General Practitioner, Dr B

A Medical Centre

A Report by the

Health and Disability Commissioner

(Case 14HDC01058)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. Mrs A, aged 35 years, had diabetes mellitus type 2, hypertension, and a risk of cardiovascular disease. Mrs A was on the statin cholvastin and the antidepressant fluoxetine. On 23 July 2013, Mrs A had a nurse-led annual diabetic review at a medical centre. Following the review and blood tests the practice nurse recommended that Mrs A see her general practitioner (GP), Dr B, to discuss whether Mrs A should recommence taking cilazapril for hypertension.

2. On 2 August 2013, Mrs A attended the above-mentioned appointment with Dr B. During the appointment, Mrs A advised HDC that she told Dr B that she was considering trying for a baby. There is no record of Mrs A's comments about pregnancy in Dr B's clinical record of the appointment. Dr B prescribed cilazapril for Mrs A, although this is contraindicated in pregnancy. Furthermore, Dr B did not discuss with Mrs A whether the other medications she was on were safe in pregnancy.

3. On 23 May 2014, Mrs A had an appointment with Dr B. During the appointment, Mrs A advised Dr B that she was pregnant. Dr B discussed Mrs A's diet and exercise, as she had suffered gestational diabetes in a previous pregnancy. The medication Mrs A was taking was not discussed.

4. On 4 June 2014, Mrs A had her first appointment with midwife and lead maternity carer Registered Midwife (RM) D. RM D was concerned about Mrs A's medications and called the Maternity Unit to discuss them with obstetrician Dr C. Dr C agreed that Mrs A should not be taking cilazapril and cholvastin, and recommended the Mrs A return to her GP and ask for the prescriptions to be changed.

5. That same day, Mrs A presented to the medical centre but was told there were no appointments available and to call the next morning for an appointment.

6. On 5 June 2014, Mrs A called the medical centre but again was told that there were no appointments available. Mrs A then asked to speak to a nurse, and she was put through to Registered Nurse (RN) E. After discussing the situation with Mrs A, RN E said she would put an enquiry through to Dr B, asking about the safety of Mrs A's medications in pregnancy. Dr B responded that Mrs A should continue taking cholvastin and cilazapril but should consider coming off fluoxetine. This information was relayed to Mrs A.

7. On 6 June 2014, Mrs A was seen at the Maternity Unit, where she was advised to stop taking cholvastin and cilazapril. Mrs A was given a prescription for a blood pressure medication not contraindicated in pregnancy. Mrs A continued to take fluoxetine.

Commissioner's findings

8. By failing to identify that cilazapril and cholvastin were contraindicated in pregnancy and ensure that Mrs A's blood pressure was monitored appropriately, Dr B did not provide services to Mrs A with reasonable care and skill, and breached Right 4(1)[1] of

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

the Code of Health and Disability Services Consumers' Rights (the Code). Furthermore, a reasonable consumer in Mrs A's circumstances would expect to receive information about the risks and benefits of continuing cilazapril, cholvastin and fluoxetine in pregnancy. I find that by not providing that information, Dr B breached Right 6(1)[2] of the Code.

9. Adverse comment is made about RN E's management of her telephone conversation with Mrs A on 5 June 2014.

10. Adverse comment is made about the medical centre's "Repeat Prescription Policy, Protocol and Procedures" (May 2013), as well as the communication between Dr B and RN E on 5 June 2014.

Complaint and investigation

11. The Commissioner received a complaint about the services provided to Mrs A between July 2013 and July 2014 at the medical centre. An investigation commenced on 6 November 2014. The following issues were identified for investigation:

- *Whether Dr B provided an appropriate standard of care to Mrs A between July 2013 and July 2014.*
- *Whether the medical centre provided an appropriate standard of care to Mrs A between July 2013 and July 2014.*

12. The parties directly involved in the investigation were:

Mrs A	Consumer, complainant
Dr B	General practitioner
Medical centre	Provider

Also mentioned in this report:

Dr C	Obstetrician
RM D	Midwife and lead maternity carer
RN E	Registered nurse

13. Information was obtained from all parties through the course of the investigation.

14. Independent expert advice was obtained from general practitioner Dr David Maplesden (**Appendix A**).

[2] Right 6(1) states: "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive."

Information gathered during investigation

Background

Mrs A

15. At the time of these events, Mrs A, aged 35 years, had diabetes mellitus type 2,[3] hypertension,[4] and a cardiovascular disease (CVD)[5] risk of 3%.[6] In 2000, Mrs A's CVD risk had been over 15%, putting her at a relatively high risk of CVD, and she commenced cilazapril[7] for hypertension at that time. Mrs A remained on cilazapril for some time but came off it after losing weight. Previously she was a smoker and was on the statin medication cholvastin[8] and the antidepressant fluoxetine. Mrs A had had a spontaneous miscarriage in 2009 and gave birth to a daughter in 2012 by Caesarean section.

16. Mrs A was a regular patient of general practitioner Dr B. Mrs A had been a patient of Dr B for many years.

Dr B

17. Dr B received her medical degree in the early eighties and later gained a fellowship with the Royal New Zealand College of General Practitioners. Dr B was the clinical director of the medical centre.

23 July 2013 appointment at the medical centre

18. On 23 July 2013, Mrs A had a nurse-led diabetes annual review at the medical centre with a practice nurse. Mrs A was noted to have elevated blood pressure (145/90mmHg)[9] and an elevated Body Mass Index (BMI) of 38.7.[10] On 30 July 2013, a practice nurse reviewed the results with Mrs A and discussed the possibility of recommencing cilazapril in view of Mrs A's hypertension.

2 August 2013 appointment with Dr B

19. On 2 August 2013, Mrs A attended the medical centre for an appointment with Dr B. The clinical record for that appointment states: "Diabetic, needs blood pressure medications and statin, as previously on cilazapril [starting in 2000], came off when she lost weight, has put weight back on, o/e [on examination] blood pressure 150/100, R/V [review] 3/12 [three months] with fasting bloods." During the appointment, Dr B prescribed Mrs A cholvastin and cilazapril.

[3] A metabolic (digestive) disorder characterised by high blood sugar and a relative lack of insulin, the hormone that assists with the absorption of sugars from the blood to other body tissues.
[4] When the blood pressure in the arteries is elevated.
[5] Risk of heart disease or stroke.
[6] Under 10% is considered a relatively low risk of CVD.
[7] Used for the treatment of hypertension. An angiotensin-converting enzyme inhibitor or "ACE inhibitor", which decreases blood pressure by causing blood vessels to dilate.
[8] Cholesterol reducing medication.
[9] Blood pressure at or over 140/90mmHg is considered high.
[10] A measure of body fat based on height and weight. A normal BMI range is 18.5–24.9.

20. Mrs A told HDC: "During the consultation I questioned if [cholvastin and cilazapril] were safe if I were to fall pregnant as my partner and I were going to try for another baby and [Dr B's] answer was that 'they are fine'."

