A Medical Centre
General Practitioner, Dr B
General Practitioner, Dr C
General Practitioner, Dr D

A Report by the
Health and Disability Commissioner

(Case 11HDC00440)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

Background

1. Mrs A was repeatedly prescribed a combined oral contraceptive pill (COC), even though she presented with a number of risk factors that should have been carefully discussed with her.

2. Mrs A was overweight, a smoker, over 35 years of age, and had a family history of thromboembolism. She was therefore at significant risk of developing a deep vein thrombosis (DVT)[1] and, given that risk, the COC was not a recommended method of contraception. However, Mrs A also had polycystic ovary syndrome (PCOS). The combined oral contraceptive Estelle is indicated for treatment of symptoms associated with PCOS.

3. Mrs A had been prescribed Estelle (or its equivalent) until 2005, when her general practitioner (GP) at that time deemed Estelle to be unsuitable because of Mrs A's risk factors for DVT. Mrs A's GP prescribed the minipill — a progesterone-only oral contraceptive that does not carry the same risks as the COC.

4. In November 2007, Mrs A transferred her primary care to another medical centre. On 5 December 2007, GP Dr C prescribed Estelle for Mrs A, but did not document the provision of that prescription. Dr C also did not document any discussion of the risks associated with Estelle or the alternative options for contraception or treatment of PCOS.

5. Between May 2008 and 2011, GPs Dr D, Dr C and Dr B provided repeat prescriptions of Estelle for Mrs A. No medical review was undertaken to determine whether Estelle was suitable, and there is little documented evidence of a discussion with Mrs A about her risk factors. Each of the GPs who prescribed Estelle for Mrs A assumed that the previous provider had discussed with her the risks of, and alternatives to, Estelle.

6. A high blood pressure recording can indicate an increased risk of stroke when on the COC, but Mrs A's blood pressure was not recorded at the second medical centre until October 2009.

7. In 2011, Mrs A underwent a cholecystectomy at a public hospital (the hospital), performed by Dr F. Mrs A developed a pulmonary embolism after surgery and, sadly, died.

Decision

8. Dr C breached Right 4(1)[2] of the Code of Health and Disability Services Consumers' Rights (the Code) by prescribing Estelle for Mrs A without

[1] A deep vein thrombosis is a blood clot in a vein located deep in the muscles of the lower torso.
[2] Right 4(1) of the Code states: "Every consumer has the right to have services provided with reasonable care and skill."

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performing a proper reassessment of her suitability, or recording her blood pressure. Dr C also breached Right 6(1)(b)[3] of the Code by failing to inform Mrs A of her risk factors or suitable alternatives to Estelle. Dr C breached Right 4(2)[4] of the Code by failing to comply with professional standards in respect of her documentation.

9. The medical centre breached Right 4(1) of the Code by failing to ensure that Mrs A's ongoing use of Estelle was adequately monitored through regular, specific medical reviews and counselling on her risk factors.

10. Dr D's documentation fell below an appropriate standard, and he should have taken steps to ascertain whether Dr C had informed Mrs A of her risk factors before issuing a repeat prescription six months after Estelle had been reinstituted by Dr C.

11. Dr B's care fell below an appropriate standard in that he failed to review Mrs A's use of Estelle, or take steps to satisfy himself that she was being monitored appropriately.

12. Although it is considered prudent to cease taking Estelle prior to major surgery, it is not clear whether Mrs A was taking Estelle at the time of surgery. The Commissioner recommended that the District Health Board include in its pre-admission questionnaire a question asking specifically about contraceptive use.

Complaint and investigation

13. The Coroner alerted my Office to concerns he had received from Mr A about the services provided to his late wife, Mrs A, by Medical Centre 2 and the hospital.

14. A formal investigation was commenced on 24 November 2011. The following issues were identified for investigation:

- *Whether Medical Centre 2 provided an appropriate standard of care in relation to Mrs A's ongoing use of a combined oral contraceptive, between 30 November 2007 and her death in 2011.*

- *Whether Dr D provided an appropriate standard of care in relation to Mrs A's ongoing use of a combined oral contraceptive, between 30 November 2007 and her death in 2011.*

[3] Right 6(1)(b) of the Code states: "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including … an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option …"
[4] Right 4(2) of the Code states: "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards."

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- *Whether Dr C provided an appropriate standard of care in relation to Mrs A's ongoing use of a combined oral contraceptive, between 30 November 2007 and her death in 2011.*

- *Whether Dr B provided an appropriate standard of care in relation to Mrs A's ongoing use of a combined oral contraceptive, between 30 November 2007 and her death in 2011.*

15. The parties directly involved in the investigation were:

Mrs A	Consumer
Mr A	Complainant
Medical centre 2	Provider
Dr B	General practitioner
Dr C	General practitioner
Dr D	General practitioner

16. Information was also reviewed from:

Mrs E	Mrs A's sister
The public hospital	Provider
Dr F	General surgeon
Also mentioned in this report:	
Dr G	General practitioner

17. Clinical advice was obtained from HDC's in-house clinical advisor, Dr David Maplesden, and is attached as **Appendix A**.

18. The care provided by the hospital and Dr F was reviewed by an independent expert general surgeon, Dr Michael Rodgers, who advised that the care was appropriate in the circumstances. Dr Rodgers' advice is attached as **Appendix C**.

Information gathered during investigation

Introduction — Estelle-35 and Estelle-35 ED

19. Estelle 35[5] (Estelle) is a third-generation combined oral contraceptive (COC) containing cyproterone acetate.[6] The New Zealand Medicines and Medical Devices Safety Authority (Medsafe), which is responsible for regulations

[5] Referred to as Estelle-35 and Estelle-35 ED.
[6] Diane 35 is also a combined oral contraceptive containing cyproterone acetate.

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governing prescribing, issues a data sheet for Estelle.[7] The data sheet in place at the time of the events of this investigation is attached as **Appendix B**.

20. According to Medsafe, Estelle is indicated for the treatment of polycystic ovary syndrome (PCOS).[8] It is also indicated as oral contraception for women who require treatment for PCOS. Estelle is not recommended solely for contraception.

21. There are several risks associated with taking a COC such as Estelle.[9] Estelle users have a five-fold increased risk of developing a venous or arterial thromboembolism.[10] COCs increase the risk of stroke in some women. There are also cardiovascular risks associated with COCs, particularly in women who already have multiple cardiovascular risk factors such as older age, smoking, diabetes, hypertension, obesity or a family history of cardiovascular disease before the age of 50 years.

22. Medsafe states that Estelle should not be used (ie, is contraindicated) if, among other things, the patient has a personal history of thromboembolism, including deep venous thrombosis (DVT) and pulmonary embolism (PE),[11] or a cerebrovascular accident (a stroke). The presence of a severe risk factor or multiple risk factors for thromboembolism may also constitute a contraindication.

23. Medsafe states that the risk of thromboembolism increases with, among other things:

- age;
- smoking (with the risk increasing for women aged over 35 who smoke);
- a family history of thromboembolism;
- obesity;
- hypertension (high blood pressure). An increase in blood pressure can occur while on a COC. If sustained clinically significant hypertension develops during the use of a COC then it is prudent for the doctor to withdraw the COC and treat the hypertension;
- migraine; and
- major surgery.

24. Medsafe further states that it is advisable to discontinue COC use before major surgery (at least four weeks in advance of elective surgery), and not to resume

[7] The data sheet was originally published in 2002 and revised in 2007, and again in 2011.
[8] Polycystic ovary syndrome is a condition in women characterised by irregular or no menstrual periods, acne, obesity, and excess hair growth.
[9] *Best Practice Journal* (*BPAC*), "Combined oral contraceptive: Issues for current users" (2008) 12:21–29.
[10] A blood clot in a vein or artery.
[11] DVT and PE are two manifestations of the disease venous thromboembolism. A DVT is a blood clot in a deep vein. It may go away naturally, but can lead to complications. The most serious complication is when the clot dislodges (embolises) and travels to the lungs to become a life-threatening PE.

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until two weeks after complete mobilisation. Other guidelines support the view that it is prudent to stop the COC the cycle before surgery, if a patient is considered at high or moderate risk of developing venous thromboembolism.[12] "Major surgery" is considered to be "any intra-abdominal operation and all other operations lasting more than 45 minutes".[13]

25. If there is a risk of venous thromboembolism, Medsafe states that the benefits of the use of Estelle should be weighed against the possible risks and discussed with the woman before she decides to start using it.[14]

26. Medsafe states that a complete medical history and examination should take place prior to initiation or reinstitution of Estelle, guided by the contraindications and warnings. A complete medical history and physical examination should also be repeated periodically during the use of Estelle, as contraindications or risk factors may appear for the first time during its use. The frequency and nature of the reassessments should be adapted to the individual woman, but such a review would include ascertaining the woman's family history of DVT, cardiovascular risk factors (including obesity, smoking, and previous thromboembolism), cervical smear status, blood pressure, and Body Mass Index (BMI).[15]

Mrs A

27. Mrs A had PCOS, was overweight, and smoked. Between 1999 and 2007, she was an enrolled patient at a medical centre (Medical Centre 1), except from November 2002 to July 2003, when she was enrolled at another medical centre (Medical Centre 2). From 1999 to 2005, she was prescribed Estelle (or its equivalent) to treat her PCOS and for contraception. Her Medical Centre 1 records from 1999 show that although the risks of thromboembolism associated with taking the COC were discussed with Mrs A, she wished to continue taking it.

28. Mrs A's mother advised HDC that both she and Mrs A's father had experienced thromboembolism in the past. Mrs A's positive family history of thromboembolism was not recorded on her Medical Centre 1 medical records. An entry in her Medical Centre 1 records on 16 November 1999 states: "[N]o fhx [family history] of thrombosis."

[12] The Australia and New Zealand Working Party on the Management and Prevention of Venous Thromboembolism. *Prevention of Venous Thromboembolism — Best Practice Guidelines for Australia and New Zealand* (3rd ed), July 2005.
[13] Ibid.
[14] In March 2002, Medsafe sent a letter to prescribers reminding them of the additional DVT risk associated with Estelle. The Ministry of Health guidelines recommend that women who are taking an oral contraceptive containing cyproterone (this includes Estelle) for an androgenic disease (this includes PCOS) in the presence of thromboembolic risk factors should be offered other contraceptive options, and counselling regarding the risks should take place to enable the woman to make an informed decision.
[15] Body Mass Index is a measurement of body mass based on height and weight.

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Change to minipill

29. On 2 November 2005, Mrs A saw Medical Centre 1 GP Dr G. Dr G noted that Mrs A's risk factors (overweight and a smoker) made Estelle unsuitable for her. Dr G documented: "[N]eeds to change to mini pill[16] … discussed happy with this." Dr G prescribed six months of a minipill, Femulen,[17] at this appointment.

30. On 2 November 2005, Mrs A wrote an entry in her diary that included: "Went to Doctor […] Changed my prescription to minipill as now over 35 and a smoker. Estelle is more likely to cause blood clots."

31. On 5 July 2006, Dr G prescribed six months of another minipill, Noriday, as Femulen had been discontinued.

Transfer of care to Medical Centre 2

32. In 2007, Mrs A transferred her primary medical care to Dr C[18] to Medical Centre 2.[19] On 30 November 2007, Medical Centre 2 received Mrs A's clinical records from Medical Centre 1.

33. Medical Centre 2 is owned and operated by a limited liability company. The directors of Medical Centre 2 at the time of the events of this investigation were Dr B, Dr C and Dr D.

May 2007 — Admission to the local hospital

34. In May 2007, when Mrs A was 16 weeks pregnant with her second child, she was admitted to the local hospital following a brief collapse. Medication to prevent DVT was commenced as a precaution, and investigations showed no evidence that she had experienced a thromboembolism at this time. Mrs A's history at this admission included a record of both parents having had pulmonary emboli.

5 December 2007 — Dr C

35. On 5 December 2007, Dr C saw Mrs A (then aged 37 years) with her seven-week-old son, who had been born by Caesarean section. Dr C told HDC that the main purpose of this consultation was a postnatal examination, in order to check the baby and Mrs A's scar from the Caesarean section.

36. Dr C documented the following in Mrs A's clinical records on 5 December:

> "7 weeks since LSCS.[20] Past history of depression[21] and wanting to recommence meds as is feeling this is recurring. restarting Estelle."

[16] The minipill is a form of oral contraceptive taken daily, containing only the hormone progestin and no oestrogen.
[17] Femulen is a minipill (containing only the hormone progestin and no oestrogen).
[18] At the time of these events, Dr C had over 20 years' experience as a GP, including in women's health issues.
[19] Mrs A saw Dr C at Medical Centre 2 on 10 July 2003, but there is no documented consultation in the electronic notes between this date and November 2007.

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37. Dr C prescribed Mrs A an antidepressant, and the provision of the prescription is documented.[22]

38. No blood pressure recording is documented.[23] In response to my second provisional opinion, Dr C advised that Medical Centre 2's routine post natal check-up process would have included the nursing staff taking blood pressure readings for Mrs A. She advised that the nurses' lack of access to a computer terminal meant that if a recording was normal it may not have been recorded subsequently on the patient's medical record.

39. Dr C advised HDC that she has a checklist to go through with patients who have recently given birth, which includes asking about contraception. Dr C said she asked Mrs A what her plans were in terms of contraception, and Mrs A said she wanted to take Estelle.

40. Dr C initially advised HDC that she did not prescribe a COC for Mrs A on 5 December 2007. There is no record at Medical Centre 2 of a prescription for a COC having been provided to Mrs A on that date. However, on 5 December 2007, a pharmacy dispensed to Mrs A a six-month prescription for Estelle, prescribed by Dr C. In response, Dr C stated that while she cannot say for certain, she suspects that she, Mrs A, and the baby had moved to another room for the baby's vaccinations, and that to save time she hand wrote the additional prescription for Estelle onto the prescription she had already given to Mrs A. Dr C suspects that she then failed to note this in Mrs A's clinical records when she returned to her office. Dr C noted that at this time not all practice rooms at Medical Centre 2 had a computer terminal.

41. Dr C advised that she discussed with Mrs A the post-surgical elevated risk of thromboembolism. Dr C said that she would have advised Mrs A not to start on a COC until three or six months after a Caesarean section, depending on whether she was breastfeeding. Dr C told HDC that Mrs A felt that Estelle was her best option for contraception and control of her PCOS, and asked for it by name. Dr C said she would certainly not choose this as contraception at a six-week check, but would offer a progesterone-only pill. In response to my second provisional opinion, Dr C stated that she does not prescribe Estelle as a contraceptive as it is primarily for the control of severe acne and PCOS, and that Mrs A would have had to request it and tell Dr C why she wanted it, which would have precipitated a discussion about PCOS, Mrs A's smoking status, and risks.

42. Dr C told HDC that Mrs A was an "extremely high risk patient", and that there were a variety of risk factors relevant to Mrs A taking Estelle at this time, including her weight (although Mrs A's weight or BMI is not documented on this

[20] Lower segment Caesarean section.
[21] Dr C advised HDC that she was referring to postnatal depression.
[22] Fluoxetine hydrochloride.
[23] The most recent blood pressure recording in the Medical Centre 1 notes is from April 2007. The result was normal.

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occasion), and the fact that she had undergone a Caesarean section seven weeks previously.

43. Dr C told HDC that Mrs A was not smoking in December 2007 as she had given up smoking while pregnant. However, Mr A noted that Mrs A gave up smoking for only three to four months during her first pregnancy in 2004/5. Mrs A's smoking status was not documented.

44. Dr C advised that she was not aware of Mrs A's family history of thromboembolism.

45. Dr C told HDC: "I would have assumed if [Mrs A] had taken [Estelle] previously then the risks and advantages must have been discussed then." Dr C stated:

> "My impression was that she was well aware of her risk factors … She had been taking the minipill prior to conception so was familiar with it but had chosen to go back to Estelle obviously when we discussed contraception, which may have related to her not smoking at that time. Estelle was [Mrs A's] choice of contraception at that time and she was familiar with it."

46. Dr C advised HDC that although Mrs A had taken the minipill in light of her risk factors, Mrs A was not happy with the minipill as it did not treat the symptoms of PCOS. Dr C also noted that the minipill was a less effective contraceptive than the COC, and that contraception was important in light of Mrs A's postnatal depression.

47. Mr A told HDC:

> "[Mrs A] had discussed with me that she felt unhappy about using the minipill as it had to be taken the same time every day for it to be most effective. She was concerned about recurrence of Polycystic Ovarian Syndrome and/or it developing into Cancer. She was keen to change back to Estelle."

48. The only documentation reflecting a discussion between Dr C and Mrs A about contraception is a note, "restarting Estelle". Dr C accepts that her documentation was insufficient. She noted that the consultation would have been under time pressure and this may have been the reason why her notes were not fully and comprehensively recorded. However, she stated that the notes were not indicative of the care that she gave Mrs A.

49. In response to my provisional opinion, Dr C stated that she strongly disputes that she prescribed Estelle without a proper reassessment of Mrs A's suitability.

31 March 2008 — Dr B

50. On 31 March 2008, Mrs A saw Dr B, complaining of vomiting and diarrhoea. Dr B documented that Mrs A was a smoker.

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16 May 2008 — Dr D

51. On 16 May 2008, Dr D saw Mrs A (then aged 38 years) and provided a six-month prescription of Estelle. Dr D does not recall whether he read Mrs A's Medical Centre 1 medical records prior to the consultation.

52. The clinical record from 16 May reads:

> "[W]ell Smear […] and keen [to give up] smoking …"

53. The clinical note implies that Mrs A was still smoking around this time. Dr D noted that he prescribed Estelle only in the knowledge that Mrs A was committed to giving up smoking.

54. There is no record of Mrs A's weight or blood pressure. Dr D told HDC that usually a nurse would record blood pressure and weight when a COC was prescribed.[24] He told HDC that the review by a nurse may occur before or after the patient sees the GP.

