General Practitioner, Dr B

A Medical Centre

A Report by the

Health and Disability Commissioner

(Case 13HDC00619)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. Between 2003 and mid-2011, Ms A consulted GP Dr C at a medical practice she had been enrolled with since 1977 (Medical Centre 1). From 1998, Ms A also consulted GP Dr B at another medical centre (Medical Centre 2). Until mid-2011, Dr C was not aware that Ms A had been consulting Dr B.

2. From 1998, Dr B requested thyroid function tests for Ms A. From September 2005 to December 2008, Ms A received prescriptions for Eltroxin (used to treat hypothyroidism).[1] There was no documented diagnosis of hypothyroidism until 3 December 2008.

3. On 11 April 2008, Dr B ordered thyroid function tests. On 16 May 2008, Dr B recommended a change to whole thyroid.[2] Whole thyroid is not an approved medicine in New Zealand. On 4 December 2008, Ms A decided that she would trial whole thyroid. Dr B said that she gave Ms A verbal and written information about hypothyroidism and whole thyroid. Ms A said that she does not recall receiving the written information, and was not informed that whole thyroid is an unapproved medicine.

4. On 26 February 2009, Dr B requested blood tests, including checking thyroid function. Two of Ms A's thyroid tests were within the normal reference range, but the level of her thyroid-stimulating hormone (TSH) was below the normal reference range, indicating possible over-replacement of thyroxine.

5. Following those blood tests, there is no review of Ms A's thyroid symptoms documented in the clinical notes until January 2011, although Medical Centre 2 dispensed repeat prescriptions of whole thyroid to Ms A during that time. Dr B intended to follow up Ms A in one year's time, but did not have in place a follow-up system to ensure that this occurred.

6. On 20 January 2011, Ms A consulted Dr B. Dr B increased Ms A's dose of whole thyroid. Dr B did not test Ms A's thyroid levels before increasing the dose. On 20 February 2011, Dr B requested blood tests to check Ms A's thyroid function. Dr B did not request TSH testing.

7. In April 2011, when Ms A was overseas, she experienced increasing levels of agitation and rapid weight loss. Ms A became clinically and biochemically hyperthyroid. On 10 May 2011, Ms A was admitted to hospital and was found to have developed atrial fibrillation in the context of thyrotoxicosis, which was iatrogenic.[3] On 12 May 2011, Ms A was discharged from hospital and, on 27 June 2011, returned to New Zealand.

[1] Hypothyroidism is a common endocrine disorder in which the thyroid gland does not produce enough thyroid hormone. It can cause a number of symptoms, such as tiredness, poor ability to tolerate cold, and weight gain. Eltroxin is a synthetic replacement thyroid hormone.
[2] Whole thyroid is a non-synthetic thyroid supplement.
[3] Illness caused by medical treatment.

8. Ms A consulted an endocrinologist and was placed back on Eltroxin with close monitoring of her thyroid function, including TSH. In August 2013, Ms A's thyroid function was assessed as stable and satisfactory, but she continued to experience episodes of atrial fibrillation.

Findings summary

9. Dr B provided suboptimal care to Ms A. Ms A was not sufficiently informed about whole thyroid. In addition, Ms A's thyroid function was not monitored appropriately. She was not reviewed, and had no thyroid function tests for almost two years after the February 2009 test results showed abnormal suppression of TSH, placing her at risk of atrial fibrillation and accelerated bone loss. Concern is expressed about Dr B's decision to increase Ms A's dose of whole thyroid, and her failure to review Ms A following that increase in dose. While follow-up tests were ordered six weeks after the medication increase, a TSH test was not ordered. In addition, Dr B's documentation was suboptimal, and she failed to establish with Ms A Dr C's role in her care and treatment, and to keep Dr C informed of her treatment of Ms A.

10. Dr B did not provide services to Ms A with reasonable care and skill. Accordingly, Dr B breached Right 4(1) of the Code.[4]

11. Medical Centre 2 lacked robust systems to ensure that an adequate quality of care was provided to Ms A. Medical Centre 2 failed to provide services to Ms A with reasonable care and skill and, accordingly, breached Right 4(1) of the Code.

Complaint and investigation

12. The Commissioner received a complaint from Ms A about the services provided to her by Dr B. The following issues were identified for investigation:

- *Whether general practitioner Dr B provided an appropriate standard of care to Ms A from January 2009 to August 2011.*
- *Whether Medical Centre 2 provided an appropriate standard of care to Ms A from January 2009 to August 2011.*

13. The parties directly involved in the investigation were:

Ms A	Consumer/complainant
Dr B	General practitioner
Medical Centre 2	Medical centre

14. Information was also reviewed from:

Dr C	General practitioner
Medical Council of New Zealand	

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

15. Medical Centre 1 and endocrinologist Dr D are also mentioned in this report.

16. In-house clinical advice was obtained from vocationally registered general practitioner Dr David Maplesden (**Appendix A**). Independent expert advice was obtained from endocrinologist Associate Professor Patrick Manning (**Appendix B**).

Information gathered during investigation

Background

17. Ms A enrolled with Medical Centre 1 in 1977. Between 2003 and mid-2011 she consulted Dr C, a general practitioner (GP) at Medical Centre 1.

18. From 1998, Ms A (then aged 55 years) also consulted Dr B at Medical Centre 2 but was not enrolled there.

19. Dr B told HDC that there was some confusion as to whether she was Ms A's regular GP, because Ms A was recorded as being registered with Medical Centre 2 rather than being a casual patient.[5]

20. Dr C stated that until mid-2011 he was not aware that Ms A had been consulting Dr B. The notes from Ms A's consultations with Dr B at Medical Centre 2, and the relevant blood test results, were not provided to Dr C or Medical Centre 1 until cardiologist Dr D wrote to Dr C in July 2011.[6]

Medical Centre 2

21. Dr B[7] is the sole director and shareholder of Medical Centre 2. Medical Centre 2 employed Dr B full time, and one other doctor part time.

22. Medical Centre 2 offers a number of complementary and alternative treatments, including Singlet Oxygen Therapy[8] and detoxification.[9]

23. Medical Centre 2 states that it works with each client individually, and looks at their health from a number of angles (biochemical, energetic, emotional and structural). It also states that both standard and unusual tests are used, including testing hair, saliva and using kinesiology.

Ms A — treatment for hypothyroidism

24. Ms A first consulted Dr B in 1998 in relation to her low bone density, on the recommendation of a family member.

[5] On 4 December 2008 and 12 March 2009, Dr B referred to Dr C in Ms A's clinical notes.
[6] Ms A stated that she remembers commenting when asked by Dr B if she wanted information shared with Medical Centre 1, that it made sense to her to do so.
[7] Dr B has been a Fellow of the Royal New Zealand College of General Practitioners (RNZCGP) since 1999. She obtained vocational registration in general practice in 1990.
[8] Medical Centre 2 states that this refers to use of a machine that activates air to produce electrons, so that patients breathe in antioxidants.
[9] Removal from the body of toxic substances that the body has been unable to eliminate.

25. From 1998, Dr B requested thyroid function tests for Ms A and, from September 2005, Ms A's clinical record shows prescriptions for Eltroxin 100mcg (levothyroxine sodium,[10] which is used to treat hypothyroidism).[11] However, there is no documented diagnosis of hypothyroidism until 3 December 2008, when the practice nurse recorded it in Ms A's clinical notes.

26. The clinical record shows that Dr B provided repeat Eltroxin prescriptions for Ms A from September 2005 to December 2008. Ms A was also receiving hormone replacement treatment and treatment for osteoporosis from Dr B.

Thyroid function tests

27. A diagnosis of hypothyroidism is based on a person's symptoms (whether he or she is clinically hypothyroid) and the results of blood tests that measure thyroid function (whether he or she is biochemically hypothyroid).[12] Thyroid function tests commonly record levels of:

- FT3 (T3) (reference range 4–6.8pmol/L);
- FT4 (T4) (reference range 12.8–20.4pmol/L); and
- TSH[13] (reference range 0.4–3.8mIU/L).

28. A high TSH level with a low FT4 level indicates an underactive thyroid (hypothyroidism), while a low TSH with a high FT4 level and a high FT3 level indicates an overactive thyroid (hyperthyroidism).

29. On 11 April 2008, Dr B ordered thyroid function tests for Ms A. Ms A's thyroid function test dated 24 April 2008 showed a low FT3 reading of 3.8pmol/L, an FT4 reading of 20.2pmol/L, and a TSH reading of 0.24mIU/L (showing adequate or mild over-replacement of thyroxine, indicating that Ms A was not biochemically hypothyroid).

30. On 16 May 2008, the practice nurse recorded in Ms A's clinical notes that she telephoned Ms A regarding her blood results. The nurse recorded:

> "[Dr B] recommends Whole [Thyroid][14] 120mg, and retest in a month. Otherwise continue on with Eltroxin if not wanting to change. Advised to make [appointment] with [Dr B] to discuss her signs and [symptoms] etc."

[10] A synthetic form of the natural hormone thyroxine (T4) used in the treatment of hypothyroidism to relieve symptoms and stabilise thyroid function. The body converts levothyroxine to liothyronine (T3) as necessary.

[11] Hypothyroidism is a common endocrine disorder in which the thyroid gland does not produce enough thyroid hormone. It can cause a number of symptoms, such as tiredness, poor ability to tolerate cold, and weight gain.

[12] http://www.mayoclinic.org/diseases-conditions/hypothyroidism/basics/tests-diagnosis/con-20021179 (accessed on 14 May 2015).

[13] TSH is produced by the pituitary gland, a tiny organ located below the brain and behind the sinus cavities. It is part of the body's feedback system to maintain stable amounts of the thyroid hormones thyroxine (T4) and triiodothyronine (T3) in the blood, and to help control the rate at which the body uses energy.

Approved medicines

31. The New Zealand Medicines and Medical Devices Safety Authority (Medsafe), which is responsible for the regulation of medicines and medical devices in New Zealand, advised HDC that whole thyroid is not an approved medicine.

