Dermatologist, Dr B

The Company

A Report by the

Health and Disability Commissioner

(Case 16HDC01119)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. Ms A, aged 26 years at the time of these events, had a history of severe acne. At the age of 16, she received her first course of isotretinoin treatment.[1] At the age of 22, Ms A consulted dermatologist Dr B about commencing isotretinoin again, but did not proceed with treatment at this time.

2. On 7 July 2015, Ms A presented to Dr B again regarding isotretinoin treatment. At the consultation, Dr B was aware that Ms A was of childbearing potential. Dr B documented that Ms A had a partner, was sexually active (albeit infrequently), and used condoms. Dr B told HDC that during the consultation, Ms A did not say anything that "indicated a risk she might be pregnant".

3. Dr B prescribed Ms A isotretinoin. Dr B excluded a pregnancy test when she ordered pre-treatment monitoring blood tests, and did not order any other form of pregnancy test.

Findings

4. The Commissioner found that by prescribing Ms A isotretinoin without carrying out a pre-treatment pregnancy test, Dr B failed to provide services to Ms A with reasonable care and skill, and therefore breached Right 4(1) of the Code.[2]

5. Adverse comment is made about Dr B not ascertaining that Ms A was clear about the need to be on appropriate contraception and, in particular, the need to be using two forms of contraception.

6. Adverse comment is also made about Dr B's documentation in that it did not reflect the content of the consultation comprehensively, and lacked clarity about the matters that were discussed. The Commissioner also endorsed the use of a written consent form in this setting, which he noted Dr B has now implemented.

7. In providing dermatology services to Ms A, Dr B was acting within the scope of her authority as an agent/member of the company. Accordingly, the Commissioner considered the company to be vicariously liable for Dr B's breach of Right 4(1) of the Code.

Recommendations

8. In response to the provisional opinion, Dr B provided a written apology to HDC for forwarding to Ms A. Dr B also arranged to enrol in the Royal Australasian College of Physicians' Communication Skills online course, and will provide this Office with a certificate of completion. As such, the Commissioner made no further recommendations in relation to Dr B.

[1] Isotretinoin is an oral pharmaceutical drug primarily used to treat severe nodular acne. Isotretinoin is teratogenic. This means that it can cause birth defects in an unborn child. For this reason, pregnancy is an absolute contraindication for the use of isotretinoin.

[2] Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code) states: "Every consumer has the right to have services provided with reasonable care and skill."

Complaint and investigation

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

- *Whether Dr B provided Ms A with an appropriate standard of care in 2015.*
- *Whether the company provided Ms A with an appropriate standard of care in 2015.*

10. The parties directly involved in the investigation were:

Ms A	Consumer/complainant
Dr B	Dermatologist
The company	Provider

Also mentioned in this report:

Dr D	Dermatologist

11. Information was reviewed from:

Dr C	General practitioner
Registered nurse	

12. Independent expert advice was obtained from dermatologist Dr Matthew Strack.

Information gathered during investigation

Introduction

Isotretinoin

13. Isotretinoin is an oral pharmaceutical drug primarily used to treat severe nodular acne.[3] It works by reducing the oily substances produced by the oil-making glands in the skin. Usually it is prescribed only when other treatments such as creams and antibiotics have been unsuccessful at treating acne. Isotretinoin is teratogenic. This means that it can cause birth defects in an unborn child. For this reason, pregnancy is an absolute contraindication for the use of isotretinoin.

The company

14. Dermatologist Dr B has been prescribing isotretinoin since approximately 1982. At the time of these events, she was providing services under a company (the company). She is a shareholder and sole director of the company but not an employee.

[3] Nodular acne is a severe form of acne characterised by the presence of large, inflamed and often painful breakouts. Nodules are larger and more serious than typical acne, and affect deeper layers of the skin.

Treatment prior to 7 July 2015

15. Ms A, aged 26 years at the time of these events, had a history of severe acne. At the age of 16, she received her first course of isotretinoin treatment. In 2015, Ms A commenced her second course of isotretinoin treatment.

Referral to Dr B in 2011

16. When Ms A was 22 years old she suffered a recurrence of moderately severe facial acne causing scarring and, on 13 October 2011, her general practitioner (GP), Dr C, referred her to Dr B.

17. Ms A was seen by Dr B on 21 October 2011. At this consultation, Dr B documented a need for Ms A to receive another course of isotretinoin. Dr B noted that Ms A used "condoms for contraception" and that "[her] concern [was] that [Ms A's] contraception [was] not adequate". Dr B asked Ms A "to discuss her contraception further [with her GP] with a view of referring her for a Mirena[4]".