55. Dr D said that he assumed from Dr C's note of 5 December 2007 ("restarting Estelle") that contraceptive options had been discussed and that Mrs A had preferred to go back on Estelle. He stated:

> "I felt comfortable [that Dr C's clinical note, "restarting Estelle"] represented a sensible considered decision by [Mrs A] and one supported by [Dr C.] …
>
> I know that [Mrs A] wanted to obtain certain birth control and symptom control of her PCOS — despite the added risk to her cardiovascular health."

56. Dr D told HDC that he "assumed [Dr C] had OK'd [the medication]". He advised that he did not think Mrs A's cardiovascular risk had shifted significantly from November 2005 to May 2008, except for Mrs A being slightly older. Dr D said that the arguments for and against taking Estelle remained the same. He noted that Mrs A was still overweight and smoking, and his comment "well" was a reference to her mental health status. Dr D told HDC that he chose to "address her smoking as a modifiable risk factor".

57. In relation to Mrs A's decision to return to Estelle, Dr D stated:

> "I believe this was a quite deliberate and informed decision by her — having tried the mini pill between the pregnancies she decided to go back on Estelle — no doubt taking into account all the information she had received previously including her consultations with [Dr G], [Dr C] and myself, and her personal experience of taking Estelle and alternative contraception."

[24] An audit done by Medical Centre 2 of all prescriptions issued for combined oral contraceptives showed that a patient's BMI was recorded in 46 of 211 patients, and blood pressure in 156 out of 211 patients.

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58. In response to my second provisional opinion, Dr D stated that Mrs A chose to continue with Estelle but knew that he strongly recommended that she give up smoking to mitigate her risk, and that he was continuing to prescribe it for her only in the expectation that she would give up smoking.

59. Dr D also said:

> "[Mrs A] was worried about her own ability to comply with the [minipill]. She realised that this would put her at risk of further pregnancy and subsequent post natal depression. She also wanted to maintain control of her PCOS."

60. Dr D initially advised HDC that no specific information was given to Mrs A on 16 May regarding the risks associated with Estelle. He stated: "[I]t is my usual practice to discuss the various risks/benefits of the medication being prescribed but I do not have a clear recollection of doing so at this consultation." In response to my first provisional opinion, Dr D said that "in all probability" he did discuss the risks.

61. In response to my second provisional opinion, Dr D stated that he was sure he did discuss Mrs A's smoking and "the risks that this posed coupled with the use of Estelle and satisfied myself that she was aware she had some choices, (to stay on this pill or not, to smoke or not,) and the attendant risks and benefits to all of them" (sic). However, he stated, "I accept that this wasn't an extensive exploration of this topic but I felt that it was sufficient as it had already been discussed with Dr C and would be regularly reviewed." Dr D considered that this was a reasonable assumption to make.

62. Dr D also advised HDC that he was not aware that Mrs A had a family history of thromboembolism, and that he "did not directly ask her".

63. Dr D accepts that this consultation was poorly documented.

22 October 2008 — Dr C

64. On 22 October 2008, Dr C saw Mrs A and provided a repeat six-month prescription of Estelle. There is no record of any of Mrs A's observations being taken between the reinstitution of Estelle on 5 December 2007 and Dr C's prescription of Estelle on 22 October 2008. Dr C advised HDC:

> "I was confident that [Dr D] would have had a conversation with [Mrs A] about her various risk factors and the other contraception options … In my experience, patients do not want a repeat of the same advice each time they attend the practice for a repeat prescription, and in October 2008 I did not perceive any need to address those matters again, given [Mrs A's] appreciation of her situation."

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4 May 2009 — Dr B

65. On 4 May 2009, Dr B did not see Mrs A face-to-face, but he provided a repeat six-month prescription of Estelle at the request of a nurse. Dr B said that he knew that Mrs A was "not a healthy person" and that she smoked, was overweight, and was unfit.

66. Dr B told HDC that the previous prescription had been provided at a face-to-face GP consultation. He said that standard practice for nurse consultations involving COCs was that the nurse would ask about any problems with the requested medication and check the patient's blood pressure, weight, and smear status. However, there is no record of those observations on 4 May.

67. Dr B advised HDC that he did not read Mrs A's medical records before issuing the prescription, as time precludes looking at notes in all instances of repeat prescribing, and sometimes he needs to delegate to the nurses. Dr B advised that if he does not see someone physically, and has concerns or doubts about the prescription, then he will check the clinical notes. He further advised that if the prescription is straightforward, and he is satisfied that the nurse has considered the relevant information, he will not consult the clinical notes.

27 October 2009 — Dr B

68. On 27 October 2009, Dr B again did not see Mrs A face-to-face, but provided a repeat six-month prescription of Estelle at the request of a nurse. The nurse made a note that Mrs A must see a GP for the next prescription. Mrs A attended Medical Centre 2 the following day to pick up the prescription, and the nurse took her blood pressure, which was normal. Dr B said that the nursing staff at Medical Centre 2 are well aware of the requirement for women to be seen for every second oral contraceptive pill prescription. Dr B told HDC he assumes that Mrs A was unable to see a GP that day. Dr B noted:

> "If the client is unable to get to see one of us then I believe it is still in their best interests to keep taking the COC rather than risk pregnancy."

69. There is no record of why Mrs A did not see Dr B in October 2009. Dr B advised HDC that he did not read Mrs A's notes before issuing the prescription, but he was well aware of Mrs A's medical issues. Dr B stated that it was clinically appropriate at this time for Mrs A to remain on Estelle.

20 April 2010 — Dr B

70. On 20 April 2010, Mrs A presented to Dr B for a repeat prescription of Estelle. Dr B's clinical note reads:

> "Repeat OCP — options incl vasectomy discussed but will stick with the Estelle at present"

71. Dr B prescribed a six-month supply of Estelle for Mrs A.

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72. As noted above, Dr B recalls Mrs A having three major risk factors for thromboembolism (age, weight, and smoking status). He stated that he explored other contraception options with her. Dr B said he "would have" discussed the use of an intrauterine contraceptive device or permanent sterilisation. He noted that he always outlines the increased risk of clots in those who are aged over 35, smoke, and are overweight. He assumes from the clinical notes that he advised Mrs A of the risks and that, despite this, she wanted to continue with Estelle. He initially advised my Office that he was "not 100% sure", but believed he did discuss Mrs A's risk factors with her. He stated that, as evidence of this, the obvious next step after a discussion of risks is a discussion of options open to the patient, which were documented in his clinical note. However, in response to my first provisional opinion, Dr B said he is 100% sure that he discussed risk factors with Mrs A.

73. Dr B recalls asking Mrs A whether she had a family history of DVT and that, to the best of his recollection, she answered "No". This was not recorded.

Referral to the hospital

74. On 30 August 2010, Dr D referred Mrs A to a hospital's Surgical Department with suspected gallstones. Dr D noted in the referral letter that Mrs A had a raised BMI and was on Estelle.

75. Mrs A saw a surgeon on 18 October 2010, and an ultrasound confirmed a diagnosis of gallstones. The surgeon placed Mrs A on the waiting list for a laparoscopic cholecystectomy.[25]

7 October 2010 — Dr B

76. On 7 October 2010, Dr B provided Mrs A (then aged 40 years) with a six-month prescription of Estelle on the request of a nurse. Dr B did not see Mrs A face-to-face. The nurse documented Mrs A's blood pressure, which was normal, and noted that Mrs A needed to see a GP for the next visit.

77. Dr B advised HDC that he did not read Mrs A's notes prior to issuing the prescription.

Early 2011

78. Mrs A saw another GP at Medical Centre 2 in early 2011 with a swollen and painful leg. This was investigated with blood tests and an ultrasound scan at the hospital, and a superficial venous thrombosis[26] (SVT) was confirmed. Mrs A was treated with Clexane,[27] ibuprofen and paracetamol.

[25] Surgery to remove the gallbladder.
[26] A superficial venous thromboembolism is a blood clot that may cause discomfort but does not cause serious consequences. The Medsafe data sheet for Estelle notes that there is no consensus about the possible role of superficial thrombophlebitis in venous thromboembolism.
[27] A medication to reduce the risk of DVT.

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79. Two days later, Mrs A saw the same GP at Medical Centre 2. Her leg was noted to be tender and reddened, and she was prescribed antibiotics. The plan was to continue with pain relief, rest and ice.

80. Dr B reviewed Mrs A the following week, at which time he noted that Mrs A was still experiencing some discomfort around the area of the SVT. The plan for treatment was regular pain relief and mobilisation. Dr B also prescribed Naproxen.[28] There is no further record of Mrs A complaining of ongoing or new lower leg pain or swelling in her Medical Centre 2 records. However, Mr A told HDC that Mrs A was limping from the time she was diagnosed with the SVT until her death.

Surgery

81. Registered nurses at the hospital conducted a preoperative assessment for Mrs A. At this time, Mrs A's BMI was 41,[29] which classified her as morbidly obese. The preoperative assessment documentation makes no mention of Mrs A taking Estelle. A line has been drawn through the space on the Pre-anaesthetic Health Questionnaire for listing Mrs A's current medications. Mrs A's signature is on the Questionnaire. Mrs A's Pre-anaesthetic Assessment noted that there was a risk of thromboembolism, and that the previous SVT had settled.

82. Mrs A underwent a laparoscopic cholecystectomy, which was performed by general surgeon Dr F at the hospital. The surgery was uncomplicated.

83. Dr F advised HDC that Mrs A was identified as being at moderate risk for venous thromboembolism based on her family history of venous thromboembolism, morbid obesity, a personal history of left superficial thrombophlebitis, her smoking status, and undergoing major abdominal surgery with an operative duration of over 45 minutes.

84. Dr F advised HDC that, in response to Mrs A's identified risk, "a decision was made that [Mrs A] required all available VTE prophylaxis", which included chemical prophylaxis (Clexane preoperatively and postoperatively) and mechanical prophylaxis (with pneumatic calf compressions whilst immobile). Subcutaneous Clexane 20mg was given preoperatively at 8.40am, and Clexane 40mg was given at 10.20pm on the evening after surgery. A pneumatic calf pump[30] was used both during and for six hours after the surgery to further reduce the risk of DVT. Dr F noted that compression stockings of a suitable size for Mrs A were not available. In contrast, Mr A said that he helped Mrs A to put on compression stockings, but they were not given to her to wear following discharge.

[28] A non-steroidal anti-inflammatory medication.
[29] Mrs A's weight is recorded as 106kg, and her height is recorded as 160.5cm.
[30] A technique designed to improve venous circulation in the limbs of patients who are at risk of DVT.

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85. As noted above, it is considered prudent to discontinue COC use prior to major surgery. There is no documented evidence that Mrs A was advised by any of her healthcare providers to stop taking Estelle before her operation.

86. Dr D advised HDC that GPs are not advised of operation dates, and therefore are not able to reinforce appropriate cessation of COCs. He said that it would be unusual for a GP to make comments about altering medications, or giving pre/perioperative advice, without the explicit directions of the surgical team, in case it conflicted with the surgical advice or confused the care plan. Medical Centre 2 considers that the giving of this advice should be the responsibility of the surgeon who books a patient for surgery, and/or the person who sees the patient at the preoperative assessment.

87. Dr F advised HDC that if a woman is known to be on a COC, his usual practice is to discuss the manufacturer's recommendation of stopping and using alternative contraceptive options. Dr F advised that his practice is to discuss the degree to which the COC may increase risk, the risks of stopping COC versus unplanned pregnancy or ovarian cyst symptoms, and any risks presented by not proceeding with surgery. He advised that venous thromboembolic risk assessment and management is adjusted accordingly, depending on other identified risk factors, and the contraception decision made by his patient. Dr F advised that this discussion usually takes place at the time of placement on the surgical waiting list.

88. Dr F advised that in Mrs A's case, his usual practice did not occur as he did not know she was on a COC. He noted that the pre-anaesthetic questionnaire and the preoperative medical assessment form stated that Mrs A had no current medications. Dr F noted that Mrs A underwent ambulatory surgery, which did not require or cause immobilisation, and she was independently ambulant on the evening of surgery and was discharged with verbal instructions to mobilise.

89. The hospital notes state that Mrs A mobilised well after surgery. Mrs A was discharged the day following surgery. Mr A said that she managed to walk to the toilet, but he pushed her to the car in a wheelchair. He advised HDC that she mobilised adequately at home.

90. Two weeks later, Mrs A died suddenly at home. The post-mortem examination attributed her death to a large PE. She was noted to have a swollen left calf, and it was thought likely that a DVT in her left calf was a source of the PE.

Further comments by Medical Centre 2

91. Dr C and Medical Centre 2 noted that Mrs A was counselled at various times to cease smoking permanently and to lose weight.

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92. Each of the three doctors noted that the risk to Mrs A from taking Estelle was far less than if she had fallen pregnant again, considering her mental health history and from a cardiovascular perspective.[31]

93. Dr D noted that the usual practice for all doctors at Medical Centre 2 at the time Mrs A was prescribed Estelle was to ask about bleeding irregularities or any medication side effects when re-prescribing oral contraceptives. There is no record of such a discussion, if one occurred.

Changes to practice

94. Medical Centre 2 has instigated a number of remedial actions, including an audit of risk identification with some deficiencies identified.[32] As a result of this audit, Medical Centre 2 identified that even women with a healthy BMI should have their readings taken and recorded, and that documentation of treatment and advice should be more explicit. This audit is due to be repeated shortly.

95. Medical Centre 2 advised that it has taken the following actions:

- It has revised its policy for registering new patients so that a nurse reviews both electronic and paper records and enters any significant information into the practice management system.
- It has reviewed its (re)prescribing policies, in particular regarding oral contraceptives. Medical Centre 2 stated that attention is now paid to documentation of risk assessment and discussion, and regular recording of weight and blood pressure. Staff members (including nurses) now clarify with patients who are requesting a prescription for an oral contraceptive, whether any of their circumstances have changed that would affect their risk of DVT (including changes in the health of the patient's family members). Any change is to be brought to the attention of the prescribing GP.
- DVT risk is now always discussed at initiation of COC treatment by the doctor and restated regularly. Nursing staff are now specifically tasked with reminding patients of their risks for VTE (venous thromboembolism) and symptoms of DVT, including recording height and weight regardless of whether the woman has a raised BMI or not.
- A full history and risk/benefit assessment is required at initial prescription or when there is a change in risk profile.
- It now has a policy that requires a nurse to record blood pressure and weight when issuing repeat prescriptions. The policy also requires that at every nurse appointment (annually) the nurse takes note of a patient's awareness of risks and benefits of each medication. Nurses have been provided with education about this.

[31] The Medsafe data sheet states that "the incidence of VTE occuring during COC use is substantially less than the incidence associated with pregnancy".
[32] The Audit of Prescribing of Combined Oral Contraceptive Pills (COC) report states: "[I]t is disappointing to see that only 73% had a recent BP recording in the last 12 months … only 21.8% ever had a BMI or height and weight recorded …"

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- The GPs at Medical Centre 2 are currently working on written information to be provided to patients regarding the COC.
- It is ensuring its staff keep more thorough documentation in light of patients seeing more than one doctor.
- A new procedure has been adopted of informing all practice staff of the death of any "practice member or of any immediate family member", and a sympathy card is sent to remind the recipient that Medical Centre 2 staff are available for support.
- Each year, through the peer group review process, all of the Medical Centre 2 doctors undergo a notes review process.
- There are now workstations in every room and extra staff to reduce the workload on individual doctors.

96. Dr B said that he has "redoubled" his efforts in relation to documentation, making sure that everything that is discussed at the consultation is recorded (including advice given to patients).

97. Dr D said that his documentation is now more thorough, particularly his record of discussions with patients about risks and benefits. He also noted that the complaint has increased Medical Centre 2's "awareness that modern team based medical care provides numerous opportunities for adverse outcomes — especially [regarding] the assumptions [regarding] our colleagues' care."

98. Dr C accepts and regrets that her documentation was insufficient.

Response to provisional opinions

99. The parties were provided with relevant sections of my first and second provisional opinions for comment. Their comments have been incorporated into the above facts, where appropriate. The following additional comments were also provided.

Dr C

100. Dr C submitted that the choice of Estelle was a good decision for Mrs A at that particular time in her life, because it controlled her PCOS and gave her contraception. Dr C does not consider that the prescribing of Estelle had a bearing on Mrs A's death.

Dr D

101. Dr D does not accept that his care fell below an appropriate standard. Dr D submitted that his prescribing was in good faith and in Mrs A's best interests. He stated that Mrs A's risk factors were discussed with her on a number of occasions, and that he respected her informed decision to proceed with Estelle. Dr D advised that Mrs A did not want to take the minipill, as she did not want to

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risk pregnancy and wanted to control her PCOS. Dr D also asserted that making assumptions that previous providers have discussed the risks of, and alternatives to, Estelle, with a patient is consistent with normal practice in a general practice setting.

102. Dr D also noted that Mrs A was very reluctant to visit Medical Centre 2.

103. Dr D noted that Mrs A was registered with Dr C, who had previously cared for her. He said that "key medication decisions are routinely referred back to the doctor whenever reasonable and appointments with that doctor are encouraged, even in the face of appointment conflict".

104. Dr D also noted that the issue of whether Mrs A gave informed consent to Estelle was not mentioned in the complaints to HDC.

Dr B

105. Dr B told HDC that Mrs A was an intelligent woman who fully understood why she was at risk of DVT on the two occasions that she was investigated for a DVT. He also noted that pharmacists provide information sheets that include risk factors for the medication being dispensed.

106. Dr B stated that the minipill was not suitable for Mrs A, and that she required a pill that took into consideration her depression and PCOS. He told HDC that he was very familiar with Mrs A, including her personality and general well-being, but that this would not necessarily be documented.