32. Companies wishing to sell a medicine in New Zealand must make an application to Medsafe for approval. Medsafe then reviews the application, including information about the quality, safety and efficacy of the medicine concerned, and makes a recommendation to the Minister of Health as to whether the medicine should be approved.[15] Medicines that are not approved medicines may still lawfully be prescribed in New Zealand.[16]

33. Medsafe in its statement "Use of Unapproved Medicines and Unapproved Uses of Medicines" states:

> "The *Code of Health and Disability Services Consumers' Rights* places obligations on the provider of services. The consumer has the right to treatment of an appropriate ethical and professional standard, and the provider has the responsibility to ensure treatment, whether approved or unapproved, meets this standard. The consumer also has the right to be fully informed. If the use of a medicine is unapproved, the consumer should be so advised and the provider should be frank about the standard of support for the use and any safety concerns."[17]

34. Ms A told HDC that although she did not understand that whole thyroid is unapproved, Dr B told her that "because [whole thyroid is] not a manmade drug there is no money for it, not patentable", and that it would be a better solution because it is more in line with what the body produces, and it is "the entire product, not just a part as thyroxine [is]".

Change to whole thyroid

35. With regard to treatments for low thyroid function with whole thyroid, Medical Centre 2 states that while low thyroid function can be treated with T4 alone and the patient making T3 from the T4, and often doctors treat it this way, there are also common reasons that individuals cannot make that conversion. Medical Centre 2 also states that whole thyroid is desiccated pigs' thyroid, which contains a combination of both T4 and T3. Medical Centre 2 states that there is a long history of clinical experience with whole thyroid, which has been shown in studies to often be more effective than T4.[18]

36. On 4 December 2008, Ms A consulted Dr B, who recorded:

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[14] Whole thyroid is a non-synthetic thyroid supplement that replaces T3 and T4.
[15] Medsafe: "Information for Consumers: Quality and Safety of Medicines: Medsafe's Evaluation & Approval Process" wwwmedsafe.govt.nz, accessed 6 May 2015.
[16] The Medicines Act 1981 permits the sale or supply of unapproved medicines to registered medical practitioners, but requires the supplier to notify the Director-General of Health.
[17] First published April 1998, revised as at 22 October 2014.
[18] There is no reference to any published clinical trials.

> "T3 disc. Cold feet, dry skin. Will try WT [whole thyroid]. Info T4-T3. Hypothyr [symptoms]."

37. In respect of that note, Dr B told HDC:

> "I am recording that I have discussed with her that she is still symptomatically hypothyroid and that examination findings show this also. I am recording that I have explained verbally and given her written information about the conversion of T4 to T3 and about hypothyroid symptoms. … I am recording that she decided she would have a trial of whole thyroid. This is the point at which I changed her from eltroxin to whole thyroid. I gave her a 'supplement script'[19] for whole thyroid. Nowadays, I would continue with eltroxin and add a little whole thyroid. This would be with a view to minimising TSH suppressing but still getting some elevation in T3."

38. Dr B told HDC that she gave Ms A two information sheets: "Factors that cause an inability to convert T4 to T3", and "Symptoms of hypothyroidism".

39. In her response to HDC, Dr B also referred to a further information sheet — "Thyroid diagnosis and monitoring at [Medical Centre 2]". With regard to that information sheet, Dr B stated: "[I]t was about 10yrs ago that I wrote the first version of it. Then I changed it slightly several times … I had the document at the time I saw [Ms A]. If I did not give it to her, this is the information I would have discussed verbally with her."

40. The version of the document provided to HDC states that it is a complicated picture. It states that as the doctors at Medical Centre 2 do, at times, make decisions about thyroid treatment that would not align with usual practice in New Zealand, that they would like the consumer to be informed about the reasoning for those decisions

41. The document discusses the efficacy of monitoring TSH levels, but does not refer to the risks of excess thyroid medication (such as heart palpitations).

42. Ms A said that she has always maintained files regarding medical visits, test results and the like, and the information sheets are not in her records. She does not recall receiving the three documents, but has a clear memory of some of the matters in the "Symptoms of hypothyroidism" information sheet being discussed.

43. Regarding the "Thyroid diagnosis and monitoring at [Medical Centre 2]" information sheet, Ms A told HDC that she has no memory of receiving anything similar in written form. She stated:

> "Several items in the document surprise me and would, I believe, have alerted my attention had they been raised at the time."

44. Ms A referred to the above extract from the document (paragraph 40), and said that it would have immediately aroused her curiosity and made her ask, "Why?" She stated:

[19] Dr B told HDC that it is her practice to give written instructions, recommendations and prescriptions in the form of a supplement script, which is an outbox document.

"I have never experienced any medical consultation that contained such [an] extensive explanation or justification of [the] philosophical and clinical approach."

45. Dr B told HDC that the rationale for changing Ms A's medication to whole thyroid was that Ms A's thyroid test results (T4 at the top of the range, T3 below the bottom of the range), together with clinical hypothyroidism, is "good evidence that the patient is not converting T4 to T3".

46. Dr B provided information to HDC to explain her reasoning in the form of a draft letter to Ms A dated 23 June 2013 (the Draft Letter), which stated:

> "Back in April 2008 when you were being treated for hypothyroidism with eltroxin (T4), your blood tests showed that you had good levels of T4 but low levels of T3 because your body was not converting much of the administered T4 to T3. T3 is the main perpetrator of the thyroid's action to increase your metabolism and warm you up. T4 acts as a reservoir of hormone to be activated to T3. You have to have good levels of T3, not just T4. Therefore we changed your thyroid preparation to whole thyroid which contains T3 as well as T4.
>
> …
>
> Clinical examination in cases of hormone deficiency or excess is not uncommonly more indicative of the health status of a patient than blood tests."

47. Ms A advised that Dr B said that the reason for the change was that whole thyroid was a more comprehensive replacement, closer to the hormone produced naturally by the body, and that the cost would not be much more than the Eltroxin she was on at the time.

48. Dr B told HDC that the treatment she provided to Ms A differed from local management recommendations, but she does not consider it to be complementary or alternative. She stated that "many doctors … are only used to treating hypothyroid patients with thyroxine, (T4) and typically only measure T4 and TSH". She said that the treatment she provided is supported by a substantial growing body of scientific literature, but acknowledges that aspects of it are different from current best practice. She stated that it is her opinion that New Zealand best practice "may not stand the test of time". She said:

> "I am attempting to show that I am not alone in my opinion amongst doctors and that there is scientific validity to my opinion. This is part of my argument that my treatment is not complementary or alternative medicine. It is a practice performed by doctors adhering to scientific principles, using prescription medicines and concerned to share knowledge and experience."

Monitoring

49. On 10 February 2009, Dr B reviewed Ms A, but there is no record that Dr B asked Ms A about the hypothyroid symptoms she had complained of two months previously. The clinical record includes: "Started [whole thyroid] end Jan."

50. On 26 February 2009, Dr B requested a number of blood tests, including ones to check Ms A's thyroid function. These were performed on 27 February 2009 and showed her FT3 level at 5.1pmol/L, her FT4 level at 14.0pmol/L, and her TSH at <0.05mIU/L (her FT3 and FT4 levels were within the normal reference range but her TSH was below the normal reference range, indicating possible over-replacement of thyroxine).

51. Dr B told HDC that Ms A came in for review after the 27 February 2009 blood tests. There is no record of any review in the clinical records. Dr B said: "Although it is not recorded, I must have been comfortable with [Ms A's] heart rhythm."

52. On 12 March 2009, Dr B reviewed Ms A and recorded: "Hip much better [with anti-inflammatories] from [Dr C]." There is no reference to thyroid symptoms. Dr B provided Ms A with a supplement script, which included Lugols solution[20] and Secretropin,[21] and asked her to come in to be retested in one year's time. The script does not specify the reason for the retesting. Dr B told HDC that, at that stage, she did not have a follow-up system in place to ensure that such requests were complied with.

53. Between 6 August 2009 and 20 January 2011, Medical Centre 2 dispensed to Ms A repeats of 120mg of whole thyroid, but Dr B did not review or monitor Ms A's thyroid symptoms over that time. Dr B explained that when Ms A started taking whole thyroid, the medication was dispensed from the Medical Centre 2 reception, and the repeat dispensing was not seen by her or the practice nurses, as would be the case if she wrote a prescription that was to be dispensed by a pharmacy. Dr B said that that process contributed to the lack of follow-up and monitoring of Ms A in 2009 and 2010. Dr B told HDC that Medical Centre 2 has since started auditing its in-house dispensing.

Increase in dose of whole thyroid

54. On 20 January 2011, Ms A consulted Dr B. Ms A said that she attended because she was told by the Medical Centre 2 receptionist that "Pharmac required 1–2 year reviews if repeat scripts were being given". Dr B documented: "Pulse 60, hands cool on hot day. Heels cracked. AJ dull r>c."[22] Dr B increased Ms A's dose of whole thyroid to 180mg daily and added this to a supplement script, but did not record this in the clinical notes. Dr B initially said that the reason she did not test Ms A's thyroid levels before increasing her dose was because Ms A had several hypothyroid signs, and earlier tests had indicated that the current thyroid dose was inadequate.

55. However, Dr B later stated:

> "I altered the dose without first testing because I had seen no clinical improvement and because I thought I would save her having to do a test and come back again before she benefited from the improvement I was hoping for. To increase the dose

[20] Lugols solution contains 5% elemental iodine in a 10% solution of potassium iodide. It is a form of elemental iodine, which some consider to be helpful in treating hypothyroidism.
[21] A natural stimulator of growth hormone production.
[22] Ankle jerks were dull with the relaxation phase longer than the contraction phase, which is a sign of hypothyroidism.

> and test her after a month on the higher dose seemed reasonable at the time. I agree now that it would have been better to do the test first in this case …"

56. She further stated:

> "I do not use the clinical examination alone but I do find there are patients whose clinical situation suggests sometimes that they may benefit from a higher dose of thyroid hormone than might be suggested by the lab tests."

57. On 20 February 2011, Dr B requested blood tests to check Ms A's FT3 and FT4, and these were performed on 14 March 2011. Dr B did not request TSH testing. The results showed an FT3 reading of 4.2pmol/L and an FT4 reading of 13.1pmol/L (both within the normal range but at the lower ends).

58. In Dr B's Draft Letter to Ms A, Dr B stated: "I ceased using your TSH as an indicator at all since it was of no use in determining your status." However, Dr B subsequently told HDC: "It is possible that TSH was accidentally left off the form because I was expecting it to remain suppressed and because the DHB had suggested to me that I was unnecessarily ordering too many tests."

Hospital admission overseas

59. In April 2011, Ms A went overseas for two months. She noticed that she had increasing levels of agitation and had experienced rapid weight loss. While overseas, Ms A became clinically and biochemically hyperthyroid.