18. At the conclusion of this consultation, Ms A decided to defer treatment until December 2011. Dr B told HDC that eventually Ms A did not proceed with isotretinoin treatment in 2011.

Referral to Dr B in 2015

19. On 20 May 2015, Ms A presented to Dr C, who observed moderately severe acne and evident scarring developing. Dr C noted that Ms A had been unresponsive to oral antibiotics. Dr C felt it important that Ms A be referred for another dermatology opinion, and referred her to Dr B.

Consultation of 7 July 2015

Pre-treatment pregnancy testing

20. On 7 July 2015, Dr B reviewed Ms A again. At this consultation, in response to Dr C's referral letter of 20 May 2015, Dr B documented the following:

> "[Ms A] presents with recurrent acne. She had a course of isotretinoin treatment when she was younger and had a period of remission, however her acne has gradually recurred over the past few years and she has not responded to repeat treatments with antibiotics or contraceptive pill …
>
> She does have a partner but she doesn't have sexual intercourse frequently and when she does she uses a condom …
>
> I entirely agree; she needs another course of isotretinoin to get her acne under better control. I have discussed this with her today and she is going to start on a low dose of 20mg per day, and I will need to review her in [two] months. I have arranged for a blood test to be done prior to starting, with review at that time."

21. At the end of the consultation, Dr B ordered pre-treatment monitoring blood tests, which included a complete blood count, liver function, lipids, and renal function. Dr B did not order a pre-treatment pregnancy test.

[4] Mirena is a hormone-releasing intrauterine device that prevents pregnancy.

22. Dr B told HDC:

> "[During the consultation] [Ms A] did not say anything to me that indicated a risk she might be pregnant. She told me she was having infrequent intercourse and had been successfully using barrier method (condoms) for contraception for some years. … [I]t has not been my practice to routinely do a pre-treatment pregnancy test unless discussion with the patient indicates that pregnancy may be a possibility."

23. Dr B reasoned that as Ms A had been using a barrier method of contraception for five years and had not fallen pregnant, it was reasonable to assume that Ms A was using condoms consistently and competently, and her risk of pregnancy was low.

24. Dr B further stated that "although [she] accept[s] that available guidelines provide that a pre-treatment pregnancy test should be arranged, from her personal experience, the occurrence of such a situation is extremely rare, and an argument can be made for a 'case by case approach'".

25. Dr B added that, in her experience, when she has discussed with patients the teratogenicity of the medication and the need to avoid pregnancy, patients have been able to decide for themselves, in a patient-led manner, whether a pre-treatment pregnancy test would be sensible.

Discussion of treatment

26. Ms A stated that Dr B told her about the risks associated with becoming pregnant while taking isotretinoin. However, Ms A said that it was only later that she became aware that she should have been on two forms of contraception whilst taking isotretinoin. Ms A told HDC that Dr B did not prescribe her any form of contraception at the consultation.

27. Dr B told HDC that she followed her usual process, including discussing with Ms A her contraception methods and advising of the need to avoid pregnancy. Dr B stated that she gave Ms A a detailed patient information booklet[5] that explains the risks and side effects of isotretinoin. One section of the booklet highlights the importance of contraception, including the need to be on two forms of contraception, and the risk of birth defects. Ms A confirmed with HDC that she had received and read a "blue book".

28. Dr B further told HDC that she felt confident from this consultation, her 2011 consultation, and the fact that Ms A had been prescribed isotretinoin previously, that Ms A was fully aware of the need to avoid pregnancy, and the potential consequences of taking isotretinoin. However, Dr B added: "[G]iven the outcome … I of course wish I had insisted on a pregnancy test and explored further with [Ms A] whether she was prepared to use two forms of contraception."

[5] *Oratane Isotretinoin Acne Treatment Programme Information.* See paragraph 33.

Documentation

29. Dr B informed HDC that her practice is fully computerised and, at the time of these events, the contents of her handwritten notes were typed into a letter to the patient's GP, and all her handwritten notes were shredded.

30. The discussion referred to by Dr B above at paragraph 27 is not recorded in her clinical notes for the consultation.

31. Dr B told HDC that she did not require patients to sign a consent form before being prescribed isotretinoin. She explained that although this was her practice 10 to 15 years ago, she had stopped requiring written consent because she felt it created a barrier to patients taking the medication. Dr B advised that generally isotretinoin treatment is very safe and well tolerated, and the use of a consent form served to reinforce any anxiety or fear a patient had, such that often they deprived themselves of a very effective treatment.