107. Dr B also noted that there were a number of reasons why Mrs A would not come in for a prescription as requested. He said that the nurses at Medical Centre 2 were experienced registered nurses and well aware of the requirement for women to be seen for every second COC prescription. He stated:

> "The GPs at [Medical Centre 2] did not assume that other providers had taken responsibility for discussing risks and alternatives. [We] all well knew [Mrs A]. [We] knew she had risk factors. Other methods of contraception were discussed with her and she was well aware of the risks. [Mrs A] knew enough to make an informed decision and it is apparent that she did make informed decisions. The GPs at [Medical Centre 2] did not make random assumptions that are unable to be substantiated. [Dr C] and [Dr D] are both experienced and knowledgeable family practitioners. [I regard] [Dr C] as an expert in women's health. [We worked as] a team and any "assumptions" made were in [my] view totally valid."

108. Dr B also noted that he has a diploma in obstetrics and gynaecology and has previously been a hospital registrar in the specialty of women's health. He noted that Estelle has been around in various generic forms for about 30 years. He said that he

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> "is well aware of its indications and risk profile … it is all about balance and what constitutes an acceptable risk — a science and an art that doctors in general practice deal with in many forms and on a daily basis".

Medical Centre 2

109. Medical Centre 2 advised that it strongly encourages patients to restrict their consultations to one primary doctor, but offer the flexibility of choice and convenience of several doctors.

110. Medical Centre 2 stated that it is not aware of any evidence that Mrs A was unhappy with the care provided to her by Medical Centre 2, but she was unhappy with the management at the hospital.

111. Medical Centre 2 submitted that the prescribing of Estelle by Medical Centre 2 did not have a bearing on Mrs A's subsequent DVT and death.

112. Medical Centre 2 considers Mrs A gave informed consent to being prescribed Estelle, and there is no evidence to suggest that she was coerced or misled into taking this option. It stated:

> "[We] feel that [Mrs A] was very aware of the health consequences of being overweight, of smoking — particularly with respect to being on the contraceptive pill or being pregnant — and of her increasing age. Indeed this was particularly so given that both of her parents had — apparently — suffered episodes of VTE. And we note that in recent years — while on Estelle — she had taken herself to hospital to investigate a suspected episode of DVT/PE. We knew that [Mrs A] was concerned about her polycystic ovarian syndrome (PCOS) symptoms, which had taken her some time to adequately control — having tried various pills over the years until she'd found the one — Estelle which suited her best. She was also concerned about controlling her fertility and about her mood symptoms post pregnancy — she had previously received medication and counselling re this."

113. Medical Centre 2 submitted that the only change in Mrs A's circumstances when she was prescribed Estelle at Medical Centre 2 was the birth of her second child, and that this was the principal reason why she specifically requested Estelle rather than the minipill. It stated:

> "It is correct that basing practice on assumptions alone is dangerous, but in this case all the doctors assessed [Mrs A] independently and repeatedly."

114. Medical Centre 2 also submitted that while it acknowledges that there is a "gap in the medical records" concerning blood pressure recordings, Mrs A had not had any concerns regarding hypertension[33] and, on either side of the gap, normal

[33] Mrs A's blood pressure had been high on three previous occasions between 2005 and 2007 (130/80mmHg on 2 August 2005, 150/90mmHg on 2 November 2005, and 146/80mmHg on 5 July 2006). A normal blood pressure recording is at or below 120/80mmHg.

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blood pressure readings were recorded. Medical Centre 2 states that there is nothing to suggest that the blood pressure readings would have been abnormal had they been taken, that Mrs A and her doctors would have acted differently, or that the gap affected her health outcomes. It also considers that the absence of a BMI recording made no material difference to the decision-making process or Mrs A's health outcomes, as her weight was well known and acknowledged as a risk factor for her health.

115. Medical Centre 2 mentioned that time constraints on GPs often result in very concise notes, which may allow a misreading or misinterpretation. It stated that general practice involves a team approach, and that "we still do have to make assumptions in medical care and we cannot document fully everything that takes place". Medical Centre 2 advised that it is confident that reasonable assumptions were made in Mrs A's case, and that Medical Centre 2's care did not jeopardise her health.

Opinion — Introduction

116. At the outset, it is important to note that my role does not extend to determining the cause of death. I am primarily concerned with the quality of care provided to Mrs A, and whether that care accorded with the expected standards of the providers' respective professions and the national guidelines issued by the New Zealand Medicines and Medical Devices Safety Authority (Medsafe).

117. Mrs A had a right to make a choice about treatment, including treatment for contraception and PCOS with Estelle. There is evidence to suggest that Mrs A did choose Estelle. However, Mrs A had the right to be fully informed before making a choice about her treatment options. My concerns about the information Mrs A was given to inform her decision to take Estelle are set out below.

118. While it is clear from the medical record that Mrs A was informed of the risks of Estelle by her GP at Medical Centre 1, by the time she transferred her primary care to Medical Centre 2 she was older and weighed more than when the information was provided, and she was still smoking. Her circumstances had changed and her risk factors had increased. Instead of taking responsibility for discussing risks and alternatives with Mrs A, her GPs assumed that other providers had done so, in the absence of any documentation to support such an assumption. In my view, basing treatment decisions and the provision of information on assumptions alone is a dangerous practice.

119. Mrs A's consultations with her GPs were one-on-one. While I have obtained evidence from her GPs, I have been unable to obtain evidence from Mrs A herself, other than some diary entries she made, which her husband provided. Accordingly, my investigation has been unable to reveal exactly what Mrs A subjectively knew about the increased risks of taking Estelle from 2007, what she

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was told by her Medical Centre 2 GPs, and whether she made an informed choice to take Estelle over other available alternatives. In such circumstances, the medical record becomes crucial.

120. A detailed and clear record of a patient's history, assessment, and management plan is one of the cornerstones of good care, and is particularly important for continuity of care at practices such as Medical Centre 2, where patients are likely to receive care from more than one doctor.[34] As noted in a previous opinion involving a medical centre similar in structure to Medical Centre 2:[35]

> "… [I]t is vital that a detailed and clear record of the history, examination, assessment and management plan of each consultation is documented, in order to assist other doctors at the Centre to provide continuity of care to the patient."

121. This Office has previously referred[36] to the decision of Baragwanath J in *Patient A v Nelson–Marlborough District Health Board*,[37] where he stated that it is through the medical record that healthcare providers have the power to produce definitive proof of a particular matter (in that case, that a patient had been specifically informed of a particular risk by a doctor). This applies to all health professionals, who are obliged to keep appropriate patient records. Health professionals whose evidence is based solely on their subsequent recollections (in the absence of written records offering definitive proof) may find their evidence discounted.

Opinion: Breach — Dr C

5 December 2007

122. Dr C saw Mrs A on 5 December 2007 when Mrs A presented for a postnatal check-up, seven weeks after giving birth. Dr C provided Mrs A with a six-month prescription for a combined oral contraceptive (COC), Estelle. I have several concerns about Dr C's prescription of Estelle on 5 December, discussed below.

123. When Dr C prescribed Estelle on 5 December, Mrs A had not been prescribed Estelle since November 2005. The Medsafe data sheet for Estelle states that a complete medical history and physical examination should take place prior to reinstitution of Estelle and, if any risks are identified, the benefits of the use of Estelle should be weighed against the possible risks for each individual woman, and discussed with her before she decides to start using it. I accept Dr

[34] See Opinion 10HDC00974 (15 June 2012) p 16.
[35] Opinion 08HDC06359. See also Opinion 03HDC03134 and Opinion 06HDC12164.
[36] Opinion 08HDC10236.
[37] *Patient A v Nelson–Marlborough District Health Board* (HC BLE CIV-2003-406-14, 15 March 2005).

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Maplesden's advice that reinstating Estelle was not necessarily clinically unreasonable, despite Mrs A's risks. However, it was reasonable only if Dr C provided Mrs A with information sufficient to enable her to make an informed decision. As the reinstituting prescribing doctor, Dr C had a responsibility to satisfy herself that Estelle was suitable for Mrs A in terms of effectiveness, tolerability, and risk.

124. Mrs A was obese and 37 years old at the time of the consultation. She had other risk factors, including being a smoker and having a family history of thromboembolism, which are listed as precautions for use of third-generation COCs. Dr C recognised that Mrs A was an "extremely high risk patient". A previous provider had prescribed the minipill in 2005 for contraception owing to Mrs A's risk factors with regard to Estelle. Dr Maplesden advised that many of his colleagues would have hesitated in prescribing Estelle for Mrs A given her DVT risk factors in spite of her having PCOS.

125. Dr C advised HDC that she "discussed contraception" with Mrs A, as was her usual practice for a postnatal visit. Dr C told HDC that she would have advised Mrs A not to start Estelle until she was at least six months postnatal if she was breastfeeding, or three months postnatal if she was not. In response to my provisional opinion, Dr C also said that she discussed with Mrs A the post-surgical elevated risk of thromboembolism.

126. Dr C told HDC that she assumed that the risks and advantages of taking Estelle had been discussed with Mrs A as she had taken the medication previously. Dr C said that Mrs A specifically asked for Estelle as it was the only medication that gave her control of symptoms associated with PCOS, and she was concerned about needing to take the minipill at the same time each day. However, there is no record of these considerations, and there is no record of Mrs A having had any problems with the minipill.

127. The only record from the 5 December consultation relating to Estelle is Dr C's note, "restarting Estelle". Dr C advised that "restarting Estelle" refers to a discussion they had about whether or not Mrs A should start Estelle at that time. In response to the second provisional opinion, Dr C stated that Mrs A would have had to request Estelle by name and tell Dr C why she wanted it, which would have precipitated a discussion about PCOS, Mrs A's smoking status, and risks.

128. However, I remain of the view that there is insufficient evidence that Dr C fully explained to Mrs A the risks and benefits associated with taking Estelle, alternatives for contraception and treatment of her PCOS, and early recognition of DVT symptoms.

129. Furthermore, Dr C's documentation is inadequate. Her brief clinical note "restarting Estelle" is ambiguous and subject to misinterpretation. There is also no record of a prescription for Estelle having been provided to Mrs A on 5 December. Providers are under a professional obligation to keep clear and

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concise records. Dr C's documentation should have detailed what was discussed with Mrs A, any recommendations or advice given to her, and the fact that a prescription was provided.[38]

130. Dr C also did not take Mrs A's blood pressure before prescribing Estelle. A blood pressure recording is an important part of assessing a patient's suitability for a COC. Neither Dr C nor any other staff member took Mrs A's blood pressure on 5 December. The previous reading had been taken at Medical Centre 1 in April 2007, when Mrs A had been pregnant. Dr C, as Mrs A's prescribing doctor, had a responsibility to ensure that Mrs A's blood pressure was taken before she left the clinic, and to review the results before reinstituting Estelle.

131. Lastly, Dr C did not ask Mrs A whether she had a family history of thromboembolism. A family history of thromboembolism is a risk factor identified in the Medsafe data sheet. My clinical advisor, GP Dr David Maplesden, advised that once a significant family history of DVT is known, hereditary thrombophilia should be excluded by appropriate testing and consultation with a haematologist. In my view, Dr C, as the reinstituting prescriber, should have elicited this information from Mrs A to determine whether further testing was warranted.

22 October 2008

132. Dr Maplesden advised that Mrs A's use of Estelle required at least annual review in light of her risk factors for DVT.[39] He also advised that a registered provider should ensure that the provision of a repeat prescription is clinically appropriate, which would include ensuring that the patient was being monitored in a manner consistent with expected practice.

133. On 22 October 2008, Dr C prescribed a repeat of Estelle for Mrs A. At that time, it had been a year since Dr C had reinstituted Estelle, and 18 months since Mrs A's blood pressure had last been recorded. Dr C did not take any steps to clarify that the prescription of Estelle remained appropriate. She should have taken Mrs A's blood pressure, reassessed her modifiable risk factors, and informed her accordingly before prescribing a repeat of Estelle.

Summary

134. Dr C did not adequately assess Mrs A's personal risk prior to reinstituting Estelle on 5 December 2007. She prescribed Estelle when Mrs A had not taken it for two years, without reassessing her suitability, or reviewing her blood pressure. Dr C then failed to adequately monitor and assess Mrs A before providing a repeat

[38] Medical Council of New Zealand, *Good Medical Practice: A guide for doctors* (Wellington: Medical Council of New Zealand, 2007), page 3: Doctors must "keep clear, accurate and contemporaneous patient records that report relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed".

[39] *Best Practice Journal* (*BPAC*), "Combined oral contraceptive: Issues for current users" (2008) 12:21–29.

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prescription in October 2008. In my view, Dr C did not take reasonable care in prescribing Estelle for Mrs A and breached Right 4(1) of the Code.

135. A reasonable consumer in Mrs A's circumstances would have expected to receive an explanation of the options available for contraception and treatment of PCOS, including an assessment of the expected risks, side effects, benefits, and costs of each option. Dr C's failure to discuss the risks associated with Mrs A taking Estelle, or inform her of alternatives for contraception and treatment of PCOS, was a breach of Right 6(1)(b) of the Code.

136. Dr C's clinical note on 5 December 2007 was poorly documented. Clear and detailed documentation is critical to providing continuity of care, and a professional standard with which GPs are required to comply. Dr C failed to comply with relevant professional standards and, accordingly, breached Right 4(2) of the Code.

Opinion: Adverse comment — Dr D

137. On 16 May 2008, Dr D saw Mrs A and gave her a repeat prescription for six months of Estelle. This was around six months after Dr C had reinstituted Estelle.

138. Neither Dr D nor any other staff member took Mrs A's blood pressure on 16 May. As Dr C had not taken Mrs A's blood pressure on 5 December, the most recent blood pressure recording available to Dr D was from April 2007, when Mrs A had been pregnant. Dr D stated that a nurse would normally take a patient's blood pressure in these circumstances, and that it may be before or after the doctor sees the patient. I accept that it may be appropriate for a nurse to take a patient's blood pressure. However, given the lack of a recent blood pressure recording, Dr D, as the prescribing doctor, had a responsibility to ensure that Mrs A's blood pressure was taken before she left the clinic, and to review the results before prescribing Estelle.

139. Dr D has provided conflicting information about whether he informed Mrs A about her risks when taking Estelle. He initially told HDC that he did not provide Mrs A with any specific information about her risks on 16 May 2008, but later said that "in all probability he did discuss the risks". He stated that he assumed Dr C had counselled Mrs A on the risks of recommencing Estelle six months previously. I accept that, as the reinstituting prescriber of Estelle, it was Dr C's role to undertake a comprehensive discussion with Mrs A about risks and alternatives to Estelle, and early recognition of DVT symptoms, at the time she reinstituted Estelle. However, if a request for a repeat prescription is received, a provider should ensure that the provision of the prescription is or remains clinically appropriate.

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140. Dr D should have been aware of Mrs A's high risk profile for Estelle as he knew she was overweight and smoked. When he read Dr C's note from 5 December ("restarting Estelle"), he should have noted the absence of a documented discussion about risks and alternatives associated with Estelle, a record of her informed consent, and a record that a previous prescription of Estelle had actually been provided. This should have prompted Dr D — before issuing the repeat prescription — to check with Mrs A or Dr C whether Mrs A was aware of the information she needed to give informed consent.

141. It would also have been prudent for Dr D to have reviewed Mrs A's use of Estelle, including assessing whether there were any problems. However, I accept that a comprehensive reassessment of all risk factors at every presentation for repeat COC prescribing is not expected practice and it was reasonable for Dr D not to have done so on that occasion.

142. Dr D's care of Mrs A fell below an appropriate standard, and he should reflect on his poor care in this case. However, I accept that he prescribed Estelle six months after Dr C had reinstituted Estelle and, in the particular circumstances of this case, I do not consider that Dr D breached the Code.

Opinion: Adverse comment — Dr B

143. Dr B first saw Mrs A in March 2008. He prescribed Estelle for her on four occasions: 4 May 2009, 27 October 2009, 20 April 2010 and 7 October 2010.

4 May and 27 October 2009 — Adverse comment

144. When Dr B first prescribed Estelle for Mrs A on 4 May 2009, her previous prescription of Estelle had been issued by Dr C following a face-to-face consultation on 22 October 2008. Dr B issued this prescription at the request of a nurse, without seeing Mrs A face-to-face.

145. My expert, Dr Maplesden, advised that it was reasonable for Dr B to assume any problems had been identified and discussed at Mrs A's previous face-to-face consultations. In my view, as noted above, basing treatment decisions on assumptions alone is a dangerous practice. I agree with Dr Maplesden that a provider should still ensure that the provision of a prescription is clinically appropriate.

146. Accordingly, on 4 May, Dr B needed to be certain that prescribing Estelle for Mrs A was appropriate. He should have been aware of Mrs A's high risk profile as he had seen her in the past and knew she was obese, over 35 years of age, and had been a smoker. This should have prompted him to review Mrs A's medical records to ascertain why Estelle, a COC carrying a particularly high risk for someone in Mrs A's circumstances, had been prescribed for her. If Dr B had reviewed Mrs A's Medical Centre 2 notes, he would have noted the absence of a

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documented discussion about risks and alternatives associated with Estelle, a record of her informed consent, and a recent blood pressure recording. At that point, he should have personally reviewed Mrs A to ensure that she was aware of her risks before issuing the prescription. As Dr Maplesden advised, if Mrs A was unable to see Dr B personally, it may have been acceptable for Dr B to have provided a shorter than usual prescription, on the condition that Mrs A return for a face-to-face consultation when a further prescription was needed.

147. On 27 October 2009, Dr B provided Mrs A with another six-month prescription of Estelle, again without seeing her face-to-face. Dr B told HDC that he assumed Mrs A was unable to come in to see a GP, and that he considered it was in Mrs A's best interests to continue the COC rather than risk pregnancy. There is no record of why Mrs A did not see Dr B personally on 27 October, but the nurse documented that Mrs A was aware that she needed to make an appointment to see a GP for her next prescription. On 28 October the nurse took Mrs A's blood pressure, which was normal.