60. On 10 May 2011, Ms A was admitted to hospital overseas, suffering atrial fibrillation.[23] Thyroid function tests taken that day showed a suppressed TSH reading of <0.05mlU/L and an FT4 reading of 20.25pmol/L.

61. On 12 May 2011, Ms A was discharged from hospital and, on 27 June 2011, after consulting a doctor in another country, she returned to New Zealand.

62. On 20 July 2011, Ms A consulted cardiologist Dr D, who noted in a reporting letter to Dr C that while overseas Ms A was found to be thyrotoxic[24] with an unrecordable TSH. Dr D noted that Ms A was unlikely to develop atrial fibrillation again, but it was possible that it could happen in times of stress, such as caused by surgery or infection. Dr D concluded:

> "She developed atrial fibrillation in the context of thyrotoxicosis, which was iatrogenic.[25] This may have been aided by the fact she has increased wall stress on the right atrium because of her small atrial shunt."

63. Subsequently, Ms A consulted an endocrinologist, and was placed back on Eltroxin with close monitoring of her thyroid function, including TSH.

[23] Atrial fibrillation is an abnormal heart rhythm.
[24] Thyrotoxicosis is a medical condition caused by an excessive amount of thyroid hormones in the bloodstream.
[25] Illness caused by medical examination or treatment.

64. In responding to these events in the Draft Letter to Ms A, Dr B stated:

> "I am not convinced that your atrial fibrillation was due to your having taken too much thyroid hormone, particularly since you say that it is ongoing intermittently and presumably your thyroid treatment has been changed. While hyperthyroidism is possible, and indeed the symptoms you were experiencing of rapid weight loss and agitation go with hyperthyroidism, there are a number of other conditions that can predispose to arrhythmias."

65. Dr B told HDC that it is possible that Ms A had intermittent atrial fibrillation because of her ongoing hypothyroidism, and stated that Ms A was certainly clinically hypothyroid on 20 January 2011 (the last time Ms A consulted Dr B).

66. In August 2013, Ms A's thyroid function was assessed as being stable and satisfactory, but she continues to experience occasional episodes of atrial fibrillation.

Dr B — other comments

67. In response to the advice provided by HDC's clinical advisor, general practitioner Dr David Maplesden, Dr B stated:

> "I do not ignore the TSH reading, but I do take notice of other tests, particularly T3, T4 and antibodies. I also place a lot of importance on clinical signs and symptoms."

68. Dr B told HDC that she was under pressure from her DHB and the Ministry of Health to reduce the number of laboratory tests she ordered.

69. Dr B also explained that she addresses concerns about increased risk of fractures when TSH becomes suppressed, by suggesting that patients take bio-identical hormones to prevent osteoporosis.

Subsequent events/changes made

70. Dr B acknowledged that she should have documented her examination findings when Ms A changed from Eltroxin to whole thyroid in 2009, and she has since improved her record-keeping. Dr B told HDC that the Medical Council of New Zealand (MCNZ) has conducted three performance assessment reviews of her practice. She said: "I have improved the systems which allowed [Ms A's] lack of follow-up to go unnoticed for so long and the lack of contact with her GP. Also, I would have tried to use less whole thyroid and more Eltroxin to normalise her TSH."

71. Dr B told HDC that the lack of communication with Dr C and other GPs has been addressed by creating a template which she uses to advise other GPs of the treatments she provides. To ensure the communication occurs, this process is reviewed monthly by a staff member at Medical Centre 2. Additionally, Dr B said that she has made the following improvements to her practice:

a) She has increased the length of standard consultation times from 15 minutes to 20 minutes.

b) Patients are categorised as general practice patients or casual, which ensures that communication with the patient's GP is ongoing.

c) She provides all new patients with an introduction to Medical Centre 2 that explains the nature of her practice.

d) The results of physical examinations are recorded in the notes.

e) If she starts a patient on a new medication, she ensures that there is a follow-up consultation and appropriate tests are conducted.

f) In-house dispensing has been audited so that patients cannot get repeat medications if they have not made an appointment or have not been tested if this has been requested.

Referral to Medical Council

72. HDC referred this complaint to the Medical Council of New Zealand. In June 2014, the Council required Dr B to undergo a performance assessment. In May 2015, the Council considered the outcome of the performance assessment and determined that Dr B meets the required standard of competence, and is required to undertake a 12-month recertification programme.

Relevant standards

73. The Medical Council of New Zealand publication *Good Prescribing Practice* (April 2010)[26] provides:

> "Prescribing unapproved medicines
>
> 1.1 You may prescribe unapproved or provide medicines for a purpose for which they have not been approved but, if you decide to do so, you should take responsibility for overseeing the patient's care, including monitoring and any follow-up treatment. You may also like to discuss the patient's treatment with a senior colleague. You should also inform the patient:
>
> - whether there are any other options available
> - of any risks, side effects, costs or benefits
> - that the medicine being prescribed is for an unapproved use
> - that details relating to the supply of the unapproved medicine will be supplied to the Director-General of Health."

74. The Medical Council of New Zealand "Statement on Complementary and Alternative Medicine" (March 2011)[27] provides definitions of "complementary" and "alternative" medicines, including the World Health Organization definition:

[26] This guideline was introduced by the Medical Council of New Zealand after Ms A commenced whole thyroid in January 2009.

> "Complementary and alternative medicine (CAM) refers to a broad set of healthcare practises that are not part of a country's own tradition and not integrated into the dominant healthcare system. Other terms sometimes used to describe these health cares include 'natural medicine', 'non conventional medicine' and 'holistic medicine'."

75. Relevant extracts from the Medical Council of New Zealand "Statement on Complementary and Alternative Medicine" include:

> "12. In a decision the Medical Practitioners Disciplinary Tribunal (the Tribunal) stated: There is an onus on the practitioner to inform the patient not only of the nature of the alternative treatment offered but also the extent to which that is consistent with conventional theories of medicine and has, or does not have, the support of the majority of practitioners …
>
> 13. The Council endorses these comments and expects that if you include CAM within your medical practice or refer patients for CAM therapies you inform the patient in the manner suggested by the Tribunal before obtaining consent (and as required by the Code of Health and Disability Services Consumers' Rights). Careful attention to the process of informed consent is particularly important when the proposed treatment is expensive or in any way innovative, and you should advise patients when scientific support for treatment is lacking.
>
> …
>
> 16. If you are not the patient's general practitioner, then you should ensure continuity of medical care is being provided elsewhere. When you see a patient whose continuity of care is being provided by another general practitioner, you should be in regular contact with the general practitioner and should fully document CAM and other treatments provided.
>
> …
>
> 17. In **assessing** patients you must:
>
> (a) perform a pertinent history and physical examination of patients, sufficient to make, or confirm, a generally recognised diagnosis, and in this meet the standard of practice generally expected of the profession
>
> (b) reach a diagnosis by using a diagnostic system demonstrated by appropriate research methodologies to have a high level of accuracy and proven benefits to patients
>
> (c) advise patients of the evidence based and conventional treatment options, their risks, benefits and efficacy, as reflected by current knowledge
>
> (d) document all of the above in accordance with sound practice.
>
> **18.** In **treating** patients and engaging in health promotion, you must:
>
> (a) ensure the treatment is efficacious, safe and cost effective

[27] Ibid.

…"

76. The Medical Council of New Zealand statement "The maintenance and retention of patient records" (August 2008) states:

> "**Introduction**
>
> Records form an integral part of any medical practice; they help to ensure good care for patients and also become critical in any future dispute or investigation.
>
> 01 **Maintaining patient records**
>
> (a) You must keep clear and accurate patient records that report:
>
> relevant clinical findings
>
> decisions made
>
> information given to patients
>
> any drugs or other treatment prescribed.
>
> (b) Make these records at the same time as the events you are recording or as soon as possible afterwards."

Opinion: Dr B — Breach

Standard of care

Introduction

77. Dr B provided repeat Eltroxin prescriptions for Ms A from September 2005 to December 2008. On 11 April 2008, Dr B ordered thyroid function tests for Ms A, which showed a low FT3 reading of 3.8pmol/L, an FT4 reading of 20.2pmol/L, and a TSH reading of 0.24mIU/L (showing mild over-replacement). Dr B recommended that Ms A commence whole thyroid, and Ms A commenced whole thyroid at the end of January 2009.

78. Dr B agreed that the treatment she provided to Ms A differed from local management recommendations, but said she did not consider it to be complementary or alternative. She said that the treatment she provided is supported by a substantial growing body of scientific literature, but acknowledges that aspects of the treatment are different from current best practice.

79. My expert advisor, endocrinologist Associate Professor Patrick Manning, advised:

> "Although the use of Whole Thyroid Extract is not my practice it is not uncommon, even though I believe there is insufficient scientific evidence regarding its efficacy and safety."

80. My general practitioner expert advisor, Dr David Maplesden, advised me that Ms A's T3 was just below the lower limit of normal and, although there is no clear evidence

for efficacy of the change to whole thyroid, it was "probably not an unreasonable strategy" so long as Ms A was adequately informed of the clinical rationale for the change, and her thyroid function was subsequently monitored appropriately.

81. I am concerned about the adequacy of the information that Dr B provided to Ms A about the reasons for the change to whole thyroid. I am also concerned that Dr B did not adequately inform Ms A about treatment with whole thyroid, and that the use of whole thyroid was not subsequently monitored appropriately.

Information and consent

82. Dr B told HDC that the rationale for changing Ms A's medication to whole thyroid was that Ms A's thyroid test results (T4 at the top of the range, T3 below the bottom of the range), together with clinical hypothyroidism, was "good evidence that the patient is not converting T4 to T3".

83. Ms A recalls that Dr B told her that the reasons for the change were that whole thyroid was a more comprehensive replacement, closer to that produced naturally by the body, and that the cost would not be much more than the Eltroxin she was on at the time.

84. When prescribing unapproved medication, the prescriber must be open and transparent in discussing the medicine with the patient. The patient should be provided with information about the medicine's use and how that fits with common practice, the risks, side effects, costs and benefits of the medication, that the medication is being prescribed for an unapproved use, and that details of the supply of the unapproved medicine will be supplied to the Director-General of Health (as required by the Medicines Act 1981).[28] The prescriber should engage the patient in that discussion and, if in doubt, obtain written consent.

85. Whole thyroid is not an approved medicine in New Zealand, and Dr Maplesden advised me that the standard treatment for hypothyroidism is by way of replacement treatment with levothyroxine (Eltroxin).