Subsequent events

32. Ms A subsequently found that she was pregnant, and the pregnancy was terminated. Dr B has submitted that conception occurred after the consultation on 7 July 2015, and that a pre-treatment pregnancy test on that date would have been negative.

Oratane Isotretinoin: Acne Treatment Programme Information (information booklet)

33. Under the heading "Oratane and potential birth defects", the booklet states:

> "Oratane should ***NEVER*** be used by pregnant women or by women who intend to become pregnant, *during or for one month after*, their Oratane treatment.
>
> All possibility of pregnancy MUST be ruled out before you start your Oratane treatment. Strict birth control methods should be used for one month before you start Oratane, during your whole Oratane treatment and for one month after you stop taking Oratane."

34. At "Section 03: Contraception" under the heading "What is strict birth control?", the booklet advises:

> "Strict birth control or contraception means carefully following a procedure to make sure you do not become pregnant. The most effective form of birth control or contraception is 'the pill' (oral contraceptive) plus a barrier method (condom or diaphragm). You should carefully follow all the directions for the use of these methods of contraception."

Further information — Dr B

Dr D

35. As part of Dr B's response to HDC, she provided a statement from dermatologist Dr D. Dr D describes his usual practice for prescribing isotretinoin to female patients with regard to pregnancy testing and informed consent as follows:

"**Isotretinoin informed consent**
In New Zealand, to the best of my knowledge the majority of prescribers no longer obtain written informed consent; they just spend time explaining the teratogenic effects and the importance of pregnancy avoidance with the patient …

Pregnancy prevention
My personal approach is to discuss the importance of not becoming pregnant during the course of treatment and for one month after with the patient. I often recommend that the patient wait until the next menstrual cycle before starting the isotretinoin and will facilitate pregnancy testing should the patient wish (but it is not a requirement). Less than half of my female patients have routine pregnancy testing. I do facilitate discussion regarding contraception, preferably through the general practitioner. I confirm these discussions with a letter to the patient (usually as a copy of my letter to the patient's general practitioner).

My understanding from colleagues is that this is a fairly standard practical approach."

Changes to Dr B's practice

36. Dr B told HDC that she has made the following changes to her practice with regard to prescribing isotretinoin to women of childbearing potential:

a) All women have a pre-treatment blood pregnancy test regardless.

b) Application for health funding authority approval to prescribe isotretinoin will be delayed until results of the above test results are to hand.

37. Dr B has now introduced the scanning of handwritten case notes into the patient's clinical record.

38. Dr B has also instigated the use of a consent form along with a handout for all patients commenced on isotretinoin. In addition, she now provides a separate A5 slip with information specific to women of childbearing potential.

39. Dr B added that all women of childbearing potential, if sexually active, are required to be on a secure form of contraception. Where patients are unable to tolerate hormonal contraception, she will specifically request that they see their GP or family planning doctor for appropriate contraceptive advice.

40. Dr B has since attended a symposium to update her skills and expertise in the management of acne.

Further information — the company

41. The company told HDC that a lengthy informal discussion involving Dr B and two employees occurred regarding this complaint. Clerical staff have been advised that a pre-treatment pregnancy test is now mandatory for all women of childbearing

potential (aged 18 years and over),[6] and understand that they can apply for a Special Authority number only following receipt of a negative pregnancy test result.

Responses to provisional opinion

Ms A

42. Ms A was provided with an opportunity to comment on the "information gathered" section of the provisional opinion. She did not provide any further comment.

Dr B and the company

43. Dr B and the company were provided with an opportunity to comment on the provisional opinion. Where relevant, parts of Dr B's response have been included in the "information gathered" section above or set out below.

Opinion: Dr B — breach

Preliminary comments

44. This investigation relates to the appropriateness of the care provided to Ms A by Dr B during the consultation of 7 July 2015, irrespective of the subsequent events. Dr B has submitted that conception occurred after the consultation on 7 July 2015, and that a pre-treatment pregnancy test on that date would have been negative. Whether Ms A was pregnant at the time of the consultation or became pregnant subsequent to the consultation is not relevant to the findings I make in this report. In particular, I make no finding as to the date of conception.