21. Dr B does not recall Mrs A asking about the medications and pregnancy. Dr B advised HDC: "I have no recollection of [Mrs A] telling me that she was intending to become pregnant and this is not recorded in my notes. It is my practice to record information like this in my notes, particularly as I would at that point have discussed pre-pregnancy folic acid and iodine and general lifestyle advice regarding drugs, smoking and alcohol in pregnancy."

Missed opportunities for blood pressure review

22. As outlined in the clinical notes at the 2 August 2013 appointment, Mrs A was to have a review after three months of taking cilazapril to determine whether her blood pressure had reduced appropriately. Dr B advised HDC that she asked Mrs A to make an appointment in three months' time so that her blood pressure could be monitored. This review did not occur.

30 September 2013

23. On 30 September 2013, Mrs A requested repeat prescriptions for fluoxetine, cilazapril and cholvastin from the medical centre and collected these prescriptions on 3 October 2013. Mrs A's blood pressure was not assessed before the prescriptions were picked up.

24. Dr B advised HDC that she accepts that the practice should have recognised at this point that Mrs A's blood pressure should be reviewed, and asked her to come in.

22 November 2013

25. On 22 November 2013, Mrs A again attended the medical centre and was seen by Dr B, this time with her daughter, who had chickenpox. At that time, Mrs A requested repeat prescriptions for fluoxetine, cilazapril and cholvastin, among others. The prescriptions were provided to Mrs A. Mrs A's blood pressure was not assessed before the prescriptions were picked up.

24 March 2014

26. On 24 March 2014, Mrs A again requested repeats of her regular prescriptions from the medical centre, including fluoxetine, cilazapril and cholvastin. These prescriptions were collected on 31 March 2014. Again, Mrs A's blood pressure was not assessed before the prescriptions were picked up.

23 May 2014 appointment

27. On 23 May 2014, Mrs A attended the medical centre and had an appointment with Dr B. The clinical notes outline that Mrs A had had three positive pregnancy tests. Mrs A was given an "antenatal pack", and Dr B noted in the clinical record that Mrs A had a "previous history of gestational diabetes".[11] Dr B prescribed Mrs A with folic acid tablets. There is no record in the clinical notes of Dr B taking Mrs A's blood pressure at this appointment.

[11] Diabetes that develops in pregnancy.

28. Mrs A advised HDC that at the appointment they discussed her diet and exercise. There is no record in the clinical notes that they discussed Mrs A's regular medications (ie, cilazapril and cholvastin) and whether these were appropriate to take while pregnant.

29. Dr B told HDC:

> "When [Mrs A] presented she was 6 weeks pregnant and we discussed antenatal care and her previous history of miscarriage and gestational diabetes and general antenatal care. I referred her for antenatal blood tests and to a midwife. However, I had a lapse of concentration and didn't address her prescriptions … I should have reviewed her medications and stopped the statin and changed her from an ACE Inhibitor to Labetalol. I let the patient and myself down. I cannot explain why this happened."

First midwifery visit

30. On 4 June 2014, Mrs A met with her Lead Maternity Carer, community-based registered midwife (RM) D.

31. Mrs A advised HDC that during the appointment RM D raised concerns about her medications in pregnancy, and rang the Maternity Unit to discuss this with obstetrician Dr C. Dr C agreed that Mrs A should not be taking cilazapril, and it needed to be changed to a safer option. RM D advised Mrs A to contact her doctor and have her medication changed. RM D recorded in the clinical record: "[Mrs A] to go back to her GP to get her hypertension medication [cilazapril] changed".

32. Following the appointment with RM D, Mrs A walked to the medical centre to book an appointment with a doctor. At this time she was told by reception staff that all the doctors were fully booked, and to telephone first thing the next morning.

Telephone conversation on 5 June 2014

33. On 5 June 2014, Mrs A telephoned the medical centre and requested a doctor's appointment to discuss changing her regular medications because of pregnancy. Mrs A was told that there were no appointments available. Mrs A then asked to speak to a nurse, and she was put through to RN E.[12] After discussing the situation with Mrs A, RN E said that she put an electronic enquiry [message] through MedTech, the practice's information technology system, to Dr B. The note from RN E to Dr B states: "Patient is pregnant. Wanting to know if needs to stop taking blood pressure and cholesterol medications? Does she need to come in for review?"

34. Dr B responded the same day via an electronic note stating: "[K]eep taking these meds [Dr B] … consider coming off fluoxetine". RN E then informed Mrs A by telephone of Dr B's advice. The only record of RN E's telephone conversations with Mrs A is the electronic enquiry to Dr B, Dr B's response, and a note "5/6 [5 June] advised" in the MedTech completed tasks record.

[12] RN E was a newly graduated nurse employed through the Nursing Entry to Practice Programme by the medical centre. At the time of the telephone conversation on 5 June 2015, RN E had been working at the medical centre for a few months.

35. Mrs A advised HDC:

> "I questioned [RN E] again about the safety of the medications and she brought up the medical background of both medications and read that they both have been associated with foetal abnormalities and other complications even she seemed confused and suggested that I speak with an obstetrician as I mentioned that I was possibly going to be going under a specialist."

36. RN E advised HDC:

> "Unfortunately I cannot recall the conversation[s] I had with the patient [Mrs A] over the telephone on 5 June 2014, nor can I remember whether I looked up the medications in MIMS.[13] I cannot recall advising Mrs A that the medications cilazapril and pravastatin [cholvastin] were a category contraindicated in pregnancy."

Follow-up by RM D

37. Following her conversation with RN E, Mrs A emailed RM D to advise that she had been unable to have her medications changed. RM D then arranged an emergency consultation for Mrs A at the Maternity Unit for 6 June 2014, to review the medication Mrs A was taking.

Consultation on 6 June 2014

38. On 6 June 2014, Mrs A met with obstetrician Dr C and a midwife at the Maternity Unit. The clinical notes record that Mrs A was to stop taking cilazapril and cholvastin and to begin taking labetalol, a blood pressure medication not contraindicated in pregnancy. In addition, Mrs A was to continue taking fluoxetine.

39. Following the appointment, the midwife recorded that she had spoken with RM D by telephone. RM D was to check Mrs A's blood pressure in a week's time and stop Mrs A's labetalol if her blood pressure had decreased to 110/70mmHg.

Letter to Dr B

40. On 13 June 2014, Mrs A wrote to Dr B outlining her concerns regarding Dr B's care of her over the previous months. Dr B responded to the letter on 18 June 2014, outlining her shock at the errors, her full acknowledgement of the mistakes, an apology, and the actions she was going to undertake as a result of the letter. Dr B advised Mrs A that she would "ensure that we have an education session to review our processes for antenatal care and safety of medications". In addition, Dr B advised Mrs A: "However I think I personally also need to reflect on what factors caused me to have this lapse in attention to your care". Dr B offered to meet with or call Mrs A at Mrs A's convenience to discuss her concerns.

Medsafe datasheets

Cilazapril

41. The New Zealand Medsafe datasheet for cilazapril outlines the following:

[13] A publisher of drug information.

"Special dosage instructions

Essential hypertension
The recommended initial dosage is half a 2.5 mg tablet once a day. Blood pressure should be assessed and dosage adjusted individually in accordance with the blood pressure response. The usual dose range of cilazapril is 2.5–5 mg once daily."