148. By 27 October 2009, it had been almost two years since Dr C had reinstituted Estelle, and a year since Mrs A had last seen a doctor face-to-face before a repeat of Estelle was prescribed. Mrs A's risk factors were changing as she grew older, and Dr B needed to be certain that prescribing Estelle for Mrs A remained appropriate. Furthermore, Mrs A's use of Estelle required at least annual review in light of her risk factors for DVT.[40] Even if Dr B assumed that Dr C had undertaken a review in October 2008, by October 2009 another year had passed and Mrs A's use of Estelle should have been reviewed in line with best practice. Dr B should have ascertained Mrs A's weight and smoking status, or taken steps to ensure that Mrs A was receiving appropriate monitoring, before providing the prescription. Alternatively, he could have provided a shorter prescription on the basis that Mrs A return for a review when the next prescription was necessary.

Summary

149. On 4 May and 27 October 2009, Dr B failed to review Mrs A's use of Estelle, or take steps to satisfy himself that she was receiving the appropriate monitoring, before providing her with a prescription for Estelle. Dr B's care of Mrs A fell below an appropriate standard, and he should reflect on his poor care in this case.

150. However, I acknowledge that the reason Mrs A did not see Dr B face-to-face on those dates is unknown, and a nurse had advised Mrs A that she needed to see a GP for her next script. I also acknowledge the view of my expert, Dr Maplesden, that Dr B's deficiencies were only mild departures from expected standards, as Mrs A could be regarded as a long-term COC user and had not experienced problems with it in the past. For these reasons, I do not consider that Dr B's failures in this case amounted to a breach of the Code.

[40] *Best Practice Journal* (*BPAC*), "Combined oral contraceptive: Issues for current users" (2008) 12:21–29.

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20 April and 7 October 2010 — No breach

151. On 20 April 2010, Mrs A again saw Dr B, and the clinical record indicates that options for contraception were discussed. It is not entirely clear from the clinical record whether Dr B also discussed Mrs A's risk factors. However, Dr B stated that he did discuss risks, because a discussion of options is the "obvious next step after a discussion of risks". I accept Dr B's explanation in this regard. However, I consider that his documentation could have been better.

152. I accept that it was reasonable for Dr B to provide a repeat prescription of Estelle for Mrs A on 7 October 2010, as it was only six months after he had reviewed Mrs A's use of Estelle on 20 April 2010.

Opinion: Breach — Medical Centre 2

153. Mrs A transferred her primary care to Medical Centre 2 in November 2007. Her primary care was managed by three different general practitioners over the next three years until her unexpected death in 2011.

154. The Medsafe data sheet for Estelle includes a precaution: the risk of thromboembolism increases with age, smoking, positive family history, obesity, and major surgery. The presence of a severe risk factor or multiple risk factors for venous or arterial thrombosis may constitute a contraindication to the prescription of Estelle.

155. Under the Code, Mrs A had the right to receive an appropriate standard of care from Medical Centre 2 and its staff. Her use of Estelle should have been reviewed regularly to ensure that its ongoing use was clinically appropriate. That did not happen.

156. Mrs A was prescribed Estelle in December 2007 and subsequently received several repeat prescriptions, despite having health risks in the context of COC prescribing in general, and Estelle in particular. She remained overweight, continued to smoke, and was aged 40 years at the time of the last prescription. Her family history of thromboembolism was not elicited by the GPs at Medical Centre 2.

157. Mrs A's blood pressure was not recorded at Medical Centre 2 until October 2009 — almost two years after she had transferred to the practice and Estelle was reinstituted.

158. As noted previously, COC use should be reviewed at least annually in line with accepted practice. Dr Maplesden advised that Mrs A should possibly have been reviewed more regularly than annually in order to reassess her modifiable risk factors (obesity and smoking) and to discuss the risks if those factors were not

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modified. Risks associated with the COC alter as a woman ages and when other risk factors (such as whether the woman is smoking) change.

159. Mrs A also had the right to receive information that a reasonable consumer in her position would expect to receive, which included being informed of her personal risk factors prior to commencing Estelle.

160. There is little evidence that Mrs A's risk factors were discussed with her after she transferred her primary care to Medical Centre 2 in 2007. Two of her GPs at Medical Centre 2 assumed that a previous GP had discussed Mrs A's risk factors with her. It was not until 2010 that Dr B discussed contraceptive options with Mrs A, and, by his account, her risk factors.

Conclusion

161. Medical Centre 2's structure allowed Mrs A to be seen by three different doctors. With that context in mind, Medical Centre 2 needed to ensure that: the service provided included a review and discussion of risks with patients; the quality of documentation was monitored; responsibilities for reviewing patients on COCs were appropriately delegated; and the practice had policies for best practice review of patients on oral contraceptives.

162. In an earlier opinion,[41] this Office stated:

> "The size and structure of the Medical Centre makes it likely that patients with ongoing problems will be seen by a number of different doctors. It is therefore vital that processes are in place to ensure that patients who are attending for general practice care … are provided with continuity of care. [Mrs A] was registered with the Medical Centre as her primary care provider. This meant that the Medical Centre was responsible for the provision of continuity of care for [Mrs A] and for the management of her health problems.
>
> The Medical Centre had a responsibility to have good systems in place to ensure patients received good quality care, and were not disadvantaged by the number of doctors involved in their care."

163. At Medical Centre 2, there was a pattern in the poor care Mrs A received, in that her GPs often assumed that a previous provider had undertaken an appropriate risk assessment and provided appropriate advice. Those assumptions were made on the basis of little, if any, evidence. Such evidence would have included full and unambiguous documentation. Where multiple providers are involved in care, good documentation is critical. As discussed in a previous opinion:[42]

> "[Mrs A's] care was jeopardised by the poor standard of documentation of her consultations on several occasions. Given the structure of the Medical

[41] Opinion 08HDC06359, 30 June 2009.
[42] Opinion 08HDC06359, 30 June 2009.

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> Centre, it is vital that a detailed and clear record of the history, examination, assessment and management plan of each consultation is documented, in order to assist other doctors at the Medical Centre to provide continuity of care to the patient."

164. Multiple providers were involved in Mrs A's care and prescribing, and this case highlights the need for practices to have policies that ensure continuity of care. As I stated in a previous opinion:[43]

> "In any healthcare system, there are a series of layers of protections and people, which together operate to deliver seamless service to a patient. When any one or more of these layers do not operate optimally, the potential for that level to provide protection, or deliver services, is compromised. When a series of such events occur, although each are often minor in themselves, the fabric that is wrapped around the patient in the delivery of a seamless service is torn. When a series of tears or holes line up, poor outcomes result. Patients are at risk of being harmed."

165. Medical Centre 2 did not have systems in place that ensured patients on COCs underwent a regular, specific, medical review and were counselled on their DVT risk if that risk was increased. Medical Centre 2 did not have policies or procedures in place ensuring best practice review of patients on oral contraceptives. Furthermore, Medical Centre 2 did not ensure that patients' blood pressure, weight or BMI and relevant family history details were elicited and documented consistently.

166. Mrs A did not receive services of an appropriate standard from Medical Centre 2. In my view, Medical Centre 2 breached Right 4(1) of the Code by not having in place adequate policies and procedures to ensure that Mrs A's use of Estelle was appropriately monitored.

Other comment

167. It is considered prudent to discontinue use of Estelle before major surgery. However, it is not clear whose responsibility it is to advise patients to discontinue Estelle before surgery (and I note that it is not the purpose of the Medsafe data sheet to clarify such responsibility). My expert, Dr Maplesden, advised that it could be argued that it is the surgeon's responsibility, and that the surgeon could notify a patient's GP or include such advice in any pre-admission documentation sent to patients. However, he also argued that a patient's GP may have some responsibility to discuss appropriate cessation of Estelle with a patient once the GP becomes aware of the anticipated date of surgery.

[43] Opinion 09HDC01883, 15 June 2012.

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168. Dr D advised HDC that GPs are not advised of operation dates and therefore are not able to reinforce appropriate cessation of COCs. His referral letter to the hospital of 30 August 2010 specifically states "on Estelle".

169. Dr F removed Mrs A's gallbladder. He did not advise her to stop taking Estelle. He advised HDC that it is his usual practice to discuss ceasing use of the COC, along with the risks of, and alternatives to, staying on the COC. However, he did not do so in Mrs A's case as he did not know that she was taking a COC at that time because she had not identified it in the preoperative questionnaires as a medication she was currently taking.

170. My expert surgeon, Dr Michael Rodgers, advised that in Mrs A's case, he would not have expected anyone to have discussed ceasing taking Estelle with her. He noted that Mrs A was at moderate risk of developing thromboembolism, taking into account her use of the COC, and advised that the level of prophylaxis provided to her by the DHB would have been adequate even for a high risk patient.

171. In my view, both referrers and surgeons have an obligation to ensure that risk factors are identified and addressed. Relevant patient risk should be managed appropriately throughout this process. Medical practitioners would benefit from increased clarity about who should advise a patient to stop a COC prior to surgery, when stopping the COC is clinically indicated. I intend to raise this matter with the Health Quality & Safety Commission.

172. However, I accept that in this case it is not clear whether Mrs A was still taking Estelle at the time of her surgery. It is therefore difficult to hold Dr F or the hospital responsible for not discussing the risks of continuing to take Estelle.

173. My clinical advisor noted that many patients do not regard the COC as medication. In my view, it would be prudent to have a question on the pre-admission questionnaire asking specifically about contraceptive use, in addition to the general question asking about medications the patient is taking. In response to my suggestion, the hospital advised that this amendment has been made.

Recommendations

Dr C

174. I recommend that Dr C apologise to Mrs A's family for her breach of the Code. Dr C's written apology should be sent to this Office, **within one month** of the date of issue of this report, for forwarding to Mrs A's family.

Medical Centre 2

175. I recommend that Medical Centre 2:

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- apologise to Mrs A's family for its breach of the Code. Medical Centre 2's written apology should be sent to this Office, **within one month** of the date of issue of this report, for forwarding to Mrs A's family;
- arrange an audit by the CORNERSTONE™ accreditation programme in relation to documentation (in particular the consultation record), systems for monitoring patients on oral contraceptives, and continuity of care, and report to HDC on these results, **within two months** of the date of issue of this report;
- provide evidence to show that its policy has been amended to ensure that the recommendations contained in the revised COC practice information document are followed for any patients new to the practice being prescribed a COC, whether or not they were taking the COC at the time of transfer, in addition to those patients being commenced on a COC for the first time. Evidence of this should be provided **within three months** of the date of issue of this report; and
- repeat the COC prescribing audit after one year to determine the effectiveness of practice process changes regarding appropriate identification and recording of risk factors.

176. I note that, since my provisional opinions were issued, Medical Centre 2 advised HDC that it has achieved CORNERSTONE™ General Practice Accreditation.

Follow-up actions

177.
- A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the Medical Council of New Zealand, and it will be advised of Drs D, C and B's names.
- A copy of this report will be sent to the Coroner and the District Health Board.
- A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the Royal New Zealand College of General Practitioners (including their CORNERSTONE™ accreditation programme). The College will also be advised of Dr C's name.
- A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the Royal Australasian College of Surgeons.
- A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the Health Quality & Safety Commission.
- 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.

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Appendix A — Clinical advice to the Commissioner

The following expert advice was obtained from my in-house clinical advisor, Dr David Maplesden, a vocationally registered general practitioner:

> "My name is David Maplesden. I am a vocationally registered general practitioner practising in Hamilton, New Zealand. My qualifications are MB ChB (Auckland University 1983), Dip Obst (1984), FRNZCGP (2003).
>
> 1. Thank you for the request that I provide clinical advice in relation to the complaint from [Mrs E] (sister of [Mrs A]) and [Mr A] (husband of [Mrs A]) about the care provided to [Mrs A] by [the] District Health Board and [Medical Centre 2]. To my knowledge, I have no personal or professional conflicts of interest. I have examined the available documentation: complaint from [Mr A] per Coroner dated [date] 2011; complaint from [Mrs E] to HDC [date]; [Medical Centre 2] ([Medical Centre 2]) responses to Coroner and HDC; [the District Health Board] report to Coroner per surgeon [Dr F]); [Medical Centre 2] clinical notes; [hospital] clinical notes; various coronial documents including post-mortem and police reports; additional statements and clinical documentation gathered following notification of investigation.
>
> 2. The complaints note that [Mrs A] (aged 40 years) had attended [Medical Centre 2] [in early] 2011 with left leg pain and swelling. She had investigations and was diagnosed with a superficial venous thrombosis (SVT). She was followed up at [Medical Centre 2] [two weeks later] and reassured all was well. She underwent laparoscopic removal of her gall-bladder as an elective operation at [the hospital] [the following month]. She appeared to recover well from this and had been mobilising at home, although she was still complaining of left leg pain. [Two weeks following the surgery] [Mrs A] died suddenly at home. Post-mortem examination attributed death to a large pulmonary embolus (PE). She was noted to have a swollen left calf at post mortem and it was thought likely she had a deep vein thrombosis (DVT) here as the source of the PE. The complainants are concerned primarily with the lack of follow-up of [Mrs A's] leg pain at [Medical Centre 2] and the failure to diagnose the DVT.
>
> 3. Use of the combined oral contraceptive (COC) is associated with an increased risk of DVT. In March 2002, Medsafe sent a letter to prescribers[1] reminding them of the additional DVT risk associated with third generation COCs and with Estelle. Excerpts include: *Studies show that the risk of venous thromboembolism (VTE) with Diane 35/35 ED™ and Estelle 35/35 ED™ is at least as great as that with third generation oral contraceptives (OCs)… The risk of VTE with third generation OCs is twice that of second generation OCs … The MARC reminds practitioners that Diane 35 and Estelle 35 are indicated only in women for the treatment of androgen-dependent diseases (including pronounced acne) and polycystic ovary syndrome, and for oral*

[1] Available at http://www.medsafe.govt.nz/profs/PUarticles/CPAletter.htm

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contraception in these women … It is important that practitioners remain vigilant about the risk of VTE with combined OCs, and the higher risk of VTE with the third generation OCs and cyproterone-containing OCs compared with second generation OCs …

4. Ministry of Health guidelines[2] on initiation of the COC and current use of third generation or cyproterone containing preparations, updated around the same time as the letter noted above, included the following points:

(i) *Before initiating … take a comprehensive personal and family history to exclude contraindications to the use of combined OCs. If there is a family history of thromboembolism, screening for thrombophilia should be considered in consultation with a haematologist. Hereditary thrombophilia and personal history of VTE are contraindications.*

(ii) *For women taking OCs containing desogestrel, gestodene or cyproterone* [Estelle]*: in the presence of thromboembolic risk factors, the woman should be advised to change to an OC that does not contain desogestrel, gestodene or cyproterone, or change to another contraceptive method, as appropriate. For women taking an OC containing cyproterone an alternative treatment for the androgenic disease may be required; offer other hormonal or non-hormonal contraception if, after counselling, the woman finds the relative risk of VTE with combined OCs containing desogestrel, gestodene or cyproterone unacceptable; respect the woman's informed choice if she chooses to continue to take her current contraceptive.* Note is made in both Medsafe articles that the risk of DVT in pregnancy far outweighs the risk of DVT while on COC.

5. Product information for Estelle[3] includes the following points:

(i) *ESTELLE-35 and ESTELLE-35 ED are indicated for the treatment of androgen dependent diseases in women* [includes polycystic ovary syndrome]*… is also indicated for oral contraception in women requiring treatment for these androgen-dependent diseases; it is not recommended in women solely for contraception.*

(ii) *Contraindications … the presence of a severe or multiple risk factor(s) for venous or arterial thrombosis may also constitute a contraindication.*

(iii) *Precautions — the risk of thromboembolism (venous and/or arterial) increases with:*

- *Age*
- *Smoking (with heavier smoking and increasing age the risk further increases especially in women over 35 years of age)*

[2] Ministry of Health (Medsafe) advice on the use of combined oral contraceptives, 2002 Update. http://www.medsafe.govt.nz/profs/PUarticles/OCAdvice2002.htm
[3] ESTELLE-35 and ESTELLE-35 ED Medsafe data sheet. 2007. www.medsafe.govt.nz

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- *A positive family history (i.e. venous or arterial thromboembolism even in a sibling or parent at a relatively early age). If a hereditary predisposition is suspected, the woman should be referred to a specialist for advice before deciding about any COC use.*
- *Obesity (body mass index over 30 kg/m2)*
- *Prolonged immobilisation, major surgery, any surgery to the legs, or major trauma. In these situations, it is advisable to discontinue COC use (in the case of elective surgery at least four weeks in advance) and not to resume until two weeks after complete mobilisation* [my emphasis].
- *There is no consensus about the possible role of varicose veins and superficial thrombophlebitis in venous thromboembolism.*

6. As discussed above, COCs increase the risk of VTE. From a baseline risk of about five cases annually per 100,000 healthy non-pregnant women not on COC, those on 1st and 2nd generation pills have a threefold increase in risk while those on 3rd generation (and Estelle) have a five fold increase (pregnant women have a 12-fold increase). COCs increase the risk of stroke in women who suffer from migraines with aura — [Mrs A] did not have this condition. A BPAC article circulated to GPs in 2008[4] states *COC use in heavy smokers* (not further defined) *substantially increases cardiovascular risk. There is weak evidence that COCs increase the risk of myocardial infarction and ischaemic stroke but the absolute risk (in the absence of additional CV risk factors) is still low. However in women with multiple cardiovascular risk factors (eg older age, smoking, diabetes, hypertension, obesity or a family history of cardiovascular disease before age 50) the risk may be increased further.* As discussed further below, [Mrs A] was older, a smoker and obese — all factors contributing, together with her COC use, to an increased risk of CVD although I cannot quantify what this increase would be. The BPAC publication refers to the UK Medical Eligibility Criteria (UKMEC) for COC use, and [Mrs A] had factors from category 3 of these criteria (Risks generally outweigh benefits but the method can be considered for use with clinical judgement and/or specialist referral if other methods are unacceptable) — aged >35 years and smoking <15 cigarettes per day ([Mrs A] stated she was smoking 14 cigarettes per day at her pre-op assessment) and possibly family history of VTE in a first-degree relative aged <45 years (age at which her parents had VTEs not recorded). She also had a factor listed in category 4 (Unacceptable health risk and should not be used) — that being obesity (BMI > 40kg/m2 — [Mrs A's] BMI was 41 at her pre-op assessment).