86. Dr B said that she provided verbal and written information to Ms A about the treatment she provided, and pointed to the entry in Ms A's clinical records on 4 December 2008: "Info T4-T3. Hypothyr sx." Dr B stated that this entry showed that she provided Ms A with verbal and written information. Dr B said that she gave Ms A two information sheets about hypothyroidism, and she also either gave, or discussed with Ms A, an information sheet titled "Thyroid diagnosis and monitoring at [Medical Centre 2]".

[28] See Right 6(1) of the Code, and the Medical Council of New Zealand's *Good Prescribing Practice*, which states that when prescribing unapproved medicines the doctor should inform the patient: whether there are any other options available; of any risks, side effects, costs or benefits; that the medicine is being prescribed for an unapproved use; and that details relating to the supply of the unapproved medicine will be supplied to the Director-General of Health. While the Medical Council guideline was introduced after Dr B initially prescribed whole thyroid in January 2009, Dr B continued to prescribe Ms A with whole thyroid until 2011.

87. Ms A said that Dr B did not provide her with any written information about whole thyroid. Ms A stated that she has always maintained files regarding medical visits, such as test results, but the information sheets Dr B said were provided to her are not in her records. In addition, Ms A told HDC that she has no memory of receiving the "Thyroid diagnosis and monitoring at [Medical Centre 2] information sheet". She stated that "several items in the document surprise me and would, I believe, have alerted my attention had they been raised at the time". Ms A referred to the extract from the document that stated that the thyroid treatment offered at Medical Centre 2 could be different from the decision most other doctors in New Zealand would make. Ms A said that that statement would immediately have aroused her curiosity and caused her to ask questions. She stated: "I have never experienced any medical consultation that contained such [an] extensive explanation or justification of [the] philosophical and clinical approach."

88. I accept Ms A's account that she did not receive any written information about whole thyroid from Dr B, and I do not consider that the entry in the clinical records on 4 December 2008, "Info T4-T3. Hypothyr sx", suggests that written information was provided.

89. With regard to the verbal information Dr B provided to Ms A about whole thyroid, Ms A said that she has a clear memory of some of the matters in the "Symptoms of hypothyroidism" information sheet being discussed. Ms A told HDC that Dr B told her that "because [whole thyroid] was not a manmade drug there is no money for it, not patentable", although Ms A did not understand that whole thyroid was unapproved. Ms A said that Dr B said it was a better solution because it was more in line with what the body produces, and that it was "the entire product, not just a part as thyroxine was". Given Ms A's recollections, I consider that it is more likely than not that Ms A and Dr B had some discussion about hypothyroidism and whole thyroid before Dr B prescribed it for Ms A. However, I am concerned that Ms A was not aware that whole thyroid is an unapproved medicine, and I am concerned that, overall, the information provided was not sufficient.

90. My expert advisor, general practitioner Dr Maplesden, also identified that there is no evidence that Ms A was adequately informed regarding: the potential risks of being maintained in a biochemically 'hyperthyroid' state with suppressed TSH levels; and the proposed management strategy of relying predominantly on clinical symptoms and her FT4 and FT3 levels while disregarding her TSH levels, which was not consistent with current evidence-based guidelines. This was clearly information that should have been discussed with Ms A.

91. As this Office has noted previously in relation to medicines at the margins, there is a continuum between freedom and safety, and where each consumer wants to be on that continuum will be different. Key, then, is the opportunity to choose — to make an informed choice about healthcare decisions on the basis of full information, including information about where on the spectrum, from mainstream to margin, the particular

healthcare option sits. While important in all healthcare interactions, the provision of full information is particularly important when considering unapproved medicines.[29]

92. In my view, Ms A should have been fully and accurately informed about the reasons why her medication was being changed from Eltroxin to whole thyroid, the risks and side effects of whole thyroid, that whole thyroid was not approved for use in New Zealand (and that details of the supply of the unapproved medicine would be supplied to the Director-General of Health), and that the management strategy Dr B proposed was not in accord with current evidence-based guidelines. On balance, in my view, Dr B did not give Ms A the information she required, and was entitled to, about whole thyroid before prescribing it for her.

Monitoring

93. On 10 February 2009, Dr B reviewed Ms A, but there is no documentation in relation to the thyroid symptoms she had complained of two months previously. The only mention of Ms A's thyroid in the clinical records for that consultation is: "Started [whole thyroid] end Jan."

94. On 26 February 2009, Dr B requested a number of blood tests, including ones to check Ms A's thyroid function. These were performed on 27 February 2009, and showed her FT3 level at 5.1pmol/L, her FT4 level at 14.0pmol/L, and her TSH at <0.05mIU/L (her FT3 and FT4 levels were within the reference range but her TSH was suppressed). Dr Maplesden advised me that Ms A's markedly suppressed TSH was suggestive of biochemical over-replacement.

95. Dr B told HDC that Ms A came in for review after the 27 February 2009 blood tests, although there is no record of the review. Dr B said: "Although it is not recorded, I must have been comfortable with [Ms A's] heart rhythm."

96. On 12 March 2009, Dr B reviewed Ms A and recorded: "Hip much better [with anti-inflammatories] from [Dr C]." There is no record of any review of thyroid symptoms. Dr B asked Ms A to come in to be retested in one year's time. Dr B told HDC that at that stage she did not have a follow-up system in place to ensure that such requests were complied with.

97. Between 6 August 2009 and 20 January 2011, Medical Centre 2 dispensed to Ms A repeats of 120mg of whole thyroid, but Dr B did not review or monitor Ms A's thyroid symptoms over that time. Dr B explained that when Ms A started taking whole thyroid, the medication was dispensed from Medical Centre 2, and the repeat dispensing was not seen by her or the practice nurses, as would be the case if she wrote a prescription that was then dispensed by a pharmacy. Dr B said that that process contributed to the lack of follow-up and monitoring of Ms A in 2009 and 2010. Dr B told HDC that Medical Centre 2 has since started auditing its in-house dispensing.

[29] "Medicine at the margins: unapproved, unregistered and off-label", HDC Medico-legal conference 2012, available at http://www.hdc.org.nz/education/hdc-medico-legal-conference-2012.

98. Dr Maplesden was critical of Dr B's failure to review Ms A for almost two years following her change in treatment to whole thyroid, other than a single consultation less than six weeks after the change of dose, at which there is no documented discussion of "thyroid" symptoms. Monitoring was particularly important given Ms A's suppressed TSH. Dr Maplesden was also critical of Dr B's failure to monitor Ms A's TSH for over two years when the February 2009 result had shown abnormal suppression of TSH.

99. I agree with Dr Maplesden. Ms A's thyroid levels and symptoms were not reviewed for almost two years, which is clearly concerning, particularly in light of her suppressed TSH in 2009, which placed her at risk of atrial fibrillation and accelerated bone loss.

Increase in dose of whole thyroid

100. On 20 January 2011, Ms A consulted Dr B for review of her intermittent bursitis. Dr B documented: "Pulse 60, hands cool on hot day. Heels cracked. AJ dull r>c." Dr B increased Ms A's dose of whole thyroid to 180mg daily (date not recorded). Dr B said that the reason she did not test Ms A's thyroid levels before increasing her dose was because Ms A had several hypothyroid symptoms, and previous tests had indicated that the current thyroid dose was inadequate. When tests were ordered around six weeks later, TSH was not ordered.

101. In May 2011, Ms A was admitted to hospital overseas with atrial fibrillation. Dr D saw her in July 2011 and concluded that Ms A had developed atrial fibrillation due to iatrogenic thyrotoxicosis, although her atrial septal defect may have made her more susceptible to the arrhythmia.

102. Professor Manning advised that the normal approach for adjusting a patient's thyroid hormone replacement is based on clinical examination, supplemented by measurement of thyroid function tests, including measurement of TSH. If the dosage is altered, then reassessment of thyroid function two months later is advised. He stated that adjustments based on clinical symptoms and examination alone is an unreliable method for deciding hormone dose requirements. Professor Manning said that TSH is the best marker of adequacy of thyroid replacement, regardless of whether the patient is receiving thyroxine or whole thyroid extract.

103. Dr Maplesden advised that, given the previous TSH result, it was important for Dr B to re-establish Ms A's baseline thyroid function before making any adjustment to her medication. Furthermore, he advised that although blood tests were performed on 14 March 2011, they did not include TSH, which is a departure from accepted standards. I accept this advice.

Documentation

104. Dr Maplesden noted that when the whole thyroid was increased in January 2011, Dr B did not record the mode of increase. There is also no record of the diagnosis of hypothyroidism until 3 December 2008, despite Dr B having prescribed Ms A with medication for hypothyroidism since at least 2005. In addition, there are very limited records of the information provided to Ms A about her treatment options. Dr B has

acknowledged that her documentation could have been better, but stated that she has improved her record-keeping standards over the years.

105. The Medical Council of New Zealand statement, "The maintenance and retention of patient records" (August 2008), establishes the professional standard. Good clinical records are integral to providing care. They demonstrate the rationale for establishing a diagnosis, and set out the key information that underpins decisions about ongoing care. Dr B's documentation in this case was suboptimal.

Co-operation with Dr C

106. Ms A had been enrolled with Medical Centre 1 since 1977 and, between 2003 and mid-2011, Dr C was her GP.

107. Dr B told HDC that there was some confusion as to whether she was Ms A's regular GP, because Ms A was recorded as being registered with Medical Centre 2 rather than being a casual patient. However, it is clear that Dr B was aware that Dr C was Ms A's GP (or was involved in caring for Ms A) as, on 4 December 2008 and 12 March 2009, Dr B referred to Dr C in Ms A's clinical notes.

108. It was not until mid-2011 that Dr C became aware that Ms A had also been consulting Dr B. The notes from Ms A's consultations with Dr B at Medical Centre 2 were not provided to Dr C or Medical Centre 1, and he was not copied into the blood test results.

109. For patients receiving both orthodox and non-orthodox healthcare, co-operation and communication is important. The duty of co-operation between providers entails a level of co-ordination of care, so that the GP can be assured that the treatment provided by the other provider will not counteract any prescription medicine, and vice versa. I am concerned that, in this case, Dr B failed to establish with Ms A Dr C's role in her care and treatment, and failed to keep Dr C informed of her treatment of Ms A, as required by the Medical Council of New Zealand's "Statement on Complementary and Alternative Medicine".