42. In regard to the safety of cilazapril in pregnancy, the Medsafe datasheet outlines:

"Category D.
Fetotoxicity[14] has been observed for ACE inhibitors[15] in animals. Although there is no experience with cilazapril, use of ACE inhibitors in human pregnancy has been associated with oligohydramnios, intrauterine growth restriction, neonatal hypotension, anuria and renal tubular dysplasia.[16]

Foetal exposure to ACE inhibitors during the first trimester of pregnancy has been associated with an increased risk of malformations of the cardiovascular system … and central nervous system … and an increased risk of kidney malformations.

Pregnant women should be informed of the potential hazards to the foetus (see Contraindications) and should not take cilazapril during pregnancy."

Cholvastin

43. The Medsafe datasheet for cholvastin outlines the following:

"Pregnancy and lactation. Atherosclerosis[17] is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolaemia.[18] Cholesterol and other products of cholesterol biosynthesis are essential components for foetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors [statins] decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause foetal harm when administered to a pregnant woman. Therefore, HMG-CoA reductase inhibitors are contraindicated during pregnancy.

Women of childbearing potential. Cholvastin should be administered to women of childbearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the patient becomes pregnant while taking this class of medicine, therapy should be discontinued and the patient again advised of the potential hazard to the foetus."

[14] Injury to the fetus from a substance that enters the maternal and placental circulation and may cause death or retardation of growth and development.
[15] An angiotensin-converting enzyme or "ACE", which indirectly increases blood pressure by causing blood vessels to constrict.
[16] Deficiency of amniotic fluid, poor growth of a baby while in the mother's uterus during pregnancy, low blood pressure in recently born babies, the non-passage of urine, and development problems for one or both of the baby's kidneys respectively.
[17] A disease in which the arteries are hardened and narrow, restricting blood flow.
[18] The presence of high levels of cholesterol in the blood.

Fluoxetine

44. The Medsafe data for fluoxetine outlines the following:

> "Fluoxetine use should be considered during pregnancy only if the potential benefit justifies the potential risk to the foetus, taking into account the risks of untreated depression."

The medical centre's repeat prescription policy

45. The medical centre provided HDC with a copy of its "Repeat Prescriptions Policy, Protocol and Procedure" (May 2013) (the policy). At the start of the policy, in bold and underlined, it states: "All medication prescribed at the medical centre will be in accordance with the NZ Medical Council's guidelines on Good Prescribing Practice and Prescribing Drugs of Abuse."

46. The policy outlines how repeat prescriptions can be obtained by patients (ie, fax, telephone, GP consultation, etc). It also outlines review requirements for patients on repeat prescriptions, as follows:

> "Patients with long-term conditions and on regular medication are required to have a six month review with their doctor. This review must specifically discuss long term medication and does not include visits for non-related matters.
>
> A nurse will advise the patient they are due for a medication review with their GP:
>
> - Via a consult note attached to the script or
> - Phone call."

47. The policy outlines "medication review guideline[s]" as follows, but does not outline whether the medication review is the requirement of the GP or practice nurses:

> "Consider the following [when reviewing repeat medications]
>
> - Documented indication for each medication?
> - Dose and directions appropriate and effective?
> - Medication still appropriate and effective?
> - Medication tolerated?
> - Any potential drug interaction?
> - Patient complaint?
> - Expected duration of therapy recorded?
> - Monitoring in place if appropriate e.g. warfarin?[19]
> - Any untreated medical conditions/indications?
> - All allergies/sensitivities recorded?
> - Date for review stated?
> - Education re medication given/required?
> - Any OTC [over the counter] meds being taken by patient?"

[19] An anticoagulant [prevents clotting of the blood] used to prevent heart attacks, strokes, and blood clots.

48. In addition, the policy outlines the prescriber's role in repeat medication prescriptions, as follows:

> "The doctor should check the drug details and review the clinical records and if appropriate sign the script. The doctor records the patient's name on the admin screen and places all signed scripts in script folder which is returned to the admin staff. If the doctor has any concerns or queries about the prescription they should contact either the patient or admin nurse."

Actions taken following complaint

Dr B

49. Dr B advised HDC: "I have given [Mrs A] my sincerest apologies and informed her that I have been personally mortified by my error and the distress that it has caused her and have contemplated it long and hard." Dr B also advised HDC that she has "endeavoured to use this event as a learning experience and advised [Mrs A] of the steps I have taken to do so". Dr B stated:

> "I have reviewed the best practice guidelines and contacted the PHO's [primary health organisation] clinical pharmacist to obtain further advice.
>
> The practice has reviewed this case at a Continuing Medical Education meeting and identified the learnings and actions to be taken. My colleagues were also unaware of the risks of statins […].
>
> Counselling patients routinely about avoidance in and prior to pregnancy has not been a routine practice and statins do not appear on the attached list of 'harmful drugs in pregnancy'. This will now be corrected.
>
> We have now completed an audit of female patients in the practice between 25 and 45 who are on ACE Inhibitors and statins so that each GP can review their management.
>
> We have also arranged for [an obstetrician] who specialises in medication management in pregnancy, to speak at a Continuing Medical Education session in the practice. This will give us up to date information to assist us to counsel any women of child bearing age on the risks of medication prior to and during pregnancy.
>
> We have also agreed to use a standardised template triggered by a 'keyword' to ensure that we cover medication review as part of the first antenatal visit. This will mean that patients who present at their first antenatal visit will have a review of their medication."

50. Dr B also advised HDC:

> "There is a risk that because we [GPs] are now very target focussed in the management of diabetes and CVD risk and because we have an epidemic of obesity and diabetes, that there will be many GPs prescribing statins and ACE Inhibitors to female patients without the need to counsel about pregnancy.

> There are no warnings or red flags in the system. Hopefully the actions that we have taken will reduce this risk. I will also recommend to the PHO clinical pharmacist that they create a bulletin for all [local] GPs to alert them to this risk."

The medical centre

51. The medical centre advised HDC that it had undertaken the following actions in addition to those listed by Dr B:

> "At a GP meeting held on 19 November 2014, individual GPs have been asked to review their patients to ensure they are aware of the risks of the drugs in pregnancy, and to take further action, as necessary.
>
> [The medical centre] has obtained copies of the Med-Info Patient Information leaflets on simvastatin, atorvastatin [types of statins] and cilazapril which will be provided to women after a CVD Risk assessment is completed.
>
> These Med-Info leaflets are now available as a resource on GP's desktop."

52. As per Dr B's response, the medical centre has obtained a Drug Information bulletin on "Drugs in pregnancy", which has been circulated to all GPs and nurses in order to increase the awareness of all providers about the risks.

53. The medical centre advised:

> "The complaint has been discussed with both [RN E] and [the nurse manager]. As a practice, we have a supportive culture which recognises the importance of team work and of nurses feeling empowered to provide a high level of care. [Dr B] together with others GPs appreciate the contribution of the nurses, and take an interest in the professional development of the nurses. They have always encouraged nurses to ask questions if they are uncertain about any instructions/treatment decisions."