Pregnancy testing — breach

45. On 7 July 2015, Dr B was aware that Ms A was 26 years old and of childbearing potential. Dr B documented that Ms A had a partner, was sexually active (albeit infrequently), and used condoms. Despite this, Dr B told HDC that during this consultation, Ms A did not say anything that "indicated a risk she might be pregnant". Dr B stated: "[I]t has not been my practice to routinely do a pre-treatment pregnancy test unless discussion with the patient indicates that pregnancy may be a possibility." Dr B concluded that as Ms A had been using a barrier method of contraception for five years and had not fallen pregnant, it was reasonable to assume that Ms A had been using condoms consistently and competently, and therefore her risk of pregnancy was low. As a result, Dr B excluded a pregnancy test when she ordered pre-treatment monitoring blood tests, and did not order any other form of pregnancy test.

46. I note that Dr B accepted that available guidelines provide for a pre-treatment pregnancy test when prescription of isotretinoin is being considered. However, she also stated that this should be tempered with a case-by-case approach, which she submitted is endorsed by her colleague, Dr D.

[6] Those under 18 who are sexually active will be tested, with their parents' consent.

47. The MedSafe data sheet for isotretinoin states:

> "Isotretinoin is contraindicated in women of childbearing potential unless the female patient meets all of the following conditions:
>
> … She has a negative pregnancy test within two weeks prior to beginning therapy."

48. My expert advisor, dermatologist Dr Matthew Strack, advised that the accepted practice is for all women of childbearing potential to have a pregnancy test prior to taking isotretinoin. He considered the failure to test for pregnancy a significant departure from accepted practice, although he advised that his peers would consider the failure to test for pregnancy a moderate departure.

49. Ms A was of childbearing age, in a relationship, and sexually active. These factors indicated a risk that she might be pregnant. While Dr B may have considered the risk to be low in this case, I consider that the guidelines and accepted practice are clear that a pregnancy test should be carried out. It was not for Dr B to make a judgement that a test was not needed in the circumstances. Therefore, in order to prescribe isotretinoin safely to Ms A, Dr B should have carried out a pregnancy test. I am critical that she did not do so, and consider that Dr B departed from the accepted practice.

50. I note Dr B's comment that, in her experience, when she has discussed with patients the teratogenicity of the medication and the need to avoid pregnancy, patients have been able to decide for themselves, in a patient-led manner, whether a pre-treatment pregnancy test would be sensible. As stated above, the guidelines and accepted practice indicate a different course of discussion and action.

51. By prescribing Ms A with isotretinoin without carrying out a pre-treatment pregnancy test, Dr B failed to provide services to Ms A with reasonable care and skill, and therefore breached Right 4(1) of the Code.

Information provided to Ms A regarding contraception — adverse comment

52. In 2011, when Ms A was considering isotretinoin, Dr B noted that Ms A used "condoms for contraception". Dr B also noted: "[My] concern is that [Ms A's] contraception is not adequate." Dr B asked Ms A "to discuss her contraception further [with her GP] with a view of referring her for a Mirena".

53. In 2015, although Dr B noted that Ms A was still using condoms for contraception, there is no documented discussion about other forms of contraception. Dr B explained that given that Ms A had been using a barrier method of contraception for five years and had not fallen pregnant, she considered it reasonable to assume that Ms A was using condoms consistently and competently. Dr B stated that an information booklet that highlights the importance of contraception, including the need to be on two forms of contraception, was provided to Ms A.

54. Ms A stated that Dr B told her about the risks associated with becoming pregnant while taking isotretinoin. However, Ms A said that it was only later that she became

aware that she should have been on two forms of contraception whilst taking isotretinoin. Ms A told HDC that Dr B did not prescribe her any form of contraception at the consultation.

55. The MedSafe data sheet for isotretinoin states:

> "Isotretinoin is contraindicated in women of childbearing potential unless the female patient meets all of the following conditions:
>
> …
>
> - She confirms that she has understood the warnings.
>
> …
>
> - She must use effective contraception without any interruption for 1 month before beginning isotretinoin therapy, during therapy and for 1 month following discontinuation of therapy. Use of two complementary forms of contraception including a barrier method should be used.
>
> …
>
> - She must fully understand the precautions and confirm her understanding and her willingness to comply with reliable contraceptive measures as explained to her."

56. Dr Strack considered that it is accepted practice for patients to use two forms of contraception while taking isotretinoin, and preferably one of these will be hormonal. He noted that in 2015, there did not appear to be any indication that a discussion about more effective forms of contraception, such as the combined oral contraceptive pill or an IUD,[7] had taken place. He added that there was also no referral to see the GP to discuss the issue further. Dr Strack advised that the fact that Dr B did not discuss these issues with Ms A amounted to a departure from the standard of care. He reasoned, however, that the departure was mild, as there were mitigating factors such as the 2011 conversation around contraception, and the information booklet that was provided to Ms A.