Conclusions

110. In my view, Dr B provided suboptimal care to Ms A. Ms A was not sufficiently informed about whole thyroid. In addition, Ms A's thyroid function was not monitored appropriately. She was not reviewed, and had no thyroid function tests, for almost two years after the February 2009 test results showed abnormal suppression of TSH, placing her at risk of atrial fibrillation and accelerated bone loss. I am concerned about Dr B's decision to increase Ms A's dose of whole thyroid, and her failure to review Ms A following that increase in dose. While follow-up tests were ordered six weeks after the medication increase, a TSH test was not ordered. In addition, Dr B's documentation was suboptimal, and she failed to establish with Ms A Dr C's role in her care and treatment, and to keep Dr C informed of her treatment of Ms A.

111. In my view, Dr B did not provide services to Ms A with reasonable care and skill. Accordingly, I find that Dr B breached Right 4(1) of the Code.

Opinion: Medical Centre 2 — Breach

Standard of care

112. Dr B is the sole director and shareholder of Medical Centre 2, and is an employee of Medical Centre 2.

113. In my view, Medical Centre 2 lacked robust systems to ensure that an adequate quality of care was provided to Ms A. In particular, Medical Centre 2 had no system to ensure that patients' GPs were advised of the treatments provided. As a result, in this case, Dr C's role in Ms A's care and treatment was not ascertained, and Dr C was not advised of Dr B's care and treatment of Ms A. It was suboptimal that, at the time, Medical Centre 2 did not have in place a clear process to ensure that patients' GPs were identified and kept informed of Dr B's treatment of their patients. Dr B told HDC that the lack of communication with other GPs has been addressed by creating a template that she now uses to advise other GPs of the treatments she provides.

114. In March 2009, Dr B requested that Ms A come in to be retested in one year's time. However, at that time, Medical Centre 2 had no system in place to ensure that such requests were followed up. In my view, it is imperative that providers are supported by robust systems to ensure that patient follow-up occurs in a timely and appropriate way.

115. Between 6 August 2009 and 20 January 2011, Dr B prescribed for Ms A repeats of 120mg of whole thyroid. Dr B explained that when Ms A started taking whole thyroid, the medication was dispensed from Medical Centre 2, and that the repeat dispensing was not seen by her or the practice nurses, as would be the case if she wrote a prescription that was then dispensed by a pharmacy. Dr B said that that process contributed to the lack of follow-up and monitoring of Ms A in 2009 and 2010. Dr B told HDC that Medical Centre 2 has since started auditing its in-house dispensing.

116. In my view, Medical Centre 2 lacked robust systems to ensure that an adequate quality of care was provided to Ms A. Accordingly, I find that Medical Centre 2 failed to provide services to Ms A with reasonable care and skill and, accordingly, breached Right 4(1) of the Code.

Recommendations

117. I recommend that Dr B and Medical Centre 2 separately apologise in writing to Ms A for the breaches 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.

118. I recommend that Dr B:

a) Review the information she provides to patients regarding unapproved medicines, and report back to HDC on any changes she has made, within one month of the date of this report.

b) Undertake an audit to identify patients taking whole thyroid, and ensure that they are receiving adequate monitoring, and report back to HDC regarding this audit, within three months of the date of this report.

c) Provide to HDC evidence of co-operation with other doctors who are also providing care to her patients, within three months of the date of this report.

119. I recommend that Medical Centre 2 and Dr B arrange an independent audit of medication dispensing processes and practices and report to HDC on the outcome within three months of the date of this report.

120. I recommend that Medical Centre 2 arrange an independent audit of its record-keeping, communication with patients' GPs, and patient follow-up and monitoring, and provide the results of the audit to HDC within three months of the date of this report.

121. I recommend that Medical Centre 2 review its public documentation to ensure that the nature of any complementary or alternative treatments is readily apparent, and report the outcome to HDC within three months of the date of this report.

Follow-up actions

122.
- A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the Director-General of Health, the Medical Council of New Zealand, the Royal New Zealand College of General Practitioners, and the relevant district health board, and they will be advised of Dr B's name in covering correspondence.

- A copy of this report with details identifying the parties removed, except the experts 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 general practice advice to the Commissioner

The following in-house clinical advice was obtained from vocationally registered general practitioner Dr David Maplesden:

"17 July 2013

1. Thank you for the request that I provide clinical advice in relation to the complaint from [Ms A] about the care provided to her by [Dr B]. In preparing the advice on this case to the best of my knowledge I have no personal or professional conflict of interest. I have reviewed the available information: complaint from [Ms A]; response from [Dr B]; [Medical Centre 2's] clinical notes. [Ms A] complains that in January 2011 [Dr B] increased her thyroid replacement medication without undertaking blood tests beforehand. As a result, [Ms A] became clinically and biochemically hyperthyroid. She developed atrial fibrillation and required hospitalisation while travelling overseas, incurring significant expense.

2. Clinical notes indicate [Ms A] was taking thyroid replacement in the form of levothyroxine 150mcg daily from at least September 2005. The circumstances of her diagnosis of hypothyroidism are not evident in the available notes. She was receiving treatment for osteoporosis and hormone replacement concurrently. At a consultation of 4 December 2008, consultation notes include *cold feet, dry skin. Will try WT* [whole thyroid]. *Info T4-T3. Hypothyr Sx.* At this point the most recent thyroid function test on file (24 April 2008) showed an FT3 of 3.8 (reference range 4–6.8 pmol/L), FT4 20.2 pmol/L (12.8–20.4 pmol/L) and TSH 0.24 (0.4–3.8 mIU/L).

Comment: Notes suggest [Dr B] felt [Ms A] was showing signs of clinical hypothyroidism despite replacement. Her blood tests showed some suppression of TSH below the lower limit of normal indicating, from a biochemical perspective, very adequate or mild over-replacement ie she was not biochemically hypothyroid. Recommended best practice (see below) is to test only TSH when monitoring patients on levothyroxine replacement. Nevertheless, [Ms A's] FT3 was just below the lower limit of normal and this observation, coupled with apparent signs of hypothyroidism, led to the suggestion that [Ms A] change her replacement from levothyroxine (T4) to Whole Thyroid (T3 and T4). As discussed below, there is no clear evidence for the efficacy of such a change but it was probably not an unreasonable strategy provided [Ms A] was adequately informed of the clinical rationale for the change, and that thyroid function was appropriately monitored subsequently.

3. [Ms A] made the change from levothyroxine to Whole Thyroid (WT) 120mg daily at the end of January 2009. She was reviewed by [Dr B] on 10 February 2009 but no comment is made regarding the previous possible hypothyroid symptoms. Follow-up blood test was performed on 27 February 2009 which was appropriate. Results showed FT3 and FT4 levels within the reference range (5.1 and 14.0 respectively) but markedly suppressed TSH (<0.05) suggestive of

biochemical over-replacement. Repeat prescriptions were provided on a regular basis but [Ms A] was not reviewed by [Dr B] again until January 2011.

Comment: I am critical of two aspects of [Ms A's] care at this point — the first being the failure to review the patient for almost two years following a change in treatment particularly given the suppressed TSH (other than the single consultation less than six weeks after the change of dose at which there was no documented discussion of 'thyroid' symptoms), and the second being the failure to monitor [Ms A's] TSH for over two years when the February 2009 result had shown abnormal suppression of TSH (placing [Ms A] at risk of atrial fibrillation and accelerated bone loss — see below).

4. On 20 January 2011 [Ms A] attended [Dr B] for review of musculoskeletal symptoms. The clinical record includes symptoms suggestive of hypothyroidism including *Pulse 60, hands cool on hot day. Heels cracked. AJ dull r>c.* At this visit, [Ms A] was evidently advised to increase her WT dose by 50 percent from 120mg per day to 180mg per day although this is not evident from the clinical notes examined. A blood test was performed on 14 March 2011 but TSH was not measured. On this occasion FT3 and FT4 levels were within the reference range (towards the lower limits) at 4.2 and 13.1 respectively. [Dr B] states [Ms A] was asked to come in for a follow-up appointment and was sent a reminder letter in July 2011, but failed to attend. I note [Dr B] continued to prescribe some medications for [Ms A] as late as August 2011, well after her diagnosis with atrial fibrillation and presumed iatrogenic hyperthyroidism.

Comment: [Ms A] demonstrated physical symptoms suggestive of hypothyroidism when [Dr B] reviewed her on 20 January 2011. However, given the previous result indicating marked suppression of TSH, I think it was important for [Dr B] to re-establish [Ms A's] 'baseline' thyroid function (given it had been two years since the previous test) before making any adjustment to her medication. Tests were ordered for about six weeks after the medication change which was appropriate, but TSH was not ordered which I think is a departure from expected standards. [Ms A] was apparently invited to re-attend for review following the medication change. See section 7 for concluding comments.

5. As background to previous and subsequent comments I have included extracts from a local evidence-based best practice publication BPAC. Management of thyroid dysfunction in adults. Issue 33, 2010. Available at: http://www.bpac.org.nz/magazine/2010/december/thyroid.asp available to all GPs at the time [Ms A] had her medication increased.

(i) thyroid dysfunction (hypo- or hyperthyroid) can be classified as overt or subclinical and treatment is guided by TSH results and the clinical situation.

(ii) *subclinical hypothyroidism affects women more than men and occurs more frequently with increasing age — up to 10% of women over 60 years of age have elevated TSH levels. It is characterised by a TSH concentration that is increased above the reference range but FT4 concentration within the normal range.*

Patients with subclinical hypothyroidism may develop overt hypothyroidism … For patients with TSH less than 10 mlU/L, treatment with levothyroxine may be considered if symptoms of hypothyroidism develop. Treatment may also be considered in patients with a rising TSH or in those who have goitre.