54. In addition, the medical centre advised HDC: "This incident has been discussed at several GP meetings, and [Dr B] has taken action to ensure that her learnings have been shared with her colleagues. Further work will be done to develop an antenatal check list as a key word on MedTech."

Response to provisional opinion

55. Mrs A, Dr B and the medical centre were provided with opportunity to respond to the provisional opinion. Mrs A and the medical centre did not wish to provide comment on the provisional opinion. Dr B's comments have been considered when finalising this report.

Relevant standards

56. The Medical Council of New Zealand publication *Good Prescribing Practice*, issued in April 2010, provides the following prescribing standards:

"You should only prescribe medicines or treatment when you have adequately assessed the patient's condition, and/or have adequate knowledge of the patient's needs and are therefore satisfied that the medicines or treatment are in the patient's best interests …

- Be familiar with the indications, side effects, contraindications, major drug interactions, appropriate dosages, effectiveness and cost-effectiveness of the medicines that you prescribe …

- Periodically review the effectiveness of the treatment and any new information about the patient's condition and health if you are prescribing for an extended period of time. Continuation or modification of treatment should depend on your evaluation of progress towards the objectives outlined in a treatment plan.

- Keep a clear and accurate patient record containing all relevant clinical findings; decisions made; information given to the patient; and the medicines and any other treatment prescribed …

Patients receiving repeat prescriptions should be assessed in a face-to-face consultation on a regular basis to ensure that the prescription remains appropriate. Patients who need a further examination or assessment should not receive repeat prescriptions without being seen by a doctor …"

Opinion: Dr B — Breach

Medication management

Prescribing of cilazapril and cholvastin

57. Mrs A had a complex history with obesity, hypertension and high cholesterol, amounting to an increased risk of CVD. Mrs A's CVD risk had been managed at the medical centre for a number of years, with relative success. On 23 July 2013, Mrs A had a nurse-led diabetes annual review at the medical centre, where it was noted that her blood pressure was elevated. As a result of this review, a practice nurse recommended that Mrs A see Dr B to determine whether recommencing cilazapril was appropriate to manage Mrs A's blood pressure.

58. On 2 August 2013, Mrs A was seen by Dr B, who considered it appropriate for Mrs A to recommence cilazapril. Dr B also provided Mrs A with a repeat prescription of cholvastin at this time. Mrs A advised HDC that during the appointment she told Dr B of her intentions to become pregnant, and asked whether cilazapril and cholvastin were safe in pregnancy. Dr B told HDC she does not recall Mrs A advising her of the intention to become pregnant.

59. Dr B told HDC: "[I]t is my practice to record information like this [a patient advising that she is trying to become pregnant] in my notes, particularly as I would at that point have discussed pre-pregnancy folic acid and iodine and general lifestyle advice

regarding drugs, smoking and alcohol in pregnancy." There is no record in the clinical notes of Mrs A advising that she was considering pregnancy.

60. In any event, whether Mrs A did or did not tell Dr B of her intention to become pregnant, I consider that Dr B should have ascertained that information, as Mrs A was of childbearing age, and the medication Dr B was prescribing was contraindicated in pregnancy. Dr B should have enquired directly of Mrs A regarding her intentions around pregnancy. My expert general practitioner advisor, Dr David Maplesden, advised:

> "At the consultation of 2 August 2013, [Dr B] was either aware (according to [Mrs A]) or should have made herself aware (by way of direct enquiry) of [Mrs A's] intention to become pregnant in the short to medium-term. Use of statin and ACE inhibitor was undesirable if this intention was established. … There should have been discussion of relative risks of these medications in pregnancy before they were prescribed and this did not occur."

61. According to the Medical Council of New Zealand, a practitioner should "only prescribe medicines or treatment when [they] have adequately assessed the patient's condition, and/or have adequate knowledge of the patient's needs and are therefore satisfied that the medicines or treatment are in the patient's best interests". Furthermore, according to the Medical Council of New Zealand, practitioners are to "be familiar with the indications, side effects, contraindications, major drug interactions, appropriate dosages, effectiveness and cost-effectiveness of the medicines that [they] prescribe". This advice is mirrored in the medical centre's "Repeat Prescriptions Policy, Protocol and Procedure" (May 2013). On 2 August 2013, Dr B's actions suggest that she did not consider the possibility of Mrs A becoming pregnant, and therefore did not take into account the contraindication of Mrs A taking cilazapril and cholvastin while pregnant.

Management of medication in pregnancy

62. On 23 May 2014, Mrs A had an antenatal appointment with Dr B. At this appointment Dr B discussed Mrs A's history of gestational diabetes in pregnancy. Dr B prescribed folic acid tablets for Mrs A. Dr B failed to consider or discuss with Mrs A the appropriateness of Mrs A continuing to take cilazapril, cholvastin and fluoxetine when pregnant.

63. On 4 June 2014, Mrs A met with midwife RM D, who was concerned about Mrs A's medications and their appropriateness in pregnancy. RM D called the Maternity Unit to discuss the medications with an obstetrician there, who advised that the medications were contraindicated in pregnancy. RM D told Mrs A to return to her GP to have her medication reassessed. In my view, RM D's actions were commendable in the circumstances. Mrs A immediately attempted to see Dr B, but all the GPs at the medical centre were fully booked, and she was told to telephone for an appointment the following day.

64. On 5 June 2014, Mrs A rang the medical centre to book an appointment, but again was told that all the GPs were booked for the day. Mrs A was then put in contact with RN E, who put an electronic enquiry through to Dr B to query Mrs A's medications

and pregnancy. Dr B responded that Mrs A should remain on cilazapril and cholvastin but should consider whether or not to keep taking fluoxetine.

65. Dr Maplesden advised me on the appropriateness of Dr B's recommendations to Mrs A via RN E:

> "The advice given to [Mrs A] by [Dr B] (via her nurse) on 5 June 2014 regarding the use of cilazapril and cholvastin are not consistent with manufacturer recommendations and was potentially harmful (although … there is some debate on evidence of potential harm in the first trimester related to both ACE inhibitors and statin use). I do not believe such advice should have been given over the telephone without the opportunity for [Mrs A] to discuss with [Dr B] the risks and benefits of continuing or stopping the medication."

66. Furthermore, Dr Maplesden advised:

> "With respect to the advice to stop fluoxetine, this might have been reasonable if accompanied by a review of [Mrs A's] psychological history and current status and discussion with her on the risks and benefits of continuing or stopping therapy. However, no such opportunity was offered or review undertaken."

67. In my view, Dr B should have requested Mrs A come in for a review before advising her which medications to continue or discontinue in pregnancy, particularly given Mrs A's history and the medications she was on. Under no circumstances should Dr B have advised Mrs A to remain on cilazapril and cholvastin without first discussing their contraindication in pregnancy.