8. A summary of clinical notes prior to 2002 was provided by [Dr D]. There is reference in some [hospital] notes to [Mrs A] having cervical cancer at the age of 17yrs but this appears unsubstantiated. GP notes indicate [Mrs A] was

[4] Best Practice Journal (BPAC) — Combined oral contraceptive: Issues for current users. 2008; 12:21–29

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prescribed Marvelon-28 for contraception between August 1989 and February 1999. During 1999, symptoms of hirsutism and irregular bleeding led to investigations (blood tests) for polycystic ovary syndrome (PCOS) and test results supported this diagnosis. A referral was made to a specialist for confirmation of the diagnosis (response not available). On 16 November 1999, [Mrs A's] provider has recorded *Wants Diane 35* [equivalent of Estelle/Ginet] *No fhx thrombosis ... discussed risks of CVA/thrombosis ... wants it still ... written info ...* On 1 October 2002 there is a record that contraceptive options have again been discussed. [Mrs A] had used progestagen-only contraception (the mini-pill) for a year from November 2005 until she wanted to become pregnant, with a positive pregnancy test on 12 March 2007. The mini-pill had been commenced by another provider who was concerned at the risks to [Mrs A] of remaining on Estelle and documented a discussion regarding this. From [Medical Centre 1] clinical notes received at [Medical Centre 2] on 30 November 2007:

(i) 15 June 2005 (provider [AAA])[5] *Brought baby for 6week imms. Requests script for contraception. Intends to go back to COC in future.* Condoms provided at this point.

(ii) 2 August 2005 ([BBB]) — *req ocp — on estelle35, 5–6 yrs use, stable no probs. No imb, no headaches ... BP 130/80 with large cuff ...* Three month supply of Estelle-35 prescribed. Blood pressure check after starting Estelle undertaken on 16 August 2005 — 110/72.

(iii) 2 November 2005 ([Dr G]) — *Rpt on COCP. Smoker, overweight and on Estelle. Needs to change to mini-pill. Discussed and happy for this. BP 150/90.* Six month supply Femulen prescribed.

(iv) Multiple consultations for a persistent shoulder injury December 2005–May 2006.

(v) 5 July 2006 ([CCC]) — *Repeat POP. On femulen but has been discontinued so switch to Noriday. No problems.* Six month supply of the progestagen only pill (POP/minipill) Noriday prescribed.

(vi) 12 March 2007 — positive pregnancy test — planned pregnancy.

(vii) I note a positive family history of DVT was recorded in […] [h]ospital notes of May 2007 when [Mrs A] was first investigated for DVT (negative investigations) while pregnant. This additional risk factor (assuming its accuracy) was never recorded in GP notes but is discussed further below.

9. GP notes for 30 November 2007 record [Mrs A] as having a diagnosis of polycystic ovary syndrome (PCOS) although there is no elaboration on

[5] Initials denote the provider involved in each consultation and have been anonymised as three letter combinations throughout the clinical notes where they do not relate to a party otherwise identified on page 3 of this opinion.

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symptoms she is currently experiencing (if any). [Mrs A] was also a cigarette smoker (up to the time of her death) and there are references through the notes to discussion of cessation and attempts at cessation. [Mrs A] was morbidly obese with a BMI of around 41 at the time of her gallbladder surgery. She had a significant family history of DVT ([Dr F] notes that her father had a post-operative DVT and her mother a spontaneous DVT). It is not apparent from the GP notes available that [Mrs A] was diagnosed with a thrombophilia, or that she had been investigated for a thrombophilia in the past. She was normotensive and had an unremarkable lipid profile. She was taking a cyproterone acetate containing combined oral contraceptive (Estelle) around the time of her death, with the most recent prescription for this having been a six-month supply provided on 7 October 2010 (provider [DDD]). In his response to the Coroner on behalf of [Medical Centre 2], [Dr D] notes that [Mrs A] had been prescribed the equivalent of Estelle for the first time in March 1999 (see section 8). He states *note was made in 2 Nov 2005 by [Dr G] that as [Mrs A] was an 'overweight smoker' she would be 'better to change from Estelle to a Minipill'.* The minipill (progestagen only pill — POP) was prescribed at that point and continued for a year until [Mrs A] wished to conceive. She fell pregnant in February 2007, delivering by caesarean section in October 2007. On 5 December 2007 Dr C has documented *7 weeks since LSCS ... restarting Estelle.* A prescription was provided at that point (although not recorded in the notes) and further prescriptions were provided on 16 May 2008 ([Dr D]), 22 October 2008 ([Dr C]), 4 May 2009 ([Dr B]), 27 October 2009 ([Dr B]), and 20 April 2010 ([Dr B]). On this latter date, notes record *Repeat OCP — options incl vasectomy discussed but will stick with the Estelle at present.*

10. On 11 May 2007 [Mrs A] was admitted to [the local] Hospital at 16 weeks pregnant following a brief collapse associated with shortness of breath and palpitations. History includes *both her parents have had Pes ...* D-dimer[6] is positive (as it can be in pregnancy). There was a 3cm differential in thigh circumference, the left being larger than the right. Clexane was commenced as a precaution while awaiting definitive tests (lung VQ scan and lower limb ultrasound) at [the hospital]. The lower limb ultrasound was negative for DVT, and VQ scan showed no evidence of PE. Clexane was stopped and [Mrs A] was discharged from [the hospital] on 15 May 2007. There is no evidence elsewhere in the notes to suggest [Mrs A] had ever had a confirmed DVT or PE prior to the event that resulted in her death [in 2011].

[6] A positive D-dimer indicates the presence of an abnormally high level of fibrin degradation products in the body which may mean significant clot (thrombus) formation and breakdown in the body, but it does not tell the location or cause. An elevated D-dimer may be due to a VTE but it may also be due to a recent surgery, trauma, infection and some clotting disorders. Elevated levels are also seen with liver disease, pregnancy, eclampsia, heart disease, and some cancers. D-dimer is recommended as an adjunct test. It should not be the only test used to diagnose a disease or condition. Both increased and normal D-dimer levels may require follow-up and can lead to further testing. However a normal D-dimer in a patient at low risk for VTE makes a diagnosis of VTE very unlikely.

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11. On 25 January 2010 ([EEE]) [Mrs A] was reviewed for a variety of issues including upper abdominal discomfort and nausea — *???atypical pains from gallstones.* Blood tests were largely unremarkable and she was advised to return if the pain recurred. This she did on 26 August 2010 ([Dr D]) — *right side pains with vomiting, severe spasms, seems very likely biliary colic, for u/s and refer ?? private …*blood tests were repeated and a referral letter was sent on 30 August 2010.

12. On 18 October 2010 [Mrs A] was seen by [a Surgeon] in relation to her right abdominal pain. Ultrasound confirmed gallstones. [The surgeon's] report to [Dr C] states *from my point of view there is a good indication for a symptomatic gallbladder that has been causing her pain for the last year. I consented her today including common bile duct injury, bleeding and trocar incisional hernia. She agrees with this plan and hopefully we can operate on her laparoscopically at the beginning of next year.* [Mrs A's] medications or DVT risk factors are not mentioned.

13. [In early] 2011 [Mrs A] was seen at [Medical Centre 2] ([FFF]) with *small area of redness — just above knee, lateral aspect, present for a week, mildly tender. Previous DVT when pregnant* [not confirmed] *Tender calf since last night and swollen +++ …* A 1.5cm calf circumference differential is noted with the left side being larger then the right. *Imp ?phlebitis or small area of cellulitis but very tender calf and foot ??DVT For urgent bloods and scan.* Bloods show a positive D-dimer and elevated CRP (31). Provider [FFF] discusses [Mrs A's] case with [the hospital] and arranges a scan for the following morning, with Clexane to be commenced empirically through [the local hospital] while awaiting the scan. Ibuprofen and paracetamol are prescribed. The negative scan result (see below) is discussed with [Mrs A] [two days later] — *still very tender and reddened. Plan — further OWC and abx, continue with analgaesia, rest/ice.* Flucloxacillin is prescribed. At review [a few days later] ([Dr B]) *still some discomfort around knee where has the tortuous vein which is still tender. For regular analgaesia and mobilise.* There is no further contact recorded between [Mrs A] and staff of [Medical Centre 2]. In particular, there is no record of [Mrs A] complaining of ongoing or new lower leg pain or swelling.

14. [In early] 2011 [the local hospital] ED notes record [Mrs A's] referral for *?DVT — for therapeutic clexane whilst awaiting USS … previous DVT while pregnant* [not correct] *high BMI, varicose veins … 1/7 hx of painful red swelling on lateral aspect of distal thigh … red thrombophlebitis over later distal aspect of thigh …* Clexane administered and booked for ultrasound the next morning. Ultrasound report [date] — *There is no evidence of deep vein thrombosis. There is evidence of thrombus in the superficial veins lateral to the knee consistent with superficial thrombophlebitis.*

15. [Mrs A] had symptoms that may have been suggestive of DVT when seen [at the first appointment in] 2011. Classic symptoms of DVT include

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swelling, pain, and discoloration in the involved extremity[7]. There is not necessarily a correlation between the location of symptoms and the site of thrombosis. Symptoms in the calf alone are often the presenting manifestation of significant proximal vein involvement, while some patients with whole leg symptoms are found to have isolated calf vein DVT. Physical examination may reveal a palpable cord (reflecting a thrombosed vein), calf pain, ipsilateral edema or swelling with a difference in calf diameters, warmth, tenderness, erythema, and/or superficial venous dilation. However, each of the above signs and symptoms is nonspecific and has low accuracy for making the diagnosis of DVT. There may also be no or minimal relevant clinical findings. Risk factors for DVT should probably be sought in all patients complaining of calf pain. Some risk factors applicable to [Mrs A] have been noted in section 6(iii). It is obvious the provider assessing [Mrs A] acknowledged her high risk and sought to exclude DVT as a cause of her symptoms. While alternative diagnoses of superficial venous thrombosis (SVT) and cellulitis were also considered, her provider followed a plan of action largely consistent with expected standards in ordering a D-dimer (although a past history of DVT, as this provider erroneously recorded, would obviate the need for D-dimer and the patient would generally be referred directly for ultrasound).

16. Areas of New Zealand where community diagnosis and/or management of DVT is promoted generally refer to the Wells criteria to determine the probability that a DVT is present, and therefore influence further management. These criteria provide a score as noted below:

Clinical feature	**Score**
Active cancer (treatment ongoing or within the previous 6 months or palliative)	1
Paralysis, paresis, or recent plaster immobilization of the lower extremities	1
Recently bedridden for more than 3 days or major surgery, within 4 weeks	1
Localized tenderness along the distribution of the deep venous system	1
Entire leg swollen	1
Calf swelling by more than 3 cm when compared to the asymptomatic leg (measured below tibial tuberosity)	1
Pitting oedema (greater in the symptomatic leg)	1

[7] Landaw S, Bauer K. *Approach to the diagnosis and therapy of deep vein thrombosis.* Uptodate — last updated January 2011. **www.uptodate.com**

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Collateral superficial veins (non-varicose)	1
Alternative diagnosis as likely or more likely than that of deep venous thrombosis	-2
Score	
High probability	≥ 3
Moderate probability	1 or 2
Low probability	≤ 0

In [Mrs A's] case (assuming no personal history of previous DVT), her score would probably have been 2 in that there were some positive physical findings, and although SVT and cellulitis were possible alternative diagnoses, they were probably no more likely than DVT on the basis of the initial presentation. D-dimer was therefore indicated and was performed. A positive result, although not confirmatory of DVT (see footnote 5), meant that ultrasound of the leg veins was then required to confirm a diagnosis. [Mrs A's] GP was conscientious in ensuring she had adequate thromboprophylaxis while awaiting the scan. The ultrasound did not confirm DVT but in fact confirmed SVT, a diagnosis that was also consistent with the clinical presentation. This was treated appropriately by the GP, who was also cautious in adding in antibiotics in case there was a complicating cellulitis. [Mrs A] was reviewed in a timely manner and findings consistent with slowly resolving SVT (which is a normal response to therapy) were evident. A repeat application of Wells criteria at this point would have given a score of zero (some persistence of the previous physical findings but -2 for the confirmed alternative diagnosis) and it was appropriate to discharge her with advice to return if her symptoms worsened or new symptoms appeared. It cannot be confirmed that such advice was given, although it is very much the norm in general practice to give such advice whatever the presentation, and the provision of such advice is often not recorded. In any event, [Mrs A] did not report any deterioration of her symptoms to [Medical Centre 2], and in fact reported to staff at the surgical preadmission clinic [a week prior to surgery] that her symptoms had cleared with antibiotics (see below). My conclusion regarding this aspect of [Mrs A's] history is that she had an SVT in [early] 2011, this was investigated and treated appropriately by her GP, and the SVT apparently resolved. SVTs do not cause pulmonary emboli and there is not likely to be a direct cause between this episode and [Mrs A's] death. However, there may be an association between SVT formation and general venous thromboembolic tendency, and I acknowledge that ultrasound does not have 100 percent sensitivity in the diagnosis of DVT.

17. At surgical pre-assessment clinic [a week prior to surgery], [Mrs A] completed a pre-operative medical assessment list. Under current medications, there is no entry. [Mrs A] has noted her smoking history (14

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per day), history of blood clots in both parents, personal history of blood clot *in left leg, secondary vein* and in another area of the form *secondary vein blood clot — settled with POABs.* I have presumed from this comment that [Mrs A's] left lower leg pain and swelling had settled at the time of this assessment. Vital signs are normal, weight 106kg and height 160.5cm. Nursing notes indicate discussion has taken place regarding post-op pain control, leg and breathing exercises, smoking cessation (NRT prescription supplied). [Mrs A] was also measured for TED stockings.

18. [Mrs A] was admitted to [the hospital] for her elective surgery. This was performed by [Dr F] who had not seen her previously. Anaesthetic record notes [Mrs A's] family history of DVT, personal history of recent thrombophlebitis and swollen leg while pregnant. Surgery was uncomplicated with total operation time being around 100 minutes (start 0854hrs, end 1033hrs) and anaesthetic time around 110 minutes. Post-operatively [Mrs A] experienced some nausea attributed to Tramadol, but was otherwise well. Clexane 20mg SC was given at 0840hrs prior to commencement of surgery and a further 40mg SC at 2220hrs on the evening of surgery. Pneumatic calf pump was used during surgery and for about six hours afterwards. At registrar review on the evening of surgery he notes *calf pumps off, mobilise, TEDS, clexane …* [Mr A] states he assisted his wife in use of TED stockings during her hospital stay but she was not provided with any stockings on discharge. However, notes indicate [Mrs A] mobilised well after surgery, and [Mr A's] own report indicated his wife had been mobilising adequately at home prior to her death. There is no reference in the notes to [Mrs A] complaining of left leg pain or swelling or any observation of such swelling. There is no mention of her being on Estelle.

19. [The hospital] discharge summary dated [the day following surgery] notes that a laparoscopic cholecystectomy was carried out without complication — *Recovered well and discharged following day. GP follow up as required. Prescription for analgaesia given.* Paracetamol and ibuprofen were prescribed on discharge. [Mrs A] had no further contact with [the hospital] staff.

20. Coronial documentation indicates that around noon [two weeks later] [Mrs A] developed severe abdominal pain and shortness of breath while sitting at home. She rang [the] Ambulance Service who attended immediately. There was some difficulty gaining access and [Mrs A] was found collapsed, pulseless and cyanotic. CPR was commenced and continued for 25 minutes with no sign of life. [Mrs A] was pronounced dead. Post-mortem examination was undertaken [the following day]. Examination findings included a swollen left calf (3cm calf circumference differential) and saddle pulmonary embolus. There was a small amount of old blood in the peritoneal cavity consistent with the recent surgery but not contributing to death. Death was attributed to pulmonary embolus, with the presence of left lower leg swelling making a DVT here the most likely source of the PE.

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21. I have examined the local guidelines for prevention of venous thromboembolism[8] referred to by [Dr F] in his response. I include the following excerpts:

(i) *The duration of prophylaxis is important. In high risk patients, the duration or prophylaxis is recommended to be a minimum of ten days.*

(ii) *There is no conclusive evidence to form conclusions for ambulatory patients. Nevertheless, it is important to be cautious with early discharge patients as they may still be at risk and may need continued prophylaxis during their convalescence.*

(iii) *Graduated compression stockings (GCS) reduce the incidence of DVT. Studies have generally involved full length stockings … it is anticipated that below knee stockings should also provide a degree of protection … stockings should be worn continuously during the period of immobility until full ambulation … stockings should be measured and fitted for the individual patient …*

(iv) *Intermittent pneumatic compression reduces the incidence of DVT and is more effective than GCS in high risk patients in combination with anticoagulants to when anticoagulants are contraindicated … they should be used during the period of immobility until full ambulation …*

(v) *It is considered prudent to stop hormone replacement therapy (HRT) or the oral contraceptive pill if the patient is in the high risk or moderate risk categories … Ideally the oral contraceptive pill should be ceased the cycle before planned surgery …*

(vi) *Screening for thombophilia before surgery is not required and specialist advice should be sought before screening is considered …*

(vii) *In non-orthopaedic surgical patients, a prior history of VTE is the most important predictor for development of VTE post-operatively. Other risk factors include malignancy, obesity, increasing age, varicose veins, the use of oestrogen-containing preparations or the presence of thrombophilic factors. The duration and type of surgery is most important … Major surgery is any intra-abdominal operation and all other operations lasting more than 45 minutes* (referring to general, vascular and gynaecological and urological surgery).