(iii) *in most cases GPs diagnose and manage hypothyroidism. Replacement treatment with levothyroxine is appropriate for symptomatic patients with TSH above 10 mlU/L. However, the decision to treat may depend on the clinical situation, e.g. a lower threshold to treat in a young woman, particularly if she may become pregnant, than in a very elderly patient. It is good practice to request a second TSH to confirm the diagnosis, as treatment is usually life-long.*

(iv) *Levothyroxine is a synthetic form of the natural hormone thyroxine (T4), and is the treatment of choice for hypothyroidism because it reliably relieves symptoms, stabilises thyroid function tests and is safe. The body converts levothyroxine to liothyronine (T3) as necessary.*

(v) *Hypothyroid symptoms generally improve within two to three weeks, however, it can take several months before a patient feels back to normal health after biochemical correction of hypothyroidism. Once the target TSH has been reached, a further TSH test in three to four months is often helpful to ensure the TSH is stable. Patients on long-term, stable replacement treatment usually require only an annual TSH, unless pregnant. If for any reason a dose adjustment takes place, TSH testing will be required after approximately six to eight weeks.*

(vi) *TSH is the most appropriate test when monitoring patients receiving levothyroxine for the treatment of hypothyroidism. It should be measured no sooner than six to eight weeks after the start of treatment. If thyroid function needs to be assessed before this time, FT4 should be used, as TSH will not have plateaued at this stage. FT3 has little value in monitoring patients with primary hypothyroidism on replacement treatment as it may be affected by other factors such as illness.*

The usual goal of treatment is for TSH to be within the reference range and symptoms to improve.

(vii) *Whole thyroid extract is produced from dried thyroid gland from domesticated animals (usually pigs). It contains both T3 and T4. There have been no clinical trials published to determine its effectiveness or safety.*

6. Relevant extracts from an international journal review service Ross D. UpToDate:

http://www.uptodate.com/
http://www.uptodate.com/contents/treatment-of-hypothyroidism?detectedLanguage=en&source=search_result&search=hypothyroidism&selectedTitle=2%7E150&provider=noProviderhttp://www.uptodate.com/contents/treatment-of-

hypothyroidism?detectedLanguage=en&source=search_result&search=hypothyroidism&selectedTitle=2%7E150&provider=noProvider
Treatment of hypothyroidism. Uptodate. Last updated April 2013.
www.uptodate.com
http://www.uptodate.com/
http://www.uptodate.com/contents/laboratory-assessment-of-thyroid-function?source=see_link&anchor=H3http://www.uptodate.com/contents/laboratory-assessment-of-thyroid-function?source=see_link&anchor=H3
Laboratory assessment of thyroid function. Uptodate. Last updated February 2013. www.uptodate.com:

(i) *The treatment of choice for correction of hypothyroidism is synthetic thyroxine (T4). Approximately 80 percent of a dose of T4 is absorbed and, because the plasma half-life of T4 is long (seven days), once-daily treatment results in nearly constant serum T4 and triiodothyronine (T3) concentrations when a steady state is reached.*

(ii) *Overreplacement with T4 should be discouraged. Overreplacement causes subclinical hyperthyroidism (normal serum T4 and T3 and low serum TSH concentrations), or even overt hyperthyroidism. The main risk of subclinical hyperthyroidism is atrial fibrillation, which occurs three times more often in older patients with serum TSH concentrations <0.1mU/L than in normal subjects. Patients with subclinical hyperthyroidism, particularly postmenopausal women, may also have accelerated bone loss. It is therefore important to educate patients about the potential adverse effects of overtreatment with T4.*

(iii) *Combination T4 and T3 therapy — Some hypothyroid patients remain symptomatic in spite of T4 replacement and normal serum TSH concentrations … this raises the question of whether hypothyroid patients might benefit from substitution of some T3 for T4, an idea that has now been evaluated in multiple randomized trials, almost all of which showed that combination T4-T3 therapy does not appear to be superior to T4 monotherapy for the management of hypothyroid symptoms. In some trials, patients preferred combined therapy to T4 monotherapy; however, in one of those studies, patients were given overzealous doses of thyroid hormone resulting in mild hyperthyroidism. In general, clinical trials of combination T4-T3 therapy have not successfully replicated physiologic T4-T3 production. Well-designed blinded studies are still needed to address this ongoing controversy.*

(iv) *One of the more common reasons for assessing thyroid function is to monitor levothyroxine therapy. Patients with primary hypothyroidism who are taking levothyroxine replacement therapy can be monitored by assessing the serum TSH. If serum TSH is high, the dose needs to be increased; if it is low, the dose needs to be reduced. Excess suppression of serum TSH can increase the risk of both atrial fibrillation and bone disease due to subclinical hyperthyroidism.*

(v) *Serum free T4 measurements are very insensitive for assessing the appropriateness of the levothyroxine dose. As an example, doses of levothyroxine*

that are 40 percent higher than optimal result in subnormal serum TSH concentrations, yet free serum T4 concentrations frequently remain within the normal range. The one setting in which the serum free T4 value should be used to titrate the thyroid hormone dose is in patients with secondary hypothyroidism due to pituitary or hypothalamic disease, who have impaired TSH release. In this situation, the free T4 level should be maintained in the upper 50 percent of the normal range.

(vi) *Liothyronine (T3) is generally not recommended for treating hypothyroidism. However, in patients with persistent symptoms on levothyroxine, T3 is sometimes added. If the ratio of T4 to T3 administered is below 10:1 (normal ratio approximately 14:1), assessment of therapy requires measurement of serum T3 and TSH, since serum T4 will remain low*.

7. Final comments

(i) [Dr B] appears very resistant to the idea that [Ms A] suffered iatrogenic hyperthyroidism which was responsible for onset of atrial fibrillation. She suggests in her response that *we have good reason to believe that you were possibly still hypothyroid when you suffered the atrial fibrillation and that you are still hypothyroid in spite of treatment and that is why you continue to have intermittent atrial fibrillation … I would like to see your thyroid status optimally treated. One has to be cautious, but effective. If anything I have erred on the side of caution in treating you with thyroid hormones ….*

(ii) In her response, [Dr B] pre-empts any criticism of her care with the comment *It has been my experience that many doctors, including endocrinologists, are unaccustomed to working with whole thyroid (T4+T3) and read the blood tests incorrectly when they meet patients being treated with it. They are only used to treating hypothyroid patients with thyroxine (T4) and typically only measure T4 and TSH. This can lead them to the conclusion that you are hyperthyroid when you are not.*

(iii) The references I have cited refer to accepted best practice and I would regard [Dr B's] management of [Ms A] as departing from these standards to a moderate degree with respect to her monitoring of, and prescribing for, [Ms A] as discussed in sections 2–4. There was also a mild departure from expected standards with respect to clinical documentation as noted in section 4. However, I take it from the comments above that [Dr B] regards herself as an expert in management of hypothyroidism to at least the level, if not surpassing the level, of some endocrinologists. I do not regard myself as an expert in this field, particularly in the use of WT, and feel under the circumstances it would be reasonable to seek a brief 'second opinion' from an **endocrinologist** to assess whether there is agreement that [Dr B's] management was inconsistent with expected standards. The expert should be asked to comment on general aspects of [Ms A's] thyroid management, and also on the content of [Dr B's] response.

(iv) [Ms A] may also have been seeing a 'regular' GP over the period concerned ([Dr C]) and, if confirmed, it may be worth seeking comment from him regarding

[Ms A's] thyroid management including his role in management and copies of any relevant blood results or specialist letters.

(v) I would like to review any additional information received, including additional expert advice, before making final recommendations.

5 September 2013

Since providing my original advice on this case dated 17 July 2013 I have been provided with additional information summarized below.

1. Reports from [Ms A's] health care providers [overseas]. These show that she was admitted [to hospital] with atrial fibrillation in May 2011. Thyroid function tests on admission (10 May 2011) showed an FT4 of 20.25 pmol/L (their reference range 10.4–22.7 pmol/L) and TSH <0.05 (0.50–8.90 uUI/ml). FT3 was not tested. Noting [Ms A] was taking thyroid replacement treatment (as prescribed by [Dr B]) and her TSH was significantly suppressed, a diagnosis of iatrogenic hyperthyroidism was made and her thyroid replacement reduced. The atrial fibrillation was felt to have been caused, at least in part, by her hyperthyroidism.

2. Specialist report from cardiologist [Dr D] with whom [Ms A] consulted on her return from [overseas]. His initial letter dated 20 July 2011 notes [Ms A's] diagnoses of *single episode of atrial fibrillation while thyrotoxic, small atrial septal defect causing slight right heart dilatation* (detected on echocardiogram [overseas]). *She is a normal healthy and active woman, who was given extra thyroid hormone for inconclusive reasons earlier this year … I think the conclusion is fairly straightforward. She developed atrial fibrillation in the context of thyrotoxicosis, which was iatrogenic. This may have been aided by the fact she has increased wall stress on the right atrium because of her small atrial shunt.*

3. Specialist reports from [the endocrinologist] with whom [Ms A] consulted on her return from [overseas]. The introductory letter dated 17 August 2011 includes the history *In 1998 [Ms A] was seen by [Dr B] who checked her thyroid function tests and found out that she was hypothyroid … [Ms A] was initially put onto Eltroxin for replacement and had stable thyroid function tests on this. She was changed onto whole thyroid by [Dr B] in 2008. [Ms A] did not notice any difference. In February of this year her dose was increased from 120mg to 180mg of whole thyroid. [Ms A] is unclear as to why that change was made. She was certainly symptomatic at the time. A blood test was done a month later … but no TSH was measured. It is then three months later that [Ms A] developed paroxysmal atrial fibrillation with a fully suppressed TSH and clear iatrogenic hyperthyroidism.* By this stage [Ms A] had been placed back on levothyroxine with close monitoring of her thyroid function including TSH. It has proved somewhat difficult to stabilize her thyroid function with increases in her replacement regime required on several occasions. However, as at 19 August 2013 [Ms A's] thyroid function was assessed as stable and satisfactory with results FT4 17.8 pmol/L, FT3 3.3pmol/L and TSH 5.3 mIU/L and [Ms A] remained well.

4. Independent expert advice received from endocrinologist A/Prof Dr P Manning. His advice will not be reiterated in detail here but concurred with my original advice — that aspects of [Ms A's] clinical management by [Dr B] departed from expected standards to a moderate degree.

5. [Ms A] provided further information:

(i) [Ms A] regarded [Dr C] as her 'regular' GP and was enrolled under his care. She consulted [Dr B] originally in 1998 (on recommendation from [a relative] — a medical practitioner) for specific advice regarding low bone density. [Dr B] diagnosed her with hypothyroidism and proceeded to manage this also. [Ms A] was happy for information from [Dr B] to be passed on to [Dr C].

(ii) [Ms A] states that [Dr B] informed her *that Whole Thyroid was a more comprehensive replacement, closer to that produced naturally by the body, as it included both T3 and T4. I understood from this that the nature and goal of the change in management was to mimic more closely the body's natural processes.* [Ms A] was not aware that the monitoring of her thyroid function, or interpretation of the blood tests she was having done, was other than consistent with expected practice.