Monitoring of blood pressure

68. On 2 August 2013, Mrs A was prescribed cilazapril to manage hypertension. According to the Medsafe datasheet, a patient's blood pressure should be monitored to ensure that the dosage of cilazapril is relieving the patient's hypertension appropriately. Dr B was aware of the need for blood pressure monitoring, and recorded this in the clinical notes of the 2 August 2013 appointment. The clinical notes outlined that Mrs A was to be reviewed after three months of taking cilazapril. Dr B requested Mrs A book an appointment in three months' time to have her blood pressure monitored. This appointment and subsequent monitoring did not occur.

69. On 3 October 2013, 22 November 2013 and 23 May 2014, Mrs A attended the medical centre and received repeat prescriptions for cilazapril, cholvastin and fluoxetine. Repeat prescriptions were provided to Mrs A on each of these occasions without a blood pressure check or a review.

70. Dr Maplesden advised: "[T]he fact blood pressure was not checked for almost a year after cilazapril was commenced, and repeat prescriptions continued to be provided without such assessment, was suboptimal management". I agree with Dr Maplesden and consider that Mrs A's blood pressure should have been monitored regularly throughout the time in question.

71. I note that the Medical Council of New Zealand *Good Prescribing Practice* (2010) outlines requirements for practitioners to review patients on repeat prescriptions regularly. Furthermore, this is highlighted in the medical centre's "Repeat Prescriptions Policy, Protocol and Procedure" (May 2013), which requires practitioners to review patients on repeat medication every six months. This did not happen in Dr B's care for Mrs A.

72. I note that the medical centre's "Repeat Prescriptions Policy, Protocol and Procedure" (May 2013) is clear that practice nurses are to check that any monitoring is in place, and arrange regular follow-up for patients (at least six monthly for long-term conditions) for medication reviews. I consider that the provision of primary care is a team effort, and the team at the medical centre failed to ensure that Mrs A's blood pressure was monitored appropriately. However, as the practitioner responsible for prescribing Mrs A with repeat prescriptions of cilazapril, Dr B had the responsibility to ensure that Mrs A's blood pressure had been monitored appropriately on each occasion. This was also a further missed opportunity for Dr B to review the appropriateness of cilazapril, and the other medications, for Mrs A.

Conclusions

73. There were compounding errors in Dr B's management of Mrs A's medication before and after she became pregnant. Even when prompted by the enquiry from RN E, Dr B failed to recognise the need to check whether cilazapril and cholvastin were appropriate for Mrs A. Furthermore, without assessing Mrs A, Dr B advised that she should consider stopping fluoxetine. In addition, Dr B failed to ensure that Mrs A's blood pressure was monitored appropriately. Dr Maplesden has advised me: "Taking into account all of the factors discussed I feel [Dr B's] management of [Mrs A] would meet with severe disapproval by my peers." I accept Dr Maplesden's advice. In my view, Dr B did not provide services to Mrs A with reasonable care and skill, and breached Right 4(1) of the Code.

74. Mrs A had a right to be informed about any risks and benefits of continuing to take cilazapril, cholvastin and fluoxetine while pregnant. Dr B did not provide that information to Mrs A on 2 August 2013, 23 May 2014 or 5 June 2014. In Mrs A's circumstances, this was information that was crucial to her. Right 6(1) of the Code provides that every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive. In my view, a reasonable consumer in Mrs A's circumstances would expect to receive information about the risks and benefits of continuing cilazapril, cholvastin and fluoxetine in pregnancy. I find that by not providing that information, Dr B breached Right 6(1) of the Code.

75. I note that Dr B has accepted her errors in the management of Mrs A's medication, and has apologised for these errors and appropriately undertaken steps to ensure that the errors do not happen again. This is commendable.

Opinion: RN E — Adverse comment

76. I have concerns about RN E's management of her telephone conversations with Mrs A on 5 June 2014. Mrs A advised HDC that RN E told her that both cilazapril and cholvastin were contraindicated in pregnancy. However, there is no record of RN E advising Mrs A of this, and RN E cannot recall what she told Mrs A or whether she looked up the MIMS sheet for cilazapril and cholvastin.

77. Given that RN E's conversations with Mrs A are not documented, and RN E cannot recall the conversations, I am unable to determine what was done or advised during those conversations. I acknowledge that RN E was following the instructions of Dr B. However, as I have stated in a previous opinion, if RN E was aware that cilazapril and cholvastin were contraindicated in pregnancy, then "a culture of nurses not questioning medical colleagues is a disservice to both professions and to the patients to whom they owe a duty of care".[20]

78. I also note RN E's lack of documentation of her conversations with Mrs A on 5 June 2014. As this Office has previously advised, "the importance of good record keeping cannot be overstated. It is the primary tool for continuity of care and it is a tool for managing patients."[21] RN E should have recorded her conversations with Mrs A in Mrs A's clinical record.

Opinion: The medical centre — Adverse comment

79. Dr B was a director and clinical director of the medical centre. Under Section 72(3) of the Health and Disability Commissioner Act 1994 (the Act), anything done by a person as the agent of an employing authority shall, for the purposes of the Act, be treated as done or omitted by that employing authority as well as by the first-mentioned person, unless it is done or omitted without that employing authority's express or implied authority.

Management of Mrs A's medication in pregnancy

80. As outlined above, when prescribing Mrs A with cilazpril and cholvastin, drugs contraindicated in pregnancy, Dr B had a professional responsibility to determine whether the drugs were appropriate for Mrs A. Similarly, when Dr B became aware that Mrs A was pregnant, she had a professional responsibility to advise Mrs A that the medications she was on, particularly cilazapril and cholvastin, were contraindicated in pregnancy. I consider that Dr B's failure to consider the risks of these drugs in pregnancy was an individual clinical error. The medical centre could reasonably have an expectation that Dr B would perform her duties appropriately, as set out by her regulatory body, in this case the Medical Council of New Zealand. I therefore consider that the medical centre is not responsible for Dr B's individual clinical failures.

[20] Opinion 13HDC00213. Available at www.hdc.org.nz.
[21] Opinion 12HDC01019. Available at www.hdc.org.nz.

Teamwork

Repeat medication management

81. The medical centre's "Repeat Prescriptions Policy, Protocol and Procedure" (May 2013) outlines that a nurse is responsible for advising patients when they are due for a medication review with their GP (at least six monthly as per the policy). There is no record in Mrs A's clinical notes between July 2013 and June 2014 that a nurse from the medical centre advised Mrs A that she required GP review of her repeat medications or checked that blood pressure monitoring was required. In this way, the practice staff failed to follow the policy for repeat prescribing.

82. As outlined above, I consider that both Dr B and the practice nurses had a responsibility to ensure that Mrs A's blood pressure was monitored. The provision of primary care is a team effort, and I am critical that the team at the medical centre failed to ensure that Mrs A's blood pressure was monitored appropriately.

Communication between doctors and nurses

83. I am concerned that when RN E raised the issue of Mrs A's medication with Dr B on 5 June 2014, an opportunity was missed to pick up on the error. As outlined above, RN E's documentation of the telephone call on 5 June 2014 is limited, as is her recollection of the call. I therefore cannot make a finding that RN E knew that the medications Mrs A was on, particularly cilazapril and cholvastin, were contraindicated in pregnancy. However, had RN E been aware of this I would expect that the environment at the medical centre would be one where RN E could raise her concern with Dr B.