(viii) [Mrs A] fulfilled the 'high risk' category: *Major surgery age 40–60 years with cancer or history of VTE or other risk factors* (in her case obesity, varicose veins, smoking, strongly positive family history. Possibly

[8] The Australia and New Zealand Working Party on the Management and Prevention of Venous Thromboembolism. *Prevention of Venous Thromboembolism. Best Practice Guidelines for Australia and New Zealand*. 3rd Edition.

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concurrent cyproterone acetate use and recent history of SVT. Presence of thrombophilia unknown).

(ix) Recommendations for 'high risk' category for general surgery is *LMWH*[9] *(10 days minimum prophylaxis) and GCS and/or IPC.*

22. Concluding comments and answers to specific questions posed (italicised):

(i) [Mrs A] had multiple risk factors for venous thromboembolism. However, there is no evidence she had a personal history of DVT or PE prior to the findings of her post-mortem examination.

(ii) *What would you expect from a practice in relation to a patient's medical records, on receiving paper notes from another practice?*

The process by which relevant clinical documentation is transcribed from old notes varies from practice to practice, and varies according to the method by which old notes are received. Until relatively recently, it was impossible for electronic notes to be transmitted between providers in different medical centres in their entirety while keeping intact relevant recalls, codes etc, even if a common practice management system was being used. There are still difficulties associated with electronic transfer of notes and the most common practice is for a 'hard copy' of notes to be received. Expected practice would be that notes are reviewed by a nurse and/or doctor prior to, or at the time of, the first presentation of the patient to the practice. Information I would expect to be transcribed includes immunisation history, relevant/important past or current medical conditions, allergies and alerts, screening history and recalls (particularly relating to cervical smears), smoking history (if recorded), and current medications. [Mrs A] had previously attended [Medical Centre 2], possibly as a casual patient, between November 2002 and July 2003, hence some relevant past history was already recorded. Following receipt of the old notes, the diagnosis of polycystic ovaries has been added together with a note of smear history. [Mrs A] was not taking any regular medication at the time of transfer. She was not allergic to Estelle therefore there was no reason to attach an alert relating to this medication. The fact [Mrs A] had been prescribed the mini-pill prior to her last pregnancy was not transcribed, nor would I expect it to be. However, I would have expected [Mrs A] to have informed her new doctors she had been prescribed the mini-pill if questioned about her contraceptive history.

(iii) *What would you expect from a medical centre's policy and procedures around initial prescribing of this kind of medication?*

In a general practice setting, the oral contraceptive is generally prescribed by a doctor. I would expect a general practice policy on processes associated

[9] Low molecular weight heparin — includes Clexane

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with first prescription of the combined oral contraceptive (COC) to reflect the content of recognised evidence-based guidelines such as the Faculty of Family Planning & Reproductive Health Care Clinical Guidance publication 2007 publication *First Prescription of Combined Oral Contraception*[10]. In order to advise on eligibility for COC use, clinicians should take a clinical history including: medical conditions (past and present), drugs use (prescription, non-prescription and herbal remedies) and family history. When considering a first prescription of COC, clinicians should specifically enquire about migraine and cardiovascular risk factors (smoking, obesity, hypertension, thrombophilia, previous venous thromboembolism and hyperlipidaemia). User preference and individual concerns about COC use should be addressed as should potential risks and benefits of the medication relevant to the individual. Cervical smear status should be ascertained. Recommended baseline recordings include measurement of blood pressure and BMI. A follow-up visit 3 months after a first prescription of COC allows an assessment of blood pressure, further instruction and assessment of any problems, with annual reviews generally recommended thereafter[11]. The patient should be instructed on appropriate use of the COC and warned regarding medication interactions and other occasions where effectiveness might be impaired, and what to do in those circumstances. Routine thrombophilia screen is not generally recommended without a significant family history to suggest such a disorder (see further discussion below on this aspect of [Mrs A's] management). New risk factors related to COC use can develop, and one reason for regular assessment of a patient on the COC is to reassess the suitability of the medication for the patient in terms of effectiveness, tolerability and risk. I am not aware how widespread the presence of a 'first COC prescription' policy would be in general practices, as appropriate assessment of a patient before such prescribing would be regarded as basic GP knowledge.

(iv) *How often should a general practitioner review have taken place prior to re-prescribing Estelle, in [Mrs A's] circumstances? What factors should be considered in such a review?*

This issue has been covered to some extent in the section above. At least annual review is recommended as standard procedure. In [Mrs A's] case, she had existing modifiable risk factors (obesity, smoking) and a known non-modifiable risk factor (increasing age). Her blood pressure had been generally satisfactory when recorded at [Medical Centre 1], but I cannot see that it was recorded at [Medical Centre 2] until 28 October 2009 — almost two years after she transferred to the practice and two years after the first prescription for Estelle had been supplied. There would be an argument for having [Mrs A] attend more regularly than annually for her COC prescription to enable reassessment of her modifiable risk factors (had she

[10] Available at http://www.fsrh.org/pdfs/FirstPrescCombOralContJan06.pdf
[11] Best Practice Journal (BPAC) — Combined oral contraceptive: Issues for current users. 2008; 12:21–29

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stopped smoking?, was she losing weight?) and discussion on the risks of continuing the COC if these factors were not modified. The BPAC publication (reference 10) states *Women whose clinical condition changes while using hormonal contraception require assessment on an individual basis. It may be appropriate to discuss risks and benefits and offer alternative contraceptive methods that pose less risk.* This is what [Dr G] did in 2005. However, it could be argued that [Mrs A's] risk factors (smoking and obesity) were relatively stable, and she had no obvious blood pressure problems or other potentially significant issues such as migraine during the time she had been on the COC. Therefore, 'at least annual' review could be regarded as a minimum standard, while many of my colleagues might have more closely monitored the modifiable risk factors of weight gain and smoking status, and regularly encouraged [Mrs A] to seriously consider alternative means of contraception and PCOS control if she continued to smoke. In terms of overall monitoring (ie ensuring at least annual review occurs) this is ultimately the responsibility of the registered provider (GP). If a request for a repeat prescription is received, the registered provider (or whoever is deputising for that provider) should ensure that provision of the prescription is clinically appropriate, and this would include ensuring the patient was being monitored in a manner consistent with expected practice. I feel that overall, [Mrs A's] monitoring in relation to her continued COC use, in light of her risk factors, was suboptimal and a moderate departure from expected practice.

(v) Management [Dr C]:

Many of my colleagues would have had hesitation in prescribing Estelle for [Mrs A] given her DVT risk factors in spite of the fact she had PCOS. With reference to section 6, it may have been reasonable for [Mrs A] to have remained on the medication if she had been counselled regarding her significant increased risk of DVT while on the medication (particularly in the presence of her additional risk factors) and had chosen to remain on the medication despite such counselling, and was made aware of clinical symptoms suggestive of DVT. I cannot determine from the available documentation if such counselling had ever taken place (and I note [Mrs A] had been on the medication for many years, with her risk increasing as she aged) apart from the discussion with [Dr G] in 2005 when Estelle was discontinued because of [Mrs A's] identified risk factors. [Dr C] did prescribe a six month course of Estelle to [Mrs A] on 5 December 2007 when she was seven weeks post-partum and this was collected from the pharmacy on that date. The prescription was not recorded in the clinical notes. [Dr C] has stated she discussed some potential risks of Estelle with [Mrs A] and assumed such risks had been discussed by her previous providers who had prescribed the medication. She states [Mrs A] had asked for the Estelle by name as it was the only medication that gave her control of symptoms associated with her polycystic ovary syndrome (PCOS). She respected [Mrs A's] right to make an informed choice. There was no

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documented record of such discussion or of the PCOS-related symptoms concerning [Mrs A]. There was no blood pressure reading recorded. [Dr C] has stated her usual practice is to advise withholding of a combined oral contraceptive for three months post-partum if the patient is not breastfeeding, or for six months if the patient is breastfeeding. She feels she would have given this information to [Mrs A]. I note [Mrs A] had used progestagen-only contraception (the mini-pill) for a year from November 2005 until she wanted to become pregnant, with a positive pregnancy test on 12 March 2007. As noted previously, the mini-pill had been commenced by another provider who was concerned at the risks to [Mrs A] of remaining on Estelle. [Mrs A] was noted to be happy with the advice to change her medication. At follow-up visits it was documented that [Mrs A] had 'no problems' on the mini-pill, and there is no documentation of concerns regarding poor cycle control, pelvic pain or fears of difficulty conceiving on stopping the medication. It is unclear therefore why [Mrs A] should have been particularly averse to restarting the mini-pill (oral contraceptive of choice for women who are breast-feeding or in the immediate post-partum period) although [Dr C] states [Mrs A] had concerns about needing to take the minipill at the same time each day. [Dr C's] recollection is that [Mrs A] was insistent on the Estelle despite discussion regarding the potential risks to her. It must be emphasized however that the risk of venous thrombo-embolic disease (VTE) is far higher with pregnancy than with use of Estelle even with [Mrs A's] identified additional risk factors. The combined oral contraceptive is also more reliable at preventing conception than the mini-pill and this may have influenced [Mrs A's] choice. If it is assumed [Dr C] did discuss the risks of Estelle with [Mrs A] together with alternative contraceptive options and PCOS treatment options, and [Mrs A] made an appropriately informed choice to take the medication, the issue becomes one of when a doctor should refuse to acquiesce to a patient's request if that request seems clinically unreasonable. Doctors have a duty to 'do no harm' and relatively frequently must deny requests for medication when the request is clinically inappropriate eg drugs of dependence in patients with known dependency issues, antibiotics where not clinically indicated. In this instance, where [Mrs A] did require contraception to avoid the high VTE risk another pregnancy would confer, it may not have been clinically unreasonable to provide the medication if she was insistent and might otherwise have been at increased risk of an unwanted pregnancy. However, because of her clinical situation there should have been clear documentation of the discussion that took place (although I would not expect comprehensive documentation of such discussion routinely) and certainly provision of the prescription should have been clearly documented. It is not uncommon practice for a prescription for a contraceptive of some description to be provided at the six-week check even if commencement of the contraception is to be deferred. In summary, I feel the failure by [Dr C] to document her discussion of risk and contraceptive options with [Mrs A], given the significant risk factors she had associated with recommencement of Estelle (which she had not been taking in the preceding two years), was a

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mild to moderate departure from expected standards. Her failure to document provision of a prescription for six months of Estelle was a moderate departure from expected standards. Had she been unable to state that [Mrs A] had insisted on Estelle, and that risks and alternative treatments had been discussed but declined by [Mrs A], provision of Estelle would have been a moderate to severe departure from expected standards. The failure to document blood pressure in December 2007 was probably not a significant departure from expected standards given a recent normal pressure reading was on the [Medical Centre 1] file (April 2007) and [Mrs A] was not currently taking the COC. However, the failure by [Dr C] to record blood pressure when she prescribed more Estelle for [Mrs A] in October 2008 (at a consultation for a back injury) was a mild departure from expected standards given it had been 18 months since the last recorded reading.

(vi) Management [Dr D]:

[Dr D] saw [Mrs A] on 16 May 2008. Consultation notes, in their entirety, read *well Smear by [initials]and keen tgu* [to give up] *smoking so ...* A six month supply of Estelle was provided. There is no recent blood pressure reading on record. Prior to this [Dr C] had seen [Mrs A] on 5 December 2007 when she documented *7 weeks since LSCS ... restarting Estelle*. [Dr D] states he renewed [Mrs A's] prescription for Estelle on 16 May 2008 assuming [Dr C] had discussed risks and benefits with her six months previously. He cannot recall whether he discussed risks with her again, although it is his practice to do so. The practice nurse would normally record blood pressure at a consultation of this nature and he is not sure why this did not occur. The consultation of 16 May 2008 was poorly documented. Blood pressure was not taken and had not been recorded since [Mrs A] had rejoined the practice six months previously. However, under the circumstances (his assumption that contraception was discussed in full at the post-natal visit undertaken by [Dr C], patient request for Estelle, expectation nurse would undertake blood pressure) management of [Mrs A] by [Dr D], and standard of clinical documentation, were mild departures from expected practice if he did not confirm with [Mrs A] that she had received adequate information from [Dr C]. If he confirmed this, rather than assuming it, my sole criticism would be mild disapproval of his standard of clinical documentation and failure to ensure blood pressure was recorded. I think it is reasonable that [Dr D] had some faith in his colleague, [Dr C's], professional competency in assuming she had not prescribed Estelle without undertaking a discussion of risks and benefits with [Mrs A]. However, I note [Dr G] in 2005 had been faced with a similar situation and had rechallenged [Mrs A] and found her to be willing to trial a less risky form of contraception at that time.

(vii) Management by [Dr B]

[Dr B] provided a repeat six-month prescription for Estelle for [Mrs A] on 4 May 2009 (no consultation). The medication had been prescribed by [Dr C]

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at a face-to-face consultation on 5 December 2007 and repeated by [Dr D] at a face-to-face consultation on 16 May 2008 and again by [Dr C] at a consultation for back problems on 22 October 2008 (no blood pressure or discussion relating to the medication is recorded on any of these occasions). I note a further six-month prescription was provided by [Dr B] without patient review on 27 October 2009 although notes on that date record *Patient is aware that they need to make appointment to see GP for next script* and blood pressure was recorded by the nurse on 28 October 2009 when [Mrs A] presented to collect the script. [Dr B] saw [Mrs A] specifically for repeat of Estelle on 20 April 2010 at which stage alternative methods of contraception (vasectomy) were discussed. No blood pressure was recorded on that occasion although I note the October 2009 level was normal (130/60). On 7 October 2010 [Dr B] signed another six-month repeat prescription for Estelle (no consultation) although again the practice nurse has recorded blood pressure (120/80) and *patient is aware that they need to make appointment to see GP for next script.* [Dr B] was not [Mrs A's] registered provider and it is unclear why he was required to write the repeat prescriptions on the occasions noted. With respect to the recommendations noted in section 22 (iv), I think it was reasonable for [Dr B] to assume any problems with [Mrs A's] Estelle prescription had been identified and discussed at the time of her previous face-to-face consultations and therefore reasonable for him to provide a further six month prescription in May 2009, assuming blood pressure would be taken by the nurse as appears was usual practice (although this did not occur). However, provision of a six-month prescription for Estelle without reviewing the patient on 27 October 2009 was inconsistent with expected practice in that [Dr B] did not take steps to ensure [Mrs A] was receiving appropriate monitoring (including reassessment of modifiable risk factors at least annually) before providing the prescription. It may have been acceptable to provide a shorter than usual prescription (say three months) if the patient was aware she needed to be reviewed but preferred to see her own doctor who was unavailable at the time. One reason for the suboptimal monitoring appears to have been the involvement of multiple prescribers, and the repeat prescribing processes at the medical centre which I understand have since been modified. [Dr B's] prescribing could be regarded as a mild (rather than moderate) departure from expected practice because [Mrs A] could be regarded as a 'long-term' COC user and had evidently had no problems with the COC in the past, although [Dr B] states he was a aware of [Mrs A's] 'medical problems'. In this case it was reasonable to assume the competency of his colleagues in terms of having previously discussed contraceptive options with [Mrs A] and concluding Estelle was a reasonable option once all factors had been taken into account. The content of the discussion [Dr B] had with [Mrs A] on 20 April 2010 evidently included discussion on risks of continuing with Estelle and alternative contraceptive options including vasectomy. I assume therefore [Mrs A] made an informed decision to continue its use (taking into account the discussion in section 22 (v) and I feel that [Dr B's] decision to prescribe it at that time, and to repeat the prescription without seeing the patient six

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months later, was consistent with expected standards although more detailed documentation of the discussion would have been desirable. Blood pressure had been recorded in October 2009 and October 2010 and was normal on both occasions. There was a lost opportunity to further discuss alternative contraceptive options or to update [Mrs A's] risk factors in October 2010 — in particular establishing the apparent change in the family history of DVT (previously recorded as negative and assuming the accuracy of the new positive history). However, comprehensive reassessment of all risk factors at every presentation for repeat COC prescribing would not be expected practice. Whether knowledge of this additional risk factor would have changed [Mrs A's] apparent determination to continue with Estelle cannot be assumed.

(viii) It remains unclear whether [Mrs A] had been formally tested for any pre-existing thrombophilia prior to having been commenced on Estelle in 1999 and such testing may have been undertaken. However, once [Mrs A's] apparently significant family history of DVT became known, I would regard the failure to exclude a hereditary thrombophilia by appropriate testing and consultation with a haematologist, as being a moderate departure from expected standards if she was to continue with Estelle (or any COC). The detection of a thrombophilia would be a contraindication to the use of Estelle. I am unable to assign this departure to any particular provider as it not clear precisely if or when the family history of DVT was confirmed to [Mrs A's] providers.

(ix) Ideally, [Mrs A's] Estelle should have been stopped the cycle before her elective surgery and alternative contraception provided, in accordance with the manufacturer's instructions and local thromboprophylaxis guidelines (see above). It should not have been recommenced for at least two weeks after surgery. I am unable to determine from the available documentation whether [Mrs A] had stopped her Estelle prior to surgery. She did not list it on the medication sheet at her pre-admission visit. However, many patients do not regard the 'pill' as a 'medication' and there should be a specific question asking after oral contraceptive use on the pre-admission form, particularly if a medical officer does not formally admit the patient prior to surgery when there might be an additional opportunity to ask about COC use. I would expect a list of relevant current medications to be included in a referral letter to a specialist. The use of a COC is relevant to both a diagnosis of gallstones and for any patient undergoing other than minor surgery. I understand Estelle was recorded in the referral letter as was reference to [Mrs A's] raised BMI. The surgeon seeing [Mrs A] at her initial appointment also explained, and consented her for, her procedure. It could be argued that it was his responsibility, if he was aware [Mrs A] was on Estelle, to inform her to stop taking it prior to surgery or to notify her GP that cessation, and alternative contraception, would be required. Such information could also be included in any pre-admission documentation sent to patients. However, it could also be argued that the GP had some responsibility to discuss

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appropriate cessation of Estelle with [Mrs A] once he or she was aware of the anticipated date of surgery. While I would expect the surgeon to be more aware of thromboprophylaxis guidelines than the GP, the GP should also be familiar with any precautions attached to medications he or she is prescribing and increased risk of DVT associated with major surgery and concurrent use of the COC is well known. This discussion may not be so relevant if it transpires [Mrs A] was not taking Estelle around the time of her surgery.

