being addressed. The medical centre told HDC:

> "With respect to the presence in the notes of an elevated HbA1C, desirable management would be that at the next contact, that item would have been reviewed.

> This is unlikely to happen unless the item in some way had attention drawn to it. … there is nothing in the notes to indicate there was an abnormal result. This would mean that a filed result would be relatively invisible unless the clinician specifically looked for it."

72. It was not until 3 August 2016 that it became apparent to any other clinician at the medical centre that Ms A had been tested for diabetes previously. At this appointment, the previous result from April 2015 was noted for the first time.

73. Dr Maplesden notes that there does not appear to have been any prompt, in terms of presentation with suspicious symptoms, to repeat Ms A's HbA1c or refer to the previous result in subsequent consultations prior to August 2016. In addition, Dr Maplesden advised that once Dr C ticked the tasks as completed (follow-up of result and reporting to patient), "there was no prompt to further review the outcome of the result notification".

74. Accordingly, there was nothing to point the medical centre, including any other clinicians caring for Ms A, to the fact that she had unreported results. In this case, I consider that the errors that occurred did not indicate broader systems or organisational issues at the medical centre. Therefore, I consider that the medical centre did not breach the Code directly.

75. In addition to any direct liability for a breach of the Code, under section 72(2) of the Health and Disability Commissioner Act 1994 (the Act), an employing authority is vicariously liable for any actions or omissions of its employees. A defence is available to the employing authority under section 72(5) if it can prove that it took such steps as were reasonably practicable to prevent the acts or omissions.

76. At the time of these events, Dr C was an employee of the medical centre. Accordingly, the medical centre is an employing authority for the purposes of the Act. As set out above, I have found that Dr C breached 4(1) of the Code.

77. At the time of these events, the medical centre provided its locums with an "orientation to the practice" package, and peer orientation occurred on commencement. In addition, a weekly peer review process was in place with an independent senior GP, who provided peer review of cases and clinical management while locums settled in. Review of the medical centre policies was an expectation for all clinicians, and was outlined in the employer/employee agreements as a standard obligation.

78. The practice was for any abnormal result to be added to the patient Medtech task list until completed, with any action taken needing to be recorded electronically on the file.

79. Initially, my expert advisor, Dr Maplesden, advised: "It seems most likely there was a deficiency of process — perhaps related to the results notification letter being used at the time which lacked clarity." However, further information was provided to Dr Maplesden, including the medical centre's policy and procedure documentation relating to prescribing and handling of clinical correspondence, including laboratory results. Dr Maplesden reviewed the information and advised:

> "The documents appear consistent with similar policies and procedures I have reviewed from other practices and, if followed appropriately, should minimise the risk of prescribing errors and follow-up oversights."

80. As noted above, at the time of the events, the medical centre had in place policies regarding the review and follow-up of tests and results. Dr Maplesden found these to be robust and consistent with accepted standards.

81. While the medical centre has improved its policies and practices to help ensure that the events do not happen again, I am satisfied that at the time of these events, the medical centre had in place appropriate systems and policies, and that the error was caused solely by Dr C not setting a reminder.

82. I note the information provided by the parties involved, and the advice I have received from Dr Maplesden. I am satisfied that the medical centre took reasonably practicable steps to prevent the error from occurring. Accordingly, I do not find the medical centre vicariously liable for Dr C's breach of the Code.

Recommendation

83. I recommend that Dr C provide a written letter of apology to Ms A for the breach of the Code identified in this report. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding.

Follow-up actions

84. A copy of the final report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Medical Council of New Zealand, and it will be advised of Dr C's name.

85. A copy of the final report with details identifying the parties removed, except the expert who advised on this case, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent clinical advice to the Commissioner

The following expert advice was obtained from Dr David Maplesden on 19 September 2016:

> "1. Thank you for the request that I provide clinical advice in relation to the complaint from [Ms B] about the care provided to her mother, [Ms A], by [the medical centre]. In preparing the advice on this case to the best of my knowledge I have no personal or professional conflict of interest. I agree to follow the Commissioner's Guidelines for Independent Advisors. I have reviewed the information on file: complaint from [Ms B]; response from [the clinical director] [at [the medical centre]; [medical centre] clinical notes. The complaint relates to a delay in the diagnosis of [Ms A's] type-2 diabetes due to an apparent deficiency in handling of lab results.
>
> 2. [Ms A] had a history of treated hypertension, hysterectomy and current smoker status when she presented to [the medical centre] locum ([Dr C]) on 23 April 2015. [Ms A] presented for a repeat of her usual blood pressure medications but it appears multiple issues were proactively addressed by [Dr C] including: history low impact fractures and possibility of osteoporosis; blood pressure control; issues with weight. A prescription was provided for [Ms A's] usual blood pressure medications (atenolol and bendrofluazide) together with Vitamin-D supplement and an appetite suppressant (Duromine). There is note that the potential risks of Duromine were discussed in detail. A lab form was provided for routine blood tests which evidently included HbA1c. According to the [the medical centre's] response, [Ms A's] HbA1c result was 53mmol/mol. The result was annotated by [Dr C] and a report sent to the patient stating the result was normal. Subsequently [Ms A] received a repeat script from [Dr C] on 2 June 2015 Duromine — patient not seen) and repeat script for blood pressure medications (provider […]) on 16 July 2015 and for Vitamin-D (AR) on 5 August 2015. She was not seen on these occasions but had face to face contact with a practice nurse on 7 July 2015 in relation to ACC certification for a hand injury. On 23 October 2015 she was seen by [initials] for renewal of blood pressure medications and counselling referral. On 5 November 2015 she was seen by [initials] for assessment of chest discomfort and knee pain and was referred for X-rays and further cardiology assessment. On 14 January 2016 [Ms A] was reviewed by provider [initials] with headache and earache and was prescribed analgesia and an antiemetic. On 11 February 2016 [Ms A] requested (via practice nurse consult) a repeat of her regular medications and a script for lorazepam (recent major stressors) which were provided by [initials]. On 25 May 2016 [Ms A] consulted with provider [initials] for review of a head lump, blood pressure medications and discussion of current stressors. On 29 July 2016 she had a practice nurse consult with symptoms of a respiratory infection and treatment was provided. It appears screening blood tests (including HbA1c) were undertaken as part of this consultation. The HbA1c result was elevated (69 according to response, a level of 73 referred to in consultation note of 3 August 2016) and [Ms A] was notified and seen by the practice nurse for lifestyle advice on 3 August 2016. Metformin was commenced at the same time and [Ms A's] glycaemic control has apparently improved since then. Nurse consultation notes dated 3 August 2016 include: *states ++ symptoms, tired, thirsty, little energy, toilet often, blurry eyesight …*

3. Comments

(i) While there is a reference to symptoms associated with diabetes in the consult dated 3 August 2016 there is no reference to [Ms A] complaining of such symptoms at any prior consultations. I would regard her therefore as being asymptomatic when she was screened for diabetes in April 2015.

(ii) The screening HbA1c performed on 23 April 2015 indicated a need to repeat the test (or perform fasting or random glucose) with further management dependent on the results of that test (see Appendix 1). I cannot predict what the results of a follow-up test (say within the next few weeks) might have been although it seems likely that a diagnosis of either type-2 diabetes or at least 'prediabetes' would have been made with lifestyle advice and follow-up then organised appropriate to that diagnosis. The decision to inform the patient that the result was 'normal' and not take any further action in terms of patient lifestyle education or structured follow-up was a significant departure from expected standards of care.

(iii) There does not appear to have been any prompt, in terms of presentation with suspicious symptoms, to repeat [Ms A's] HbA1c or refer to the previous result in subsequent consultations prior to August 2016. There was perhaps a missed opportunity to detect the oversight when [Ms A] was reviewed with possible cardiac symptoms in November 2015 as a formal cardiovascular risk assessment performed at this point might have prompted recognition of the borderline HbA1c result.

(iv) There was open disclosure regarding the previous 'missed' result when a subsequent elevated HbA1c was detected 29 July 2016, and [Ms A's] management following detection of the result was clinically appropriate.

4. Recommendations

(i) There is no response from provider [Dr C] on file and I am not sure if he/she is available to respond.[2] The issue here is whether treatment of the HbA1c result as normal was simply an oversight (ie intention to follow-up but failure to do this for whatever reason) or whether there is an issue of clinical competency (did [Dr C] not recognise the need to follow-up the result). I think a response from [Dr C] should be sought if possible in an attempt to gain some clarity over why the result was managed as a 'normal' result.

(ii) The clinical notes on file are incomplete. The practice should be asked to provide the following: all blood results on file for [Ms A] from April 2015 to August 2016; all outbox documents including referral letters and letters sent to the patient over the same period; record of annotation of the blood result in question as referred to in the practice response.