Recommendations

84. In accordance with the recommendation in my provisional opinion Dr B has provided a written apology to Mrs A.

85. I recommend that the Medical Council of New Zealand undertake a competency review of Dr B and report back to HDC on the outcome of that review.

86. I recommend that the medical centre:

a) Further clarify the roles and responsibilities of practice nurses, doctors and administration staff in its "Repeat Prescriptions Policy, Protocol and Procedure". Evidence of this should be forwarded to HDC within three months of the date of this report.

b) Audit its clinical staff's compliance with its "Repeat Prescriptions Policy, Protocol and Procedure". A report on this audit should be forwarded to this Office within three months of the date of this report.

c) Include in its training and induction for all staff, information that the asking of questions and reporting of concerns is expected and accepted from all members of the multidisciplinary team. A copy of the training and induction material is to be

provided to this Office within three months of the date of this report, to ensure that the medical centre is supporting a culture that encourages these actions.

Follow-up actions

87.
- A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Medical Council of New Zealand and the District Health Board, and they will be advised of Dr B's name.

- A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Royal New Zealand College of General Practitioners, the New Zealand Nurses Organisation, and the New Zealand College of Midwives, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A — Independent general practitioner advice to the Commissioner

The following expert advice was obtained from general practitioner Dr David Maplesden on 14 October 2014:

> "1. Thank you for providing this file for advice. To the best of my knowledge I have no conflict of interest in providing this advice. I have reviewed the available information: complaint from [Mrs A]; response from [Dr B]; GP notes [the medical centre] from July 2013 to present; response from manager [the medical centre]; [the DHB's clinical notes]. [Mrs A] complains about the management of her medication by [Dr B] in relation to intended and then actual pregnancy.
>
> 2. Brief clinical synopsis from available documentation
>
> (i) [Mrs A] had been attending [the medical centre] since the mid-1990s. She was diagnosed with type-2 diabetes in 2006 and had evidently been taking cilazapril (Inhibace) at some stage prior to her presentation to [Dr B] in August 2013, but was not taking it at the time of this presentation. [Mrs A] had had a previous miscarriage (date unclear) and had caesarean section delivery of a daughter in [year]. [Mrs A] had a history of depression which had been stable for several years on fluoxetine.
>
> (ii) On 23 July 2013 [Mrs A] had a nurse-led diabetes annual review. [Mrs A] was noted to have elevated blood pressure (145/90) and elevated BMI (38.7). Blood tests taken on 25 July 2013 showed elevated lipids (total cholesterol (TC) 4.7 mmol/L, LDL cholesterol 3.1 mmol/L, TC:HDL ratio 4.9, triglycerides normal) and fasting glucose within normal limits. There was no significant albuminuria on albumin:creatinine ration (ACR) measurement. Results were reviewed with [Mrs A] and the nurse on 30 July 2013 and the possibility of recommencing cilazapril was discussed in view of [Mrs A's] hypertension. The nurse has also recorded *raised alb creat ratio 2.3* — however a level of < 3.5 mg/mmol is acceptable in females[1].
>
> (iii) On 2 August 2013 [Mrs A] was seen by [Dr B] to discuss management of her blood pressure and cardiovascular risk (CVR). Five-year CVR had been calculated on 29 July 2013 as 3% with moderate risk of diabetes complications (on the basis of elevated blood pressure and elevated total cholesterol). [Dr B] recorded *Diabetic, needs BP meds and statin, was previously on cilazapril, came off when she lost weight, has put weight back on …BP 150/100, R/V in 3/12 with fasting bloods.* Prescriptions were provided for pravastatin (Cholvastin) 20mg daily and cilazapril 2.5mg daily. Bloods were repeated on 9 September 2013 at which stage TC was 5.0 mmol/L and TC:HDL ratio 4.4 and HbA1c 37 mmol/mol (indicating excellent glycaemic control). [Mrs A] was sent a letter with dietary advice. Repeat prescriptions for regular medications was provided on 30 September 2013 (no consultation), 22 November 2013 (at the time of consultation with [Mrs A's] daughter) and 24 March 2014 (no consultation). There is no record of [Mrs A's]

[1] Ministry of Health. New Zealand Primary Care Handbook. 2012.

blood pressure being checked in the 11-month period following commencement of her medications until a consultation on 4 July 2014 […]. While there is no record of discussion regarding safety of the prescribed medications during pregnancy in the consultation notes of 2 August 2013, [Mrs A] has stated *during the consultation I questioned if either of the … medications* [cilazapril and pravastatin] *were safe if I were to fall pregnant as my partner and I were going to try for another baby and your answer was that 'they are fine'.*

(iv) On 23 May 2014 [Mrs A] attended [Dr B] for a first antenatal appointment. LMP was [date] giving an estimated delivery date of [date] and current gestation of around six weeks. Blood pressure was not recorded nor was there any record of discussion regarding continuation of [Mrs A's] current medications during pregnancy. An antenatal information pack was provided and prescription given for folic acid tablets. Routine antenatal bloods were ordered.

(v) [Mrs A] states she met with her lead maternity carer (LMC) [RM D] on 4 June 2014 and [RM D] expressed some concern that [Mrs A] was taking cilazapril. LMC antenatal notes dated 4 June 2014 include: *Booking visit with [Mrs A]. I will do a referral to MAU due to her history of gestational diabetes, hypertension and high cholesterol. I have prescribed aspirin 75mg OD. [Mrs A] to go back to GP to get her hypertension medication changed.* Blood pressure was 140/80. Routine follow-up was scheduled for 2 July 2014 with forms provided for dating scan and combined screening.

(vi) [Mrs A] states she attended [the medical centre] later on 4 June 2014 to discuss her medications with [Dr B] but was unable to make an appointment that day. She was advised to phone the centre the next day which she did, was still unable to make an appointment with [Dr B] but spoke with a nurse who discussed the issue with [Dr B]. [Mrs A] states the nurse called her back and told her *do not stop taking either Cholvastin … or Cilazapril … but I could try and stop taking Fluoxetine.* While on the phone, [Mrs A] asked the nurse to check on the medications and was told they were both of a category contraindicated in pregnancy and she should discuss this with her obstetrician. [Mrs A] then sought advice from a pharmacist who reiterated that both drugs [Mrs A] had been told to continue were contraindicated in pregnancy, but stopping fluoxetine *might do more harm than good.* [Mrs A] relayed the sequence of events to [RM D] who then requested urgent specialist review which was undertaken the following day (6 June 2014). [Medical centre] notes 5 June 2014 record a task sent to [Dr B] and her response: *Hi [Dr B], Pt is pregnant. Wanting to know if needs to stop taking BP and cholesterol meds? Does she need tci for rv?* Response: *keep taking these meds [Dr B], consider coming off fluox cetirizine* [cetirizine is an antihistamine [Mrs A] had been taking intermittently].

(vii) [The public hospital's] obstetric service notes dated 6 June 2014 summarise [Mrs A's] medical and obstetric history including current medications. Notes include: *Discuss that Cilaxapril & Cholvastin contraindicated in pregnancy.* The cilazapril and pravastatin were stopped and the antihypertensive labetalol commenced, dose to be titrated by [RM D] according to blood pressure response.