6. On 5 September 2013 I spoke with [Dr C] regarding his contact with [Ms A] and established:

(i) [Ms A] was his registered patient and had been for 10 years but he saw her relatively infrequently prior to mid-2011

(ii) he was not aware [Ms A] had been attending [Dr B]. He never received any correspondence from [Dr B] and was not copied in to any blood tests undertaken on [Ms A]

(iii) [Ms A] did not inform him (prior to mid-2011) that she was seeing [Dr B] or receiving treatment from [Dr B]

7. The comments [Dr B] has made in her response to [Ms A], particularly around the rationale for abandoning monitoring of TSH and her insistence that [Ms A] was likely to be hypothyroid at the time of her atrial fibrillation onset, and to have remained so, indicates an approach to management and monitoring of thyroid dysfunction that is not consistent with local management recommendations (as quoted in my original advice) which is in turn based on international evidence-based guidelines. [Dr B] uses an approach I would regard as within the realm of complementary or alternative medicine and this approach, while quite reasonable in many situations, does require the patient to be fully informed.

8. Relevant extracts from the Medical Council of New Zealand guidance for members practising alternative and complementary medicine: Medical Council of New Zealand. Statement on complementary and alternative medicine. March 2011. Available at:

http://www.mcnz.org.nz/assets/News-and-Publications/Statements/Complementary-and-alternative-medicine.pdf include:

(i) *In a decision the Medical Practitioners Disciplinary Tribunal (the Tribunal) stated: There is an onus on the practitioner to inform the patient not only of the nature of the alternative treatment offered but also the extent to which that is consistent with conventional theories of medicine and has, or does not have, the support of the majority of practitioners …*

(ii) *The Council endorses these comments and expects that if you include CAM within your medical practice or refer patients for CAM therapies you inform the patient in the manner suggested by the Tribunal before obtaining consent (and as required by the Code of Health and Disability Services Consumers' Rights). Careful attention to the process of informed consent is particularly important when the proposed treatment is expensive or in any way innovative, and you should advise patients when scientific support for treatment is lacking.*

(iii) *If you are not the patient's general practitioner, then you should ensure continuity of medical care is being provided elsewhere. When you see a patient whose continuity of care is being provided by another general practitioner, you should be in regular contact with the general practitioner and should fully document CAM and other treatments provided.*

(iv) *In assessing patients you must:*

(a) perform a pertinent history and physical examination of patients, sufficient to make, or confirm, a generally recognised diagnosis, and in this meet the standard of practice generally expected of the profession

(b) reach a diagnosis by using a diagnostic system demonstrated by appropriate research methodologies to have a high level of accuracy and proven benefits to patients

(c) advise patients of the evidence based and conventional treatment options, their risks, benefits and efficacy, as reflected by current knowledge

(d) document all of the above in accordance with sound practice.

9. A Medical Council of New Zealand publication on practise of medicine in New Zealand includes the following advice relevant to this case: Holt S 2013. Doctors who use complementary and alternative medicine. Chapter 24 in St George IM (ed.). Cole's medical practice in New Zealand, 12th edition. Medical Council of New Zealand, Wellington:

In assessing complaints or concerns related to the practice of a doctor who has adopted or advocated CAM investigations or treatments, the Medical Council will apply the standards that have been developed for reviewing the competence of any practitioner. In the case of CAM practices it will particularly consider the above comments.

The Health Practitioners Disciplinary Tribunal will also consider whether:

- *the methodology promoted for a diagnosis is reliable*
- *the risk/benefit ratio for any treatment is acceptable*
- *the treatment is extrapolated from reliable scientific evidence or is supported by a credible scientific rationale*
- *there is a reasonable expectation that the treatment will result in a favorable outcome compared with placebo*

- *the practitioner is excessively compensated for the service (ie, is there any suggestion of exploitation?)*
- *informed consent has been adequately documented in the medical record.*

In assessing the performance of a doctor practising CAM, the Council will not attempt to evaluate the alternative therapy itself, although the critical appraisal skills of doctors may be of concern. The usual domains of competence are assessed, rather than the principles of CAM practice.

10. [Dr B] is recognized by the Medical Council of New Zealand as being vocationally registered in the field of general practice. [Medical Centre 2 information] includes the comment *I became a fellow of the college* [RNZCGP], *a body which ensures general practitioners maintain the required standards and undergo ongoing education.* [Dr B has various qualifications.] Other than the RNZCGP, these faculties do not appear on the list of specialties recognized by the Medical Councils of either New Zealand http://www.mcnz.org.nz/assets/News-and-Publications/Gazette/Gazette-2012-A4.pdf or Australia http://www.amc.org.au/images/Recognition/AMC-list-of-specialties.pdf.

11. Concluding comments and recommendations

(i) Taking into account the additional information reviewed, I remain of the view that [Dr B's] clinical management of [Ms A] departed from expected standards to a moderate degree with respect to her monitoring of [Ms A's] thyroid function and prescribing of thyroid replacement as discussed in sections 2–4 of my original advice.

(ii) [Dr B's] standard of clinical documentation departed from expected standards to a mild degree with respect to annotation of [Ms A's] thyroid replacement dose as noted in section 4 of my original advice.

(iii) Based on the additional information reviewed, I believe [Dr B] failed to adequately inform [Ms A] that her stated management strategy of relying predominantly on clinical symptoms, FT4 and FT3 levels while disregarding TSH levels indicating thyroid suppression indicative of hyperthyroidism (subclinical or clinical) was not consistent with current evidence-based guidelines. [Dr B] failed to keep [Ms A's] general practitioner ([Dr C]) informed regarding her client's treatment regime or blood results. These are moderate departures from expected practice.

(iv) I am concerned that [Dr B] remains of the view (as evidenced in her letter to [Ms A]) that it is clinically reasonable to ignore the TSH reading when monitoring a patient on thyroid replacement, and that she continues to believe it is likely [Ms A] was hypothyroid at the time she developed atrial fibrillation with the implication that she required an increase in her thyroid replacement. I believe these issues raise a question of clinical competency and potential risk to patients whether or not [Dr B] feels that 'traditional' clinical guidelines should apply to her practice. In this regard, **I recommend referral of [Dr B] to the Medical Council of New Zealand.**

16 June 2014

I have reviewed the detailed response (dated 4 June 2014) and associated appendices from [Dr B].

1. [Dr B] has made several improvements to her practices since this complaint, in part related to MCNZ review undertaken following a previous complaint. These changes include improvements in standards of clinical documentation, recall systems to ensure adequate patient follow-up is maintained, communication with colleagues, and audit processes relating to dispensing of medication from the medical centre. While it is encouraging to see such changes have been made, it does not alter my original advice in relation to those issues identified with follow-up and documentation arising from my initial review of the complaint. However, any recommendations regarding remedial actions would be influenced by the additional information supplied by [Dr B] as it appears she has subsequently addressed, in a satisfactory manner, some of those identified deficiencies.

2. [Dr B] states she has continued to research the area of thyroid replacement and monitoring and has made some changes in her prescribing of whole thyroid, particularly in patients previously taking thyroxine only. She has provided several references supporting her assertion that her management of thyroid dysfunction (including monitoring), although not entirely consistent with common practice or accepted practice in this country, is not without an international evidence base and is therefore not 'complementary' or 'alternative'. While this may be the case, I remain of the view that [Ms A] was not adequately informed regarding the degree to which [Dr B's] practice varied from 'accepted' practice, and she was not adequately informed regarding the potential risks of being maintained in a biochemically 'hyperthyroid' state (with suppressed TSH levels). However, I acknowledge [Ms A] was provided with more written information regarding her therapy than was evident in the information supplied to me initially. [Dr B] may be right in asserting her management of thyroid dysfunction could become mainstream in the future as or if an evidence base supporting her approach expands, but the fact remains that her approach does not currently represent 'mainstream' recommended practice, and is adopted by a minority of clinicians internationally.

3. I remain unconvinced of the rationale [Dr B] offers for her failure to adequately monitor [Ms A's] TSH level when changes were made to her thyroid replacement regime. The information she has supplied does not indicate to me that [Dr B] has ever been discouraged or prevented from ordering appropriate evidence-based and cost-effective pathology tests, and TSH would fall into this category. However, it could be argued that her continued ordering of FT3 and FT4 levels without TSH was not consistent with evidence-based recommended practice for standard monitoring of patients being treated for thyroid dysfunction. BPAC. Management of thyroid dysfunction in adults. Best Practice Journal. 2010, Issue 33

4. I do not see the need to make any changes to my additional recommendations based on the additional information received from [Dr B]. However, I am aware the MCNZ are likely to view this referral in the context of their recent contact with [Dr B] and the changes she has made to her practice since their involvement."

Appendix B — Independent endocrinology advice to the Commissioner

The following expert advice was obtained from consultant endocrinologist Associate Professor Patrick Manning:

"I respond to your letter dated 30 July requesting expert advice to the Commissioner on [Ms A's] complaint about [Dr B] at [Medical Centre 2].

Section 1: Background

1. [Ms A] had been a patient of [Dr B] since 1998. She is currently 70 years of age.
2. There is no information provided as to when [Ms A] was diagnosed with hypothyroidism or on what basis the diagnosis was established.
3. The first evidence of the patient being on thyroxine therapy from the notes provided was 29 September 2005 when she was receiving Eltroxin 100mcg tablets at a dose of 100mcg alternating with 200mcg per day (equivalent to 150mcg per day).
4. The first set of thyroid function tests that have been included in the information provided are from 24 April 2008:

TSH	0.24 mIU/L	(Normal range: 0.4–3.8)
FT4	20.2 pmol/L	(Normal range: 12.8–20.4)
FT3	3.8 pmol/L	(Normal range: 4–6.8)

   At this time the patient continued to receive 100mcg alternating with 200mcg of Eltroxin per day.