(iii) The practice should be asked to provide a copy of their current written policies on handling of laboratory results and provision of repeat prescriptions (particularly repeat prescribing of controlled drugs such as Duromine), noting any changes that have been incorporated since this complaint was received.

[2] Information was later received from Dr C and provided to Dr Maplesden. This is commented on below.

Appendix 1. From: *New Zealand Guidelines Group. New Zealand Primary Care Handbook. 3rd ed. 2012.*

Table 29 What to do following a screening test for type 2 diabetes

Result	Action	Why
Symptomatic		
HbA1c ≥50 mmol/mol **and,** if measured Fasting plasma glucose ≥7.0 mmol/L **Or** Random plasma glucose ≥11.1 mmol/L	No further tests required	Diabetes is confirmed
Asymptomatic		
HbA1c ≥50 mmol/mol **and,** if measured Fasting plasma glucose ≥7.0 mmol/L **Or** Random plasma glucose ≥11.1 mmol/L	Repeat HbA1c or a fasting plasma glucose	Two results above the diagnostic cut-offs, on separate occasions are required for the diagnosis of diabetes*
HbA1c 41–49 mmol/mol **and,** if measured Fasting plasma glucose 6.1–6.9 mmol/L	Advise on diet and lifestyle modification. If over 35 years, a full cardiovascular risk assessment and appropriate management is indicated Repeat the test after 6–12 months	Results indicate 'prediabetes' or impaired fasting glucose*
HbA1c ≤40 mmol/mol **and,** if measured Fasting plasma glucose ≤6.0 mmol/L	Retest at the next cardiovascular risk reassessment interval	This result is normal

* When HbA1c and fasting plasma glucose are discordant with regard to diagnosis of diabetes, repeat testing at an interval of 3–6 months is recommended. The test that is above the diagnostic cut point should be repeated – if the second test remains above the diagnostic threshold then diabetes is confirmed. If the second result is discordant with the first, then subsequent repeat testing at intervals of 3–6 months is recommended. Patients with discordant results are likely to have test results near the diagnostic threshold.

."

Further comment was provided by Dr Maplesden on 26 January 2017:

"(i) Further information was received from locum [Dr C].. She is unable to recall precise details of this incident but is adamant she would not have told [Ms A] that her HbA1c result was normal. She recalls she would usually type her own instruction/results letter for the patient. [Dr C] notes she left [the medical centre] shortly after [Ms A] was notified of her result and follow-up by other providers would have been expected.

(ii) I have reviewed clinical notes supplied by [the medical centre] and these are mostly consistent with the original response. The result in question was annotated '53' and an audit trail indicates [Dr C] annotated the result. The usual process in place at the time for notifying patients of results consisted of a pre-formatted letter (see (iii) below) with options other than the relevant options being removed prior to signing and sending. The letter on [Ms A's] file contained all options and it is presumed by [the medical centre] (but denied by [Dr C]) that the 'Your results are within normal tolerances' section was ticked manually in error and sent to [Ms A]. Since these events the results notification letters have been changed to ensure the retained copy accurately reflects the information provided to the patient.

(iii) Copy of letter presumably sent to [Ms A]:

Dear

We have received your lab results.

___ Your results are within normal tolerances.

___ Please phone the surgery.

___ Please make an appointment to see the nurse.

___ Please make an appointment to see the doctor.

If any concerns please make a GP appointment to discuss your results.

Kind regards

(iv) I have confirmed [Ms A's] HbA1c result on 29 July 2016 was 73 mmol/mol dropping to 69 mmol/mol when repeated on 29 August 2016.

(v) The cardiology referral made on 5 November 2015 (see section 2) was for an exercise tolerance test only, hence no blood results were provided with the referral letter.

(vi) I have reviewed [the medical centre's] policy and procedure documentation related to prescribing and handling of clinical correspondence inclusing laboratory results. The documents appear consistent with similar policies and procedures I have reviewed from other practices and, if followed appropriately, should minimise the risk of prescribing errors and follow-up oversights.