Fluoxetine was to be continued and booking made for specialist review with respect to [Mrs A's] diabetes.

(viii) […].

3. With respect to expected standards of prescribing, I have used the Medical Council of New Zealand publication 'Good Prescribing Practice' April 2010[2]. The publication includes the following comments:

(i) *You should only prescribe medicines or treatment when you have adequately assessed the patient's condition, and/or have adequate knowledge of the patient's needs and are therefore satisfied that the medicines or treatment are in the patient's best interests.*

(ii) *Be familiar with the indications, side effects, contraindications, major drug interactions, appropriate dosages, effectiveness and cost-effectiveness of the medicines that you prescribe.*

(iii) *Keep a clear and accurate patient record containing all relevant clinical findings; decisions made; information given to the patient and the medicines and any other treatment prescribed.*

(iv) *Periodically review the effectiveness of the treatment and any new information about the patient's condition and health if you are prescribing for an extended period of time. Continuation or modification of treatment should depend on your evaluation of progress towards the objectives outlined in a treatment plan.*

(v) *Patients receiving repeat prescriptions should be assessed in a face-to-face consultation on a regular basis to ensure that the prescription remains appropriate. Patients who need a further examination or assessment should not receive repeat prescriptions without being seen by a doctor.*

4. With respect to medical management of [Mrs A's] diabetes and cardiovascular risk, leaving aside the issue of intended or actual pregnancy, I have referred to the New Zealand Primary Care Handbook 2012[1].

(i) [Mrs A] had a calculated CV risk of 3% on 29 July 2013. She was assessed as having a moderate risk of developing diabetes-related complications on the same date. These assessments were appropriate.

(ii) Noting [Mrs A's] relatively long history of diabetes I think it was reasonable to assume she had previously been given, and attempted to apply, appropriate lifestyle advice. In that case, it was reasonable to discuss achieving 'target' levels of blood pressure (<130/80) and lipids (TC < 4 mmol/L) with the use of medication. However, the guidelines cited also recommend monitoring of blood pressure, HbA1c and eGFR 3-monthly in patients at moderate to high risk of

[2] Accessed 14 October 2014 at: http://www.mcnz.org.nz/assets/News-and-Publications/Statements/Good-prescribing-practice.pdf

complications. Given [Mrs A's] excellent glycaemic control and normal ACR I do not feel such close monitoring was necessarily warranted, although it would be expected that blood pressure would have been monitored more regularly than it was, particularly following the introduction of anti-hypertensive medication. The fact blood pressure was not checked for almost a year after cilazapril was commenced, and repeat prescriptions continued to be provided without such assessment, was suboptimal management.

(iii) The medications provided to [Mrs A] were consistent with the guidelines cited, noting there is no specific reference in these guidelines to management of diabetes complication risk and cardiovascular risk in females of childbearing age and who are planning pregnancy. However, there is information freely available regarding use of medication in pregnancy and this is discussed further below — such information indicating [Dr B] should at least have established if [Mrs A] was contemplating a pregnancy prior to commencing the medication and should have discussed with [Mrs A] the potential risks of the medication in relation to pregnancy. If [Dr B] was prepared to prescribe the medications concerned, she had a duty to realise they were contraindicated in pregnancy (as per the product information) and to have given [Mrs A] appropriate advice when she was aware [Mrs A] was contemplating pregnancy (and [Mrs A] states [Dr B] was aware of this at the consultation of August 2013) and certainly when pregnancy was confirmed in June 2014.

5. Cilazapril

(i) The New Zealand Medsafe data sheet for cilazapril[3] includes the following relevant information: *Category D[4]. Fetotoxicity has been observed for ACE inhibitors in animals. Although there is no experience with cilazapril, use of ACE inhibitors in human pregnancy has been associated with oligohydramnios, intrauterine growth restriction, neonatal hypotension, anuria and renal tubular dysplasia. Foetal exposure to ACE inhibitors during the first trimester of pregnancy has been associated with an increased risk of malformations of the cardiovascular system (atrial and/or ventricular septal defect, pulmonic stenosis, patent ductus arteriosus) and central nervous system (microcephaly, spina bifida) and an increased risk of kidney malformations. Pregnant women should be informed of the potential hazards to the foetus and should not take cilazapril during pregnancy.*

(ii) Earlier advice from Medsafe in 1998[5] confirmed the risks associated with second and third trimester use of ACE inhibitors but commented that evidence for harm associated with use in the first trimester was scant. Advice regarding fetal exposure included: *If pregnancy is confirmed in a woman taking an ACE inhibitor, she should be referred promptly to a specialist for a switch to an*

[3] http://www.medsafe.govt.nz/profs/datasheet/c/Cilazapril-AFTtab.pdf
[4] FDA pregnancy category D: There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.
[5] Medsafe. ACE Inhibitors in Early Pregnancy. Prescriber Update December 1998.17:25–27. Accessed 14 October 2014 at: http://www.medsafe.govt.nz/profs/PUarticles/aceinhibitors.htm

alternative means of management for her condition. The woman should be advised not to discontinue her medication prior to the consultation because of the risk to mother and foetus of inadequately controlled hypertension. With regard to the safety of the foetus, the woman should be counselled according to the exposure of the foetus and the seriousness of her disease. A woman whose foetus has been exposed to an ACE inhibitor only during the first trimester can be assured that the foetus is unlikely to be harmed. Nevertheless, the woman should not be led to believe that the safety of the baby is guaranteed. Women who are not found to be pregnant until their use of an ACE inhibitor has continued into the second trimester should be advised that there is a significant risk of foetal toxicity which increases as the pregnancy advances. The consequences of continuing the pregnancy should be discussed and a referral made for assessment and appropriate management.

(iii) A more current reference[6] supports the information provided by Medsafe in 1998, concluding that that it is likely that any teratogenic effects previously attributed to ACE inhibitors taken during the first trimester of pregnancy are the result of the underlying hypertension and not the medications themselves, and that untreated hypertension was associated with greater risks of any malformation, congenital heart defects, and neural tube defects.