(x) The management of [Mrs A's] abdominal pain by referral for ultrasound and surgical review, and subsequent decision to perform laparoscopic cholecystectomy, was consistent with expected standards. There is nothing to suggest the surgery was undertaken in other than a technically competent manner.

(xi) The management of [Mrs A's] swollen and painful left leg in [early] 2011 was consistent with expected standards as discussed in sections 14–16.

(xii) The management of [Mrs A's] thromboprophylaxis at [the hospital] does not appear to be entirely consistent with guideline recommendations (see 21(ix)) although I note [Mrs A] ambulated well after surgery. IPC was used for most of the day of surgery and [Mrs A] was ambulating by the end of this day. To comment further on this aspect of care is outside my scope of expertise. I acknowledge the argument put forward by [Dr F] regarding cost effectiveness of prolonged Clexane therapy following laparoscopic cholecystectomy, but wonder whether adequate consideration was taken of [Mrs A's] multiple risk factors and the contribution her inability to be fitted with GCS might have made to this risk. I note also that adherence to best practice guidelines is variable in this country and there is room for improvement[12]. I note expert opinion has been obtained on this aspect of [Mrs A's] care.

23. I would like to pass my condolences on to [Mr A] at the tragic loss of his wife at such a young age, and acknowledge the stresses he now encounters raising two young children on his own. It is very difficult to state whether, in retrospect, any specific changes in [Mrs A's] management would have altered her outcome and I realise this lack of certainty may prove frustrating for him."

[12] Wiseman D et Harrison J. A retrospective review of the use of thromboprophylaxis in patients who subsequently developed a venous thromboembolism after discharge from hospital. NZMJ. 2010;123:1309

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Appendix B — Medsafe data sheet for Estelle

ESTELLE-35 and ESTELLE-35 ED

Cyproterone Acetate/Ethinyloestradiol Tablets

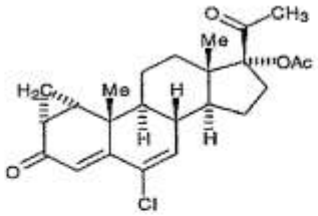
Name of the Medicine

ESTELLE-35 and ESTELLE-35 ED
Cyproterone Acetate/Ethinyloestradiol Tablets

Description

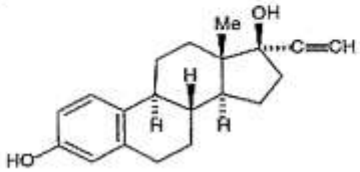
The chemical name of cyproterone acetate is 6-chloro—3,20-dioxo-1β,2β-dihydro-3`H-cyclopropa[1,2]pregna-1,4,6-trien-17-yl acetate. The chemical formula is $C_{24}H_{29}ClO_4$ and the molecular weight is 416.9.

The structural formula is:



The chemical name of ethinyloestradiol is 19-Nor-17α-pregna-1,3,5(10)-trien-20-yne-3,17-diol, the chemical formula is $C_{20}H_{24}O_2$ and the molecular weight is 296.4.

The structural formula is:



The yellow active tablets contain as excipients: lactose, microcrystalline cellulose, povidone, croscarmellose sodium, magnesium stearate, Opadry White, Opadry Buff, Quinoline yellow, sucrose, Opagloss 6000 white.

The white inactive tablets contain as excipients: lactose, microcrystalline cellulose, and magnesium stearate.

Pharmacology

Mechanism of Action

The pilosebaceous unit comprises the sebaceous gland and the hair follicle and is an androgen-sensitive skin component. Acne, seborrhoea, hirsutism and androgenic alopecia are clinical conditions that result from aberrations of this target organ. The clinical conditions may be caused by either an increased sensitivity to or by higher plasma levels of androgen. Both the substances contained in ESTELLE-35 and ESTELLE-35 ED beneficially influence the hyperandrogenic state. Cyproterone acetate is a competitive antagonist on the androgen receptor, which has inhibitory effects on the androgen-synthesis in target cells and produces a decrease on the

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androgen blood concentrations through an anti-gonadotropic effect. This anti-gonadotropic effect is amplified by ethinyloestradiol, which also up-regulates the synthesis of Sex Hormone-Binding Globulin (SHBG) in plasma. By this mechanism, it reduces free, biologically available androgen in the circulation.

Treatment with ESTELLE-35 or ESTELLE-35 ED leads – usually after 3 to 4 months of therapy – to the healing of existing acne efflorescences. The excessive greasiness of the hair and skin generally disappears earlier. The loss of hair, which frequently accompanies seborrhoea, also diminishes. In women experiencing mild forms of hirsutism (in particular, slightly increased facial hair) results do not become apparent until after several months of treatment.

The contraceptive effect of ESTELLE-35 and ESTELLE-35 ED is based on the interaction of various factors, the most important of which are seen as the inhibition of ovulation and the changes in the cervical secretion. As well as protection against pregnancy, oestrogen/progestogen combinations have several positive properties that, next to the negative properties, can be useful in deciding on the method of birth control. The cycle is more regular and the menstruation is often less painful and bleeding is lighter. The latter may result in a decrease in the occurrence of iron deficiency.

Apart from this, with the higher-dosed combined oral contraceptives (COCs) containing 50 mcg of ethinyloestradiol, there is evidence of a reduced risk of fibrocystic breast tumours, ovarian cysts, pelvic inflammatory disease, ectopic pregnancy and endometrial and ovarian cancer. This may also apply to lower dosed COCs.

Pharmacokinetics

Cyproterone acetate

Absorption
Following oral administration cyproterone acetate is completely absorbed in a wide dose range. Peak serum concentrations of 15 ng/mL are reached approximately 1.6 hours after ingestion of cyproterone acetate. Bioavailability is approximately 88 %.

Distribution
Cyproterone acetate is almost exclusively bound to serum albumin. Only 3.5 - 4.0 % of the total serum drug concentrations are present as free steroid. The ethinyloestradiol-induced increase in SHBG does not influence the serum protein binding of cyproterone acetate. The apparent volume of distribution is about 986 ± 437 L.

Metabolism
Cyproterone acetate is almost completely metabolised. The main metabolite in plasma was identified as 15ß-OH-CPA, which is formed via the cytochrome P450 isoenzyme CYP3A4. The clearance rate form serum is about 3.6 mL/min/kg.

Elimination
Cyproterone acetate serum levels decrease in two phases, which are characterised by half-lives of 0.8 hours and approximately 2.3 - 3.3 days, respectively. Cyproterone acetate is partly excreted in unchanged form. Its metabolites are excreted at a urinary to biliary ratio of about 1:2. The half-life of the metabolite excretion is about 1.8 days.

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Steady state conditions
The pharmacokinetics of cyproterone acetate are not influenced by SHBG levels. Following daily ingestion drug serum levels increase about 2.5 fold reaching steady-state conditions during the second half of the treatment cycle.

Ethinyloestradiol

Absorption
Orally administered ethinyloestradiol is rapidly and completely absorbed. Peak serum concentrations of approximately 70 pg/mL are reached at 1.6 hours. During absorption and first-liver passage, ethinyloestradiol is metabolised extensively, resulting in a mean oral bioavailability of about 45 % with a large interindividual variation of about 20 – 65 %.

Distribution
Ethinyloestradiol is highly but non-specifically bound to serum albumin (approximately 98 %) and induces an increase in the serum concentrations of SHBG. An apparent volume of distribution of about 2.8 – 8.6 L/kg was determined.

Metabolism
Ethinyloestradiol is subject to pre-systemic conjugation in both small bowel mucosa and the liver. Ethinyloestradiol is primarily metabolised by aromatic hydroxylation but a wide variety of hydroxylated and methylated metabolites are formed, and these are present as free metabolites and as conjugates with glucuronides and sulphate. The clearance rate was reported to be approximately 2.3 – 7 mL/min/kg.

Elimination
Ethinyloestradiol serum levels decrease in two dispositional phases characterized by half-lives of about 1 hour and 10 – 20 hours, respectively. Unchanged drug is not excreted. Ethinyloestradiol metabolites are excreted at a urinary to biliary ratio of 4:6. The half-life of the metabolite excretion is about 1 day.

Steady-state conditions
Steady-state conditions are reached during the second half of a treatment cycle when serum drug levels are higher by 60 % as compared with a single dose.

Indications

ESTELLE-35 and ESTELLE-35 ED are indicated for the treatment of androgen-dependent diseases in women, such as acne (where oral antibiotics or local treatment alone has not been successful), especially pronounced forms and those which are accompanied by seborrhoea or by inflammation or formation of nodes (acne papulopustulosa, acne nodulocystica), androgenic alopecia, mild forms of hirsutism.

ESTELLE-35 and ESTELLE-35 ED is also indicated for oral contraception in women requiring treatment for these androgen-dependent diseases; it is not recommended in women solely for contraception. ESTELLE-35 and ESTELLE-35 ED is also indicated for the treatment of polycystic ovary syndrome.

Contraindications

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Preparations containing oestrogen/progestogen combinations should not be used in the presence of any of the conditions listed below. Should any of these conditions appear for the first time during use, the product should be stopped immediately.

- Presence or a history of venous of arterial thrombotic/thromboembolic events (eg. deep venous thrombosis, pulmonary embolism, myocardial infarction) or a cerebrovascular accident
- Presence or history of prodromi for a thrombosis (eg. transient ischaemic attack, angina pectoris)
- History of epilepsy
- History of migraine with focal neurological symptoms
- Diabetes mellitus with vascular involvement
- The presence of a severe or multiple risk factor(s) for venous or arterial thrombosis may also constitute a contraindication
- Pancreatitis or a history of pancreatitis if associated with severe hypertriglyceridemia
- Presence or history of severe hepatic disease as long as liver function values have not returned to normal
- Presence or history of liver tumours (benign or malignant)
- Known or suspected sex-steroid influenced malignancies (eg: of the genital organs or the breasts)
- Undiagnosed vaginal bleeding
- Known or suspected pregnancy
- Lactation
- Hypersensitivity to any of the ingredients of ESTELLE-35 or ESTELLE-35 ED

ESTELLE-35 and ESTELLE-35 ED are not for use in men.

Precautions

The clinical and epidemiological experience with oestrogen/progestogen combinations like ESTELLE-35 and ESTELLE-35 ED is predominantly based on combined oral contraceptives (COCs). Therefore, the following warnings related to the use of COCs apply also for ESTELLE-35 and ESTELLE-35 ED.

If any of the conditions/risk factors mentioned below is present, the benefits of the use of ESTELLE-35 and ESTELLE-35 ED should be weighed against the possible risks for each individual woman and discussed with the woman before she decides to start using it. In the event of aggravation, exacerbation or first appearance of any of these conditions or risk factors, the woman should contact her doctor. The doctor should then decide on whether its use should be discontinued.

Circulatory Disorders

Epidemiological studies have suggested an association between the use of COCs and an increased risk of arterial and venous thrombotic and thromboembolic diseases such as myocardial infarction, stroke, deep venous thrombosis, and pulmonary embolism. These events occur rarely.

Venous thromboembolism (VTE), manifesting as deep venous thrombosis and/or pulmonary embolism, may occur during the use of all COC's. The approximate incidence of VTE in users of low oestrogen dose (<50 mcg EE) OC's is up to 4 per 10,000 woman years compared to 0.5 - 3 per 10,000 woman years in non-COC users. However, the incidence of VTE occurring during COC use is substantially

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less than the incidence associated with pregnancy (i.e. 6 per 10,000 pregnant woman years).

Extremely rarely, thrombosis has been reported to occur in other blood vessels (eg. hepatic, mesenteric, renal or retinal veins and arteries) in COC users. There is no consensus as to whether the occurrence of these events is associated with the use of COCs.

Symptoms of venous or arterial thrombotic/thromboembolic events or of a cardiovascular accident can include: unilateral leg pain and/or swelling; sudden severe chest pain, regardless of whether it radiates to the left arm; sudden breathlessness; sudden onset of coughing; any unusual, severe, prolonged headache; sudden partial or complete loss of vision; diplopia; slurred speech or aphasia; vertigo; collapse with or without focal seizure; weakness or very marked numbness suddenly affecting one side or one part of the body; motor disturbances; 'acute' abdomen.

The risk of thromboembolism (venous and/or arterial) increases with:

- Age
- Smoking (with heavier smoking and increasing age the risk further increases especially in women over 35 years of age)
- A positive family history (i.e. venous or arterial thromboembolism even in a sibling or parent at a relatively early age). If a hereditary predisposition is suspected, the woman should be referred to a specialist for advice before deciding about any COC use.
- Obesity (body mass index over 30 kg/m^2)
- Dyslipoproteinaemia
- Hypertension
- Migraine
- Valvular heart disease
- Atrial fibrillation
- Prolonged immobilisation, major surgery, any surgery to the legs, or major trauma. In these situations, it is advisable to discontinue COC use (in the case of elective surgery at least four weeks in advance) and not to resume until two weeks after complete mobilisation.

There is no consensus about the possible role of varicose veins and superficial thrombophlebitis in venous thromboembolism.

The increased risk of thromboembolism in the puerperium must be considered.

Other medical conditions, which have been associated with adverse circulatory events include: diabetes mellitus, polycystic ovary syndrome, systemic lupus erythematosus, haemolytic uraemic syndrome, chronic inflammatory bowel disease (Crohn's disease or ulcerative colitis) and sickle cell anaemia.

An increase in frequency or severity of migraine during COC use (which may be prodromal of a cerebrovascular event) may be a reason for immediate discontinuation of the COC.

Biochemical factors that may be indicative of hereditary or acquired predisposition for venous or arterial thrombosis include: Activated Protein C (APC) resistance, hyperhomocysteinaemia, antithrombin-III deficiency, protein C deficiency, protein S deficiency, antiphospholipid antibodies (anticardiolipin antibodies, lupus anticoagulant).

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When considering risk/benefit, the doctor should take into account that adequate treatment of a condition may reduce the associated risk of thrombosis and that the risk associated with pregnancy is higher than that associated with COC use.

Tumours

The most important risk factor for cervical cancer is persistent human papilloma virus (HPV) infection. Some epidemiological studies have indicated that long-term use of COCs may further contribute to this increased risk, but there continues to be controversy about the extent to which this finding is attributable to the confounding effects (eg: cervical screening and sexual behaviour including use of barrier contraceptives).

A meta-analysis from 54 epidemiological studies reported that there is a slightly increased relative risk (RR=1.24) of having breast cancer diagnosed in women who are currently using COCs. The excess risk gradually disappears during the course of 10 years after cessation of COC use. Because breast cancer is rare in women under 40 years of age, the excess number of breast cancer diagnoses in current and recent COC users is small in relation to the overall risk of breast cancer. These studies do not provide evidence for causation. The observed pattern of increased risk may be due to an earlier diagnosis of breast cancer in COC users, the biological effects of COCs or a combination of both. The breast cancers diagnosed in users tend to be less advanced clinically than the cancers diagnosed in non users.

In rare cases, benign, and even more rarely, malignant liver tumours have been reported in users of COCs. In isolated cases, these tumours have lead to life-threatening intra-abdominal haemorrhages. A hepatic tumour should be considered in the differential diagnosis when severe upper abdominal pain, liver enlargement or signs of intra-abdominal haemorrhage occur in women taking COCs.

Other precautions

Women with hypertriglyceridemia, or a family history of hypertriglyceridemia, may be at an increased risk of pancreatitis when using COCs.

Although small increases in blood pressure have been reported in many women taking COCs, clinically relevant increases are rare. However, if a sustained clinically significant hypertension develops during the use of a COC then it is prudent for the doctor to withdraw the COC and treat the hypertension. Where considered appropriate, COC use may be resumed if normotensive values can be achieved with antihypertensive therapy.

The following conditions have been reported to occur or deteriorate with both pregnancy and COC use, but the evidence of an association with COC use is inconclusive: jaundice and/or pruritus related to cholestasis; gallstone formation; porphyria; systemic lupus erythematosus; haemolytic uraemic syndrome; Sydenham's chorea; herpes gestationis; otosclerosis-related hearing loss.

Acute or chronic disturbances of liver function may necessitate the discontinuation of COC use until markers of liver function return to normal. Recurrence of cholestatic jaundice that initially occurred during pregnancy or previous use of sex steroids necessitates the discontinuation of COCs.

Although COCs may have an effect on peripheral insulin resistance and glucose tolerance, there is no evidence for a need to alter the therapeutic regimen in diabetes using COCs. However, diabetic women should be carefully observed while taking COCs.

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Crohn's disease and ulcerative colitis have been associated with COC use.

Chloasma may occasionally occur, especially in women with a history of chloasma gravidarum. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation whilst taking COCs.

If in women suffering from hirsutism, symptoms have recently developed or increased substantially, the causes (androgen-producing tumor, adrenal enzyme defect) must be clarified by differential diagnosis

Medical examination

A complete medical history and physical examination should take place prior to the initiation or reinstitution of ESTELLE-35 or ESTELLE-35 ED, guided by the contraindications and warnings. This should be repeated periodically during the use of ESTELLE-35 or ESTELLE-35 ED.