5. In December 2008 the patient was changed to Whole Thyroid Extract (presumably at a dose of 120mg per day — this is not recorded). The notes indicate that the patient complained of cold feet and dry skin. An additional note on 10th February 2009 indicates that the patient commenced the Whole Thyroid Extract at the end of January 2009.
6. The next thyroid function tests that are included in the documentation were performed on 27th February 2009 (approximately 1 month after commencing Whole Thyroid Extract 120mg per day):

TSH	<0.05 mIU/L	(Normal range: 0.4–3.8)
FT4	14.0 pmol/L	(Normal range: 12.8–20.4)
FT3	5.1 pmol/L	(Normal range: 4–6.8)

7. The patient continued on Whole Thyroid Extract at 120mg per day between January 2009 and January 2011. There are no further thyroid function tests included in the documentation for this period of time apart from the set taken on 27th February 2009 as shown above.
8. On 20th January 2011 the notes indicate that the patient complained of cool hands on a hot day and had cracked heels and split nails. Her pulse was 60 beats/minute and the ankle jerks (AJ) were 'dull' with the relaxation phase

longer than the contraction phase (r>c). Although there is no record in the notes it is presumably at this time that the dose of Whole Thyroid Extract was increased to 180mg per day.

9. Blood tests to check FT4 and FT3 were performed on 14th March. These showed the following results:

FT4	13.1 pmol/L	(Normal range: 12.8–20.4)
FT3	4.2 pmol/L	(Normal range: 4–6.8)

10. In April 2011 the patient [went overseas] and claims to have been experiencing weight loss and agitation.

11. The patient was admitted to [an overseas hospital] in May 2011 with atrial fibrillation. The thyroid function tests [taken on] 10/5/2011 (the day she was in atrial fibrillation) revealed a **TSH of <0.05mIU/L** (N: 0.5–8.9) and a FT4 of 20.5pmol/L (N: 10.4–22.7).

12. During this admission she was changed to thyroxine, and commenced on anticoagulation and Carvedilol. On return to New Zealand she was taking thyroxine 0.075mg per day, aspirin and Carvedilol 6.25mg per day. She was seen by [Dr D], cardiologist, in July 2011. The ECG at that time showed sinus rhythm with partial right bundle branch block and an echocardiogram showed a slightly enlarged right heart with a small atrial septal defect (ASD) with a small insignificant shunt. The cardiologist's opinion was that she had developed atrial fibrillation due to iatrogenic thyrotoxicosis but that the atrial septal defect may have made her more susceptible to this arrhythmia.

Opinion: This patient had subclinical thyrotoxicosis at the time of her admission to [the overseas hospital] with atrial fibrillation (TSH <0.05miu/L with normal free T4 level). The atrial fibrillation was probably precipitated by iatrogenic thyrotoxicosis although her atrial septal defect may have placed her at higher risk of this rhythm disturbance.

Section 2: Comments regarding the letter from [Dr B] (dated 23/6/13)

1. **That [Ms A's] atrial fibrillation may not be related to 'too much thyroid medication' because it is 'on-going intermittently and presumably your thyroid medication has been changed'.**

Opinion: Atrial fibrillation, once induced by thyrotoxicosis, can be an on-going problem despite the resolution of thyrotoxicosis. To what extent this patient's minor ASD has contributed to her risk of atrial fibrillation is unclear.

2. **The blood tests prior to leaving for [overseas] showed the 'thyroid levels were still low if anything'.**

Opinion: The thyroid blood tests showed normal FT4 and normal FT3. There is no indication that the thyroid levels were 'low'.

3. **Changing to Whole Thyroid Extract was based on a 'low level of T3' in April 2008.**

Opinion: The decision to change to Whole Thyroid Extract was based on the patient's symptoms and a reduced FT3 level. At this time the patient was

receiving 150mcg of Eltroxin (thyroxine) per day. The TSH level was 0.24 mIU/L, which is below the lower limit of normal, indicating that this dose of thyroxine is mildly excessive. The usual response in this situation is either to reduce the dose of thyroxine e.g. to 125 mcg/day, or simply repeat the tests in a further 2 months and only change the dose if the TSH remains low.

4. **'Clinical examination in cases of hormone deficiency or excess is not uncommonly more indicative of the health status of a patient than blood tests'.**

Opinion: In my opinion clinical examination on its own (without corroborating thyroid function testing) is unreliable when determining whether to adjust the dose of thyroid hormone replacement.

5. **The patient having 'subclinical hypothyroidism' as evidenced by a low TSH concentration.**

Opinion: This patient's blood tests do not demonstrate the biochemical features consistent with subclinical hypothyroidism. Subclinical hypothyroidism is a situation in which the FT4 and FT3 are normal and the TSH concentration is **raised**.

6. **The use of TSH in this patient's case as having 'no use' in determining her thyroid status.**

Opinion: TSH remains an accurate indicator of adequacy of thyroid hormone replacement regardless of whether the patient receives thyroxine or Whole Thyroid Extract. The only situation in which TSH is not a useful test is in patients with secondary hypothyroidism due to hypopituitarism which is not the case in this patient.

7. **That the blood tests in patients receiving Whole Thyroid Extract require different interpretation and the unaccustomed clinician may interpret them as showing hyperthyroidism.**

Opinion: I disagree that TSH cannot be used to monitor adequacy of thyroid hormone replacement therapy even with Whole Thyroid Extract. I am unaware of any scientific basis upon which [Dr B] makes this statement.

8. **Atrial fibrillation may be due to hypothyroidism.**

Opinion: There is no biochemical evidence that this patient was hypothyroid at any time since the first test that is available in April 2008. Thus the basis that this patient may have developed atrial fibrillation due to hypothyroidism is not substantiated. In my experience, I have never come across a patient with atrial fibrillation induced by hypothyroidism. On the other hand I have seen many patients with atrial fibrillation due to thyrotoxicosis.

9. **The conclusion that 'we have good reason to believe that you were still possibly hypothyroid when you suffered the atrial fibrillation and that you are still hypothyroid in spite of treatment and is why you continue to have intermittent atrial fibrillation.'**

Opinion: There is clear cut biochemical evidence indicating subclinical thyrotoxicosis at the time of admission to hospital [overseas] with atrial fibrillation. Therefore the assertion that the atrial fibrillation was caused by hypothyroidism is incorrect.

Section 3: Response to your specific questions:

1. Review of [Ms A] following her change in treatment.

The normal approach to assessing the requirements for adjusting a patient's thyroid hormone replacement is based on clinical assessment (history of symptoms and medication compliance and physical examination) supplemented by measurement of thyroid function tests including measurement of TSH. If the dosage is altered then reassessment of thyroid function 2 months later is advised to determine whether the dose adjustment was correct or whether further adjustment is required. In [Ms A's] case the adjustment of the dosage of Whole Thyroid Extract was based on clinical symptoms and examination alone which is an unreliable method for decision making on thyroid hormone dose requirements. The thyroid function tests were measured some 7 weeks later but this did not include a measurement of TSH.

2. The monitoring of [Ms A's] TSH levels

TSH concentrations were measured on 2 of the 3 sets of thyroid function that are provided prior to the development of atrial fibrillation, although was not monitored prior to the dose increase of Whole Thyroid Extract. TSH is the best marker of adequacy of thyroid replacement regardless of whether the patient is receiving thyroxine or Whole Thyroid Extract.

3. The appropriateness of replacing levothyroxine with Whole Thyroid Extract

Endocrinologists seldom use desiccated thyroid extract because of concerns about the exact dosages of the thyroid hormones that the preparation contains. 60mg of whole thyroid extract would contain approximately 38mcg of T4 and 9mcg of T3. Therefore when [Ms A] was prescribed 180mg per day she would have been receiving approximately 114mcg of T4 and 27mcg of T3 per day. However, the dosage for a particular patient needs to be individualised according to their symptoms in combination with their thyroid function tests.

4. The adequacy of [Dr B's] documentation of [Ms A's] care

There are several instances of omissions in the patient record. For example, there is no written record that the dose of Whole Thyroid Extract was increased to 180mg per day.

5. Any other issues you may wish to comment on.

I am concerned that [Dr B] believes that clinical examination can be used as a sole arbiter to assess thyroid status; and that measurement of TSH is not useful to determine adequacy of thyroid hormone replacement in a case such as [Ms A]. In addition, I believe it is important that a clinician who prescribes Whole Thyroid

Extract has a thorough understanding of the care of patients with hypothyroidism including the interpretation of thyroid function tests and knowledge of the difference between subclinical hypothyroidism and subclinical thyrotoxicosis.

6. Was the care provided appropriate in the circumstances?

In my opinion there are several deficiencies in the care of [Ms A].

- Firstly it would have been appropriate to measure the thyroid function prior to increasing the dose of whole thyroid extract and to have included a TSH measurement on 14th March 2011 to determine whether the new dose of Whole Thyroid Extract was appropriate.
- Secondly, I do not agree that assessment of the adequacy of thyroid hormone replacement by way of clinical examination alone is appropriate.

Although the use of Whole Thyroid Extract is not my practice it is not uncommon, even though I believe there is insufficient scientific evidence regarding its efficacy and safety. I believe there is sufficient evidence to indicate that [Ms A] developed atrial fibrillation on the basis of iatrogenic thyrotoxicosis, although her atrial septal defect may have been a contributing factor.

You have asked that I grade the departure from care as being mild, moderate or severe. In my opinion I believe that the deficiencies noted above represent a moderate departure from the expected standard of care of a patient being treated for hypothyroidism. I base this on the belief that the expected level of care would include appropriate monitoring of full thyroid function testing prior to and following adjustment of thyroid hormone replacement therapy.

Yours sincerely,

A/Prof Patrick Manning
Consultant Endocrinologist

A Medical Council of New Zealand publication on practise of medicine in New Zealand includes the following advice relevant to this case[30]:

In assessing complaints or concerns related to the practice of a doctor who has adopted or advocated CAM investigations or treatments, the Medical Council will apply the standards that have been developed for reviewing the competence of any practitioner. In the case of CAM practices it will particularly consider the above comments.

The Health Practitioners Disciplinary Tribunal will also consider whether:

[30] Holt S 2013. Doctors who use complementary and alternative medicine. Chapter 24 in St George IM (ed.). Cole's medical practice in New Zealand, 12th edition. Medical Council of New Zealand, Wellington.

- *the methodology promoted for a diagnosis is reliable*
- *the risk/benefit ratio for any treatment is acceptable*
- *the treatment is extrapolated from reliable scientific evidence or is supported by a credible scientific rationale*
- *there is a reasonable expectation that the treatment will result in a favorable outcome compared with placebo*
- *the practitioner is excessively compensated for the service (ie, is there any suggestion of exploitation?)*
- *informed consent has been adequately documented in the medical record.*

In assessing the performance of a doctor practising CAM, the Council will not attempt to evaluate the alternative therapy itself, although the critical appraisal skills of doctors may be of concern. The usual domains of competence are assessed, rather than the principles of CAM practice."