6. Pravastatin

(i) The Medsafe data sheet for pravastatin[7] includes the following information: *Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolaemia. Cholesterol and other products of cholesterol biosynthesis are essential components for foetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause foetal harm when administered to a pregnant woman. Therefore, HMG-CoA reductase inhibitors are contraindicated during pregnancy …Safety in pregnant women has not been established. Although pravastatin was not teratogenic in rats at doses as high as 1000mg/kg daily, nor in rabbits at doses of up to 50mg/kg daily, Cholvastin should be administered to women of child-bearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking Cholvastin, it should be discontinued and the patient advised again as to the potential hazards to the foetus.*

(ii) A recent meta-analysis and review article on use of statins in pregnancy[8] included the following abstract: *Statins enjoy widespread acceptance as effective drugs to reduce morbidity and mortality in patients with and without cardiovascular disease, and are considered safe for long-term use. However,*

[6] Li D-K et al. Maternal exposure to angiotensin converting enzyme inhibitors in the first trimester and risk of malformations in offspring: a retrospective cohort study. BMJ 2011;343:d5931
[7] http://www.medsafe.govt.nz/profs/datasheet/c/cholvastintab.pdf
[8] Kusters D et al. Statin use during pregnancy: a systematic review and meta-analysis. Expert Rev Cardiovasc Ther. 2012 Mar;10(3):363–78.

these compounds are contraindicated during pregnancy based on their potential teratogenic effects. Owing to the increasing number of young women eligible for statin therapy and the concern that the discontinuation of statin therapy might be harmful for both mother and child with hypercholesterolemia, gestational exposure to statins has increasingly become an issue of significant clinical importance. In this systematic review of both human and animal studies on the teratogenic effects of statins during pregnancy, we found that most of the available data in fact suggests that statins are unlikely to be teratogenic. In humans, the observed congenital anomalies were isolated and no consistent pattern has emerged to suggest that a common mechanism could underlie these observations. Animal studies show conflicting results, but in the reports in which an excess of congenital anomalies was reported in the statin-treated rodents, excessive doses were used compared with the regimens we commonly prescribe to human subjects.

7. Fluoxetine

The Medsafe data sheet for fluoxetine[9] includes the following information:

(i) *Fluoxetine use should be considered during pregnancy only if the potential benefit justifies the potential risk to the foetus, taking into account the risks of untreated depression. Experimental animal studies do not indicate direct or indirect harmful effects, with respect to the development of the embryo or foetus or the course of gestation. Because animal reproduction studies are not always predictive of human response, this medicine should be used during pregnancy only if clearly needed. Results of a number of epidemiological studies assessing the risk of fluoxetine exposure in early pregnancy have been inconsistent and have not provided conclusive evidence of an increased risk of congenital malformations. However, one meta-analysis suggests a potential risk of cardiovascular defects in infants of women exposed to fluoxetine during the first trimester of pregnancy compared to infants of women who were not exposed to fluoxetine.*

(ii) *This drug crosses the placenta. At the end of pregnancy, caution should be exercised, as transitory withdrawal symptoms (eg. transient jitteriness, difficulty feeding, tachypnea and irritability) have been reported rarely in the neonate after maternal use near term. Neonates exposed to fluoxetine and other SSRIs or serotonin and noradrenaline reuptake inhibitors (SNRIs), late in the third trimester have been uncommonly reported to have clinical findings of respiratory distress, cyanosis, apnoea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycaemia, hypotonia, hypertonia, hyperreflexia, tremor, jitteriness, irritability and constant crying. Such events can arise immediately upon delivery and are usually transient. These features could be consistent with either a direct effect of SSRIs and SNRIs or, possibly, a drug discontinuation syndrome. When treating a pregnant woman with fluoxetine during the third trimester, the physician should carefully consider the potential risks and benefits of treatment.*

[9] http://www.medsafe.govt.nz/profs/datasheet/f/Fluoxcaptab.pdf

(iii) *Although untreated depression is a risk factor for preterm delivery, epidemiological data suggests that the use of SSRIs and SNRIs in pregnancy may be associated with a further additional increased risk of pre-term delivery. Recent data suggests the use of SSRIs, including Fluoxetine, after the first 20 weeks of pregnancy may be associated with an increased risk of persistent pulmonary hypertension of the newborn (PPHN). The data shows the absolute risk among those who used SSRIs late in pregnancy was reported to be about 6 to 12 per 1000 women, compared to 1 to 2 per 1000 women in the United States general population. These findings should be taken into account by the physician when making decisions whether to continue the use of SSRIs during pregnancy.*

(ii) *Discontinuation symptoms have been reported in association with selective serotonin reuptake inhibitors (SSRIs). Because of the long elimination half-life of fluoxetine, and its active metabolite norfluoxetine, plasma fluoxetine and norfluoxetine concentrations decrease gradually at the conclusion of therapy, which reduces greatly the likelihood of developing discontinuation symptoms and makes dosage tapering unnecessary in most patients.*

8. Conclusions

(i) There was inadequate monitoring of [Mrs A's] blood pressure following commencement of cilazapril on 2 August 2013.

(ii) At the consultation of 2 August 2013, [Dr B] was either aware (according to [Mrs A]) or should have made herself aware (by way of direct enquiry) of [Mrs A's] intention to become pregnant in the short to medium-term. Use of statin and ACE inhibitor was undesirable if this intention was established. I do not feel [Mrs A's] lipid profile was sufficiently abnormal to justify prescribing of statins noting the potential risk in pregnancy of such prescribing. Blood pressure control was probably more important but alternative anti-hypertensives which are 'safer' in pregnancy were available, and I note [Mrs A] did not have any evidence of renal damage in terms of significant albuminuria (no eGFR on record). In any case, there should have been discussion of relative risks of these medications in pregnancy before they were prescribed and this did not occur.

(iii) [Dr B] failed to consider or discuss the risks and benefits of ongoing use of cilazapril and pravastatin during pregnancy with [Mrs A] at the first antenatal consultation of 23 May 2014. She also failed to measure [Mrs A's] blood pressure at this consultation.

(iv) The advice given to [Mrs A] by [Dr B] (via her nurse) on 5 July 2014 regarding use of cilazapril and pravastatin in pregnancy was not consistent with manufacturer recommendations and was potentially harmful (although as noted above there is some debate on evidence of potential for harm in the first trimester related to both ACE inhibitor and statin use). I do not believe such advice should have been given over the telephone without the opportunity for [Mrs A] to discuss with [Dr B] the risks and benefits of continuing or stopping the various medications. With respect to the advice to stop fluoxetine, this might have been reasonable if accompanied by a review of [Mrs A's] psychological history and

current status and discussion with her on the risks and benefits of continuing or stopping therapy. However, no such opportunity was offered or review undertaken. It would have been equally reasonable to advise [Mrs A] to continue fluoxetine (as was done at [the public hospital]) provided [Mrs A] was making an informed decision.

(v) […]

(vi) Taking into account all of the factors discussed I feel [Dr B's] management of [Mrs A] would meet with severe disapproval by my peers with her advice to [Mrs A] to continue taking medications contraindicated in pregnancy when a concern had been raised by the LMC a major determining factor. I feel aspects of [Dr B's] management of [Mrs A] may raise concerns regarding her clinical competency and patient safety, and referral to the Medical Council of New Zealand might be considered.

(vii) I am mildly critical (assuming the accuracy of [Mrs A's] complaint) that the practice nurse she spoke to on 5 July 2014 did not recheck with [Dr B] the advice to continue taking cilazapril and pravastatin when she had apparently established herself that both were contraindicated in pregnancy (see 2(vi)).

(viii) The remedial measures undertaken by [Dr B] and [the medical centre] to date, as outlined in their responses and including an audit of all pregnant patients taking regular medications and an antenatal care template including medication review, are appropriate and should reduce the risk of a similar event occurring in the future. However, as per the cited Medical Council of New Zealand recommendations, every GP has a responsibility to be aware of the contraindications of any medication he or she is prescribing and such information is readily available."