Periodic medical assessment is also of importance because contraindications (eg. a transient ischaemic attack) or risk factors (eg: a family history of venous or arterial thrombosis) may appear for the first time during the use of ESTELLE-35 or ESTELLE-35 ED. The frequency and nature of these assessments should be adapted to the individual woman but should generally include special reference to blood pressure, breasts, abdomen and pelvic organs, including cervical cytology, and relevant laboratory tests.

Women should be advised that ESTELLE-35 and ESTELLE-35 ED do not protect against HIV infections (AIDS) and other sexually transmitted diseases.

Reduced Efficacy

The efficacy of ESTELLE-35 or ESTELLE-35 ED may be reduced in the event of missed tablets, vomiting or concomitant medication.

Reduced Cycle Control

With oestrogen/progestogen combinations, irregular bleeding (spotting or breakthrough bleeding) may occur, especially during the first months of use. Therefore, the evaluation of an irregular bleeding is only meaningful after an adaptation interval of about three cycles.

If bleeding irregularities persist or occur after previously regular cycles, non-hormonal causes should be considered and adequate diagnostic measures are indicated to exclude malignancy or pregnancy. These may include curettage.

In some women withdrawal bleeding may not occur during the tablet-free interval. If the COC has been taken according to the suggested directions, it is unlikely that the woman is pregnant. However, if the COC has not been taken according to these directions prior to the first missed withdrawal bleeding or if two withdrawal bleeds are missed, pregnancy must be ruled out before COC use is continued.

Use in Pregnancy

The administration of ESTELLE-35 or ESTELLE-35 ED is contraindicated in pregnancy.

If pregnancy occurs during medication with ESTELLE-35 or ESTELLE-35 ED, the preparation is to be withdrawn immediately.

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Use in Lactation

The administration of ESTELLE-35 or ESTELLE-35 ED is also contraindicated during lactation. Cyproterone acetate is transferred into the milk of lactating women. About 0.2 % of the maternal dose will reach the newborn via milk corresponding to a dose of about 1 mcg/kg. During established lactation 0.02 % of the daily maternal dose of ethinyloestradiol could be transferred to the newborn via milk.

Effects on Ability to Drive or Operate Machinery

No negative effects have been observed.

Pre-Clinical Safety Data

Ethinyloestradiol

The toxicity profile of ethinyloestradiol is well known. There are no preclinical data of relevance to the prescriber that provide additional safety information to those already included in other sections of the product information.

Cyproterone acetate

Preclinical data reveal no specific risk for humans based on conventional studies of repeated dose toxicity.

No animal-experimental studies into a possible sensitising effect of ethinyloestradiol and cyproterone acetate have been carried out.

Embryotoxicity/Teratogenicity

Investigations into embryotoxic or teratogenic effects, using the combination of the two active ingredients, showed no effects indicative of a general teratogenic effect following treatment during organogenesis before development of the external genital organs.

Administration of cyproterone acetate during the hormone-sensitive differentiation phase of the genital organs (after approximately day 45 of pregnancy) could lead to signs of feminisation in male foetuses following higher doses. Observation of male newborn children who had been exposed *in utero* to cyproterone acetate did not show any signs of feminisation. However, pregnancy is one of the contraindications for the use of ESTELLE-35 or ESTELLE-35 ED.

Genotoxicity and carcinogenicity

Recognised first-line tests for genotoxicity gave negative results when conducted with cyproterone acetate. However, further tests showed that cyproterone acetate was capable of producing adducts with DNA (and an increase in DNA repair activity) in liver cells from rats and monkeys and also in freshly isolated human hepatocytes, whereas the DNA-adduct level in dog liver cells was extremely low.

This DNA-adduct formation occurred at exposures that might be expected to occur in the recommended dose regimens for cyproterone acetate. *In vivo* consequences of cyproterone acetate treatment were the increased incidence of focal, possibly pre-neoplastic, liver lesions in which cellular enzymes were altered in female rats and an increase of mutation frequency in transgenic rats carrying a bacterial gene as a target for mutation.

Clinical experience and well-conducted epidemiological trials to date do not support an increased incidence of hepatic tumours in man. Nor did investigations into the tumorigenicity of cyproterone acetate in rodents reveal any indication of specific

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tumorigenic potential. However, it must be borne in mind that sexual steroids can promote the growth of certain hormone-dependent tissues and tumours.

On the whole, the available findings do not raise any objection to the use of ESTELLE-35 or ESTELLE-35 ED in humans if used in accordance with directions for the given indication and at the recommended dose.

Interactions

Interactions between oestrogen/progestogen combinations like ESTELLE-35 and ESTELLE-35 ED and other drugs may lead to breakthrough bleeding and/or contraceptive failure. The following interactions have been reported in the literature.

Hepatic metabolism

Interactions can occur with drugs that induce microsomal enzymes, which can result in increased clearance of sex hormones. This has been established for phenytoin, barbiturates, primidone, carbamazepine, rifabutin, rifampicin, oxcarbamazepine, topiramate, felbamate, fitonavir, griseofulvin and products containing St John's wort.

Interference with Enterohepatic circulation

Some clinical reports suggest that enterohepatic circulation of oestrogens may decrease when certain antibiotic agents are given, which may reduce the ethinyloestradiol concentrations (eg: penicillins, tetracyclines).

Women on treatment with any of these drugs should temporarily use a barrier method in addition to ESTELLE-35 or ESTELLE-35 ED or choose another method of contraception. With microsomal enzyme-inducing drugs, the barrier method should be used during the time of concomitant drug administration and for 28 days after their discontinuation.

Women on treatment with antibiotics (except rifampicin and griseofulvin) should use the barrier method until 7 days of discontinuation. If the period during which the barrier method is used includes the inactive tablets, they should not be taken and the next pack started without delay.

Oestrogen/progestogen combinations like ESTELLE-35 and ESTELLE-35 ED may interfere with the metabolism of other drugs. Accordingly, plasma and tissue concentrations may be affected (eg: cyclosporin).

Laboratory Tests

The use of preparations like ESTELLE-35 or ESTELLE-35 ED may influence the results of certain laboratory tests, including biochemical parameters of liver, thyroid, adrenal and renal function, plasma levels of carrier proteins (eg. corticosteroid binding globulin and lipid/lipoprotein fractions, parameters of carbohydrate metabolism and parameters of coagulation and fibrinolysis). Changes generally remain within the normal laboratory range.

Adverse effects

The most serious undesirable effects associated with the use of ESTELLE-35 or ESTELLE-35 ED have been referred to in the contraindications and warnings sections.

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Other side effects that have been reported in users of ESTELLE-35 and ESTELLE-35 ED, but in which the association has been neither confirmed nor refuted are listed below, along with frequencies of occurrence.

Common (≥ 1/100)
Nausea, abdominal pain, weight gain, headache, depressed or altered mood, breast pain or tenderness.

Uncommon (≥ 1/1000 and <1/100)
Vomiting, diarrhoea, fluid retention, migraine, decrease in libido, breast hypertrophy, rash or urticaria.

Rare (<1/1000)
Contact lens intolerance, hypersensitivity, weight loss, increase in libido, vaginal or breast discharge erythema nodosum or erythema multiforme.

Dosage and Administration

ESTELLE-35 and ESTELLE-35 ED are to be taken regularly in order to achieve therapeutic efficacy and the required contraceptive protection. Previously used hormonal contraception should be discontinued. The dose regimen of ESTELLE-35 and ESTELLE-35 ED is similar to the usual regimen for most combined oral contraceptives. Thus, the same administration rules must be considered.

The irregular intake of ESTELLE-35 or ESTELLE-35 ED can lead to intermenstrual bleeding and could lead to deterioration of the therapeutic and contraceptive reliability.

How to take ESTELLE-35 or ESTELLE-35 ED

Tablets must be taken in the order directed on the package every day at about the same time with some liquid as needed. One hormonal tablet is to be taken daily for 21 consecutive days. Each subsequent pack is started after a 7-day tablet free interval or 7-day period of non-hormonal tablets, during which a withdrawal bleeding usually occurs. This usually starts on day 2-3 after the last tablet and may not have finished before the next pack is started.

How to start ESTELLE-35

Where there has been no previous hormonal contraceptive use the first tablet of ESTELLE-35 must be taken on the first day of the cycle (first day of bleeding). Starting on day 2 to 5 is allowed, but during the first cycle a barrier method is recommended for the first 7 days of tablet taking.

Changing from another combined oral contraceptive (COC)
The woman should start with ESTELLE-35 preferably on the day after the hormonal tablet of her previous COC, but at the latest on the day following the usual tablet free or non-hormonal tablet interval of her previous COC.

Changing from a progestogen only method (minipill, injection, implant)
The woman may change any day from the minipill (from an implant on the day of its removal, from an injectable when the next injection would be due) but should in all cases be advised to use additional contraception (barrier methods) for the first 7 days of tablet taking.

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Following first trimester abortion

The woman may start immediately. When doing so, she need not take additional contraceptive measures.

Following delivery or second trimester abortion

Women should be advised to start at day 21 to 28 after delivery or second trimester abortion. When starting later, the woman should be advised to use additional contraception (barrier methods) for the first 7 days of tablet taking. However, if intercourse has already occurred, pregnancy should be excluded before the actual start of ESTELLE-35 use or the woman has to wait for her first menstrual period.

How to start ESTELLE-35 ED

Where no preceding hormonal contraceptive use has occurred, ESTELLE-35 ED should be started on the first day of bleeding, taking the tablet in the red section marked with the appropriate day of the week. One yellow hormonal tablet is to be taken daily for 21 consecutive days. The white non-hormonal tablets are then taken daily for 7 days. Withdrawal bleeding should usually occur within 2 - 4 days after taking the last small yellow hormonal tablet.

In the first cycle only, an additional form of contraception (except the rhythm and temperature methods) must be used for the first 14 days of tablet taking.

Tablets should be taken at the same time each day if possible.

Changing from another combined oral contraceptive

The woman should start ESTELLE-35 ED in the red section on the day after the last hormonal tablet of her previous COC.

Changing from a progestogen only method (minipill, injection, implant)

The woman may switch any day from the minipill (from an implant on the day of its removal, from an injectable when the next injection would be due), but should, in all of these cases, be advised to use additional contraception (barrier methods) for the first 14 days of tablet taking.

Following first trimester abortion

The woman may start immediately. When doing so, she need not take additional contraceptive measures.

Following delivery or second trimester abortion

Women should be advised to start at day 21 - 28 after delivery or second trimester abortion. When starting later, the woman should be advised to use additional contraception (barrier methods) for the first 14 days of tablet taking. However, if intercourse has already occurred, pregnancy should be excluded before the actual start of ESTELLE-35 ED use or the woman has to wait for her first menstrual period.

Management of missed tablets

Errors in taking the non-hormonal (white) tablets contained in ESTELLE-35 ED can be ignored.

If one or two yellow hormone tablets have been missed at any time:

- She should take the most recent missed tablet as soon as she remembers
- She should continue taking the remaining tablets daily at her usual time
- She does not require additional contraceptive protection

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- She does not require emergency contraception

If three or more yellow hormone tablets have been missed at any time:

- She should take the most recent missed tablet as soon as she remembers
- She should continue taking the remaining tablets daily at her usual time
- She should be advised to use condoms or abstain from sex until she has taken tablets for 7 days in a row.

In addition:
If tablets are missed in Week 1 (Days 1-7) (because the tablet free interval has been extended)

- Emergency contraception should be considered if she had unprotected sex in the tablet-free interval or in week 1

If tablets are missed in Week 3 (Days 15 –21) (to avoid extending the tablet-free interval)

- She should finish the tablets in her current pack and start a new pack the next day; thus omitting the tablet free interval.

Extra Contraceptive Precautions
When you need extra contraceptive precautions, either:

- Do not have sex; or
- Use a cap plus spermicide; or
- Use a condom.

Do not use the rhythm or temperature methods as extra contraceptive precautions. This is because oral contraceptives alter the usual menstrual cycle changes such as changes in temperature and cervical mucus.

Advice in case of vomiting

If severe gastrointestinal disturbances occur, absorption may not be complete and additional contraceptive measures should be taken. The advice concerning missed tablets should be followed.

If vomiting occurs within 3-4 hours after tablet taking, absorption may not be complete. If the woman does not want to change her normal tablet taking schedule, she has to take the extra tablet(s) needed from another pack.

How to shift periods or how to delay a period

To delay a period a woman should continue with small yellow hormonal tablets from another pack of ESTELLE-35 or ESTELLE-35 ED without a tablet-free interval or the white non-hormonal tablets. The extension can be carried on for as long as desired until the end of the second pack. During the extension the woman may experience breakthrough bleeding or spotting.

To shift her periods to another day of the week than the woman is used to with her current scheme, she can be advised to shorten her forthcoming tablet-free interval or omit the non-hormonal tablet in ESTELLE-35 ED by as many days as she likes. The shorter the interval, the higher the risk that she does not have a withdrawal bleed and will experience breakthrough bleeding and spotting during the second pack (just as when delaying a period).

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Length of Use

The length of use depends on the severity of the treated condition and the patient's response. In general, treatment should be carried out over several months.

It is recommended to take ESTELLE-35 or ESTELLE-35 ED for at least another 3 to 4 cycles after the signs have subsided. Should there be a recurrence of the treated condition weeks or months after discontinuation of ESTELLE-35 or ESTELLE-35 ED, treatment should be resumed. A longer period of treatment may be recommended for polycystic ovary syndrome.

Overdosage

There have been no reports of serious deleterious effects from overdose.

Symptoms

Symptoms that may occur in this case are nausea, vomiting and, in young girls, slight vaginal bleeding.

Treatment

There are no antidotes and further treatment should be symptomatic.

Presentation and Storage conditions

ESTELLE-35: One calendar pack contains 21 yellowish buff, round, biconvex, active tablets plain on both sides, with a diameter of 5.0 mm. Each tablet contains 2 mg cyproterone acetate and 35 micrograms (0.035 mg) ethinyloestradiol.

ESTELLE-35 ED: One calendar pack contains 21 yellow active tablets and 7 white inactive tablets. Each active tablet is a yellowish buff, round, biconvex tablet, plain on both sides with a diameter of 5.0mm, containing 2 mg cyproterone acetate and 35 micrograms (0.035 mg) ethinyloestradiol. Each inactive tablet is a white, round, biconvex, tablet, plain on both sides with a diameter of 7.1 mm.

Storage

Shelf life is 3 years. Store below 30 °C.

Pack quantities

ESTELLE-35: Three calendar packs of 21 tablets.
ESTELLE-35 ED: Three calendar packs of 28 tablets; sample pack containing one calendar pack of 28 tablets.

Medicine Classification

Prescription Medicine.

Name and Address of Sponsor

Douglas Pharmaceuticals Limited
P.O. Box 45027

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Date of Preparation

September 2007

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Appendix C — Expert advice to the Commissioner

The following preliminary expert advice was obtained from an independent general surgeon, Dr Michael Rodgers:

> "My name is Michael Rodgers. I am a consultant surgeon working for Waitemata DHB and qualified with MBChB (Auckland) in 1990 and FRACS in 1998.
>
> [Facts deleted for brevity]
>
> *Opinion:*
> [Mrs A] died unexpectedly from a pulmonary embolism 2 weeks after an uneventful laparoscopic cholecystectomy. She had a number of risk factors for DVT — obesity, smoking, oral contraceptive and a history of superficial thrombophlebitis.
>
> The latter seems to have been interpreted in her husband's letter as a deep vein thrombosis (DVT), which would carry a much higher risk. Normally surgery would not have gone ahead with a DVT, but in fact the ultrasound in January showed there was no DVT.
>
> The operative team seem to have been very careful with their VTE prophylaxis giving both pre and postoperative Clexane, pneumatic calf compression and early mobilization. The embolization stockings did not fit, but would have been of marginal additional benefit. While an argument could be made for longer term VTE prophylaxis this is not standard practice and I feel the decision made in this regard was appropriate.
>
> Regarding oral contraceptive advice: Normally I would expect a patient to continue with their oral contraceptive throughout and do not necessarily offer any specific advice, nor would I expect a GP or other medical professional to necessarily do so."

Further expert advice obtained from Dr Rodgers in June 2012

[Facts deleted for brevity]

> "*Opinion:*
> [Mrs A] died unexpectedly from a pulmonary embolism 2 weeks after an uneventful laparoscopic cholecystectomy. She had a number of risk factors for DVT — obesity, smoking, oral contraceptive and a history of superficial thrombophlebitis.
>
> *Standard of Care Regarding VTE Prophylaxis*
> It is my view that the operative team has been very careful with the VTE prophylaxis giving both pre and postoperative Clexane, pneumatic calf compression and early mobilization. The embolization stockings did not fit,

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but would have been of marginal benefit. Poorly fitting stockings can actually increase the risk of leg clots. I agree with the assessment that [Mrs A] was at moderate risk, but this level of prophylaxis would have been adequate even for a high risk patient.

It is not at all clear from the literature whether superficial venous thrombosis is a risk factor for deep vein thrombosis. Looking at both local and international guidelines I note that superficial venous thrombosis is ***not*** included as a risk factor for VTE.

The question of ongoing prophylaxis (Warfarin or stockings) after discharge is an evolving one with most of the focus on orthopaedic patients. I am not aware of moves to do this in general surgical patients except for those undergoing bariatric surgery. In [Mrs A's] case, based on her history and under current standards of care, I would not have expected this to have been done.

Standard of Care Regarding VTE guidelines
While not mandatory as yet, all surgical departments are encouraged to have guidelines around VTE prophylaxis. I note that a national guideline is currently being drawn up under the auspices of the [Health Quality and Safety Commission].

Standard of Care Regarding Surgery
I do not see any reason based on [Mrs A's] history to suggest her surgery should not have gone ahead. Further it appears to have been completed in a satisfactory and professional manner.

I would not have advised [Mrs A] to stop the oral contraceptive, I would not expect any of my colleagues would have either. It is not a topic I would expect anyone from [the] DHB to have discussed with her. I am not aware of any data supporting the idea that stopping the [oral contraceptive] in this setting is of any benefit."

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