(vii) Final comment: I do not think it is possible to determine unequivocally the circumstances leading to the oversight regarding [Ms A's] HbA1c result of 23 April 2015 leading to a delay in her diagnosis of diabetes. It seems most likely there was a deficiency of process — perhaps related to the results notification letter being used at the time which lacked clarity and which may have been completed incorrectly by [Dr C] (although this cannot be confirmed). The form of this letter has since been altered to minimise misinterpretation or error. It also appears likely that [Dr C] did not use a reminder system (the Medtech Task Manager) recommended in the relevant practice policies to ensure timely follow-up was provided to [Ms A] once the results letter had been sent, given the potential significance of the result. The reasons for this possible oversight are not clear but I think reinforce the need for appropriate orientation of locum staff with an emphasis on practical aspects of the PMS including use of the reminder and alert systems. In summary, I think the management of [Ms A's] HbA1c result from April 2015 departed from expected standards of care to a moderate degree despite the relevant written policies [the medical centre] had in place at the time being robust and consistent with accepted standards. The process of results notification has been improved since this incident (format of results letter) and the incident has been discussed at length by practice staff, and an audit undertaken of HbA1c results. Provided the practice has an adequate locum orientation process in place which covers use of the Task Manager system and the application of this to management of clinical correspondence I have no additional recommendations. I presume [Ms A] has received a personal apology for any distress caused by the incident, and that she has been reassured the complaint has been used constructively to improve practice systems and reduce the risk of further similar incidents."

Further comment was provided by Dr Maplesden on 3 October 2017:

"(i) I noted in my initial advice that [Dr C] had reviewed the result and annotated it as '53' but I am unable to now see the record on which that comment was based (would be evident from an audit of inbox documents). I note [the clinical director] states in his initial response that the result was annotated by [Dr C] indicating it had been viewed by her, but it is not clear to me what the actual annotation was (there may be more detail on file somewhere but difficult to find on the electronic file).

(ii) However, it does seem clear that [Dr C] viewed the result. She set a task to follow-up the result when the test was first ordered (23 April 2015) and ticked the result as being completed on 24 April 2015 with the result filed electronically on 25 April 2015.

(iii) In her April 2017 response, [Dr C] has outlined what would be her usual practice for general management of results, and management of an elevated HbA1c in particular. Her description is consistent with [the medical cnetre's] results management policy and with expected practice.

(iv) As you note, [the clinical director] has provided an example of a 'usual' results letter generated by [Dr C] (in this case for another patient but around the same time she saw [Ms A]). This letter is accurate and informative and consistent with expected standards of clinical documentation and communication. It is also consistent with the impression I gained from review of [Dr C's] documentation for the consultation with [Ms A] on 23 April 2015 — that consultation addressing several clinical issues in a conscientious and clinically appropriate fashion, and including the recommendation

that [Ms A] present in one week for a blood pressure check and in four weeks for general review (which would presumably include review of the blood test results from the previous month). I note [Ms A] did not present for either of the follow-ups advised by [Dr C].

(v) It is not clear to me, and I am not sure if it has been established, whether [Ms A] ever actually received a copy of the pro-forma results letter generated by [Dr C] on 24 April 2015 and what that letter actually stated. If a letter was received with the 'normal results' section ticked, I would be somewhat more critical than if a letter was never received. On reviewing the complaint, my suspicion is that no letter was received (ie there was no communication at all with the reasonable assumption by [Ms A] that the results must have been normal). Please correct me if this is not the case.

(vi) Based on the assumption above, and taking into account the responses and associated documentation from [Dr C] and [the clinical director], I think the most likely scenario is that [Dr C] had an intention to notify [Ms A] of her abnormal result and need for follow-up but for some reason the pro-forma results letter was generated but not completed, or completed but not sent. A deficiency in [the medical centre's] process at the time was that the letter could be completed by hand meaning there was potential for no electronic record kept of the advice provided, and this issue has since been addressed by the practice. If this was the case, and noting [Ms A] had been advised to reattend the practice in one week and then one month, I think the major criticism would have to relate to [Dr C] overlooking the fact the results letter had not been completed and/or sent but once the 'Task completed' had been ticked (as [Dr C] evidently did) there was no prompt to further review the outcome of the result notification.

(vii) Noting [Dr C] is unable to precisely recall her actions in this case, and depending on whether a letter was ever received by [Ms A] and the content of that letter, there are other possible scenarios:

a. A letter noting need for follow-up was completed by [Dr C] and sent but never received by [Ms A]

b. A letter stating the results were normal was completed by [Dr C] and received by [Ms A] (I would remain at least moderately critical of her actions if this was the case)."