57. I do not consider that it was adequate for Dr B to rely on a conversation that took place four years previously, to discharge her obligations to discuss appropriate contraception with Ms A in 2015, particularly as Dr B was aware that Ms A was using only one form of contraception at the time.

58. I acknowledge that a detailed information booklet was provided to Ms A, which Ms A confirmed with HDC that she had read. The booklet does highlight the importance of following "strict birth control procedures", which includes "oral contraception plus a barrier method". The booklet refers the reader to her doctor or family planning clinic for more information about contraception.

[7] Intrauterine device.

59. I am unable to determine exactly what was said by Dr B to Ms A in the July 2015 consultation, and, in particular, whether Dr B informed Ms A that two forms of contraception should be used.

60. Under these circumstances, I am critical of Dr B for not ascertaining that Ms A was clear about the need to be on appropriate contraceptive methods, and in particular the need to be using two contraceptive methods, in the July 2015 consultation.

Documentation — adverse comment

61. Dr B informed HDC that her practice is fully computerised. At the time of these events, the contents of her handwritten notes were typed into a letter to the patient's GP. All of her handwritten notes were then shredded.

62. Dr Strack advised that this method of record-keeping is not his current practice, although he understands that it is a method used by a number of specialist clinicians in New Zealand. He commented that "if a letter to the general practitioner is to be used in such a way … then the letter should reflect what happened during the consultation". Dr Strack noted:

> "Nothing is said in relation to possible warnings that may have been given in relation to pregnancy, printed information that may have been given to this patient regarding isotretinoin and precautions that need to be taken and there is no record of a written consent form having been signed by the patient regarding the need to avoid pregnancy and to use contraception while taking isotretinoin."

63. Dr B also told HDC that she did not document Ms A's consent to the use of isotretinoin. She explained that although this was her practice 10 to 15 years ago, she had stopped requiring written consent because she felt it created a barrier to patients taking the medication.

64. Dr Strack considered that the guidelines regarding the need for consent forms in this clinical setting have not changed in New Zealand over the years. He advised that, given the high risk of congenital abnormalities and cognitive impairment from the use of isotretinoin, the need for a written consent form on a routine basis is easily justifiable. Dr Strack said that he is not aware of any published guideline that states that consent forms are unnecessary in this situation.

65. Dr Strack advised that Dr B's record-keeping in this case represented a mild departure from accepted practice. I accept this advice. I am critical that the documentation did not comprehensively reflect the content of the consultation, and lacked clarity about the matters that were discussed. I also agree that it would be good practice to use a written consent form in this setting, and I note that Dr B has now implemented this.

Opinion: The company — breach

66. Dr B is the sole director and a shareholder of the company. Under section 72(3)/(4) of the Health and Disability Commissioner Act 1994 (the Act), an employing authority is vicariously liable for any act or omission by an agent/member, unless it is done or omitted without that employing authority's express or implied authority, precedent or subsequent.

67. Dr B is an agent/member of the company.

68. At the time of these events, the company did not have policies in place that required mandatory pregnancy testing before prescribing isotretinoin to women of childbearing potential.

69. In providing dermatology services to Ms A, Dr B was acting within the scope of her authority as an agent of the company. Accordingly, I consider that the company is vicariously liable for Dr B's breach of Right 4(1) of the Code.

Recommendations

70. In response to the recommendations in the provisional opinion, Dr B has:

a) Arranged to enrol in the Royal Australasian College of Physicians' Communication Skills online course and advised that she will provide HDC with a copy of the certificate of completion within three months of this report.

b) Provided a written apology to HDC for forwarding to Ms A.

Follow-up actions

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

72. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the district health board, and it will be advised of Dr B's name.

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

Appendix A: Independent dermatology advice to the Commissioner

The following expert advice was obtained from dermatologist Dr Matthew Strack:

"I have received the document [Ms A]/[Dr B] C16HDC01119 with a letter from [HDC] dated 17 October 2016, a copy of the complaint, [Dr B's] response, and the clinical notes and I have read these. I have read the 'Guidelines for Independent Advisors' from the Office of the Health and Disability Commissioner and I will follow these in this report.

I have an MB ChB from the University of Otago, graduating in 1986. Subsequent to graduation I have worked as a junior doctor, in general practice and then either in dermatology training or as a consultant dermatologist. I have practised as a consultant dermatologist in Dunedin since 1995. For ten years I was visiting consultant dermatologist at Dunedin Hospital, including being Head of Service for the last six of those ten years. I have been a visiting consultant dermatologist at Southland Hospital for fifteen years and I have run a private practice for over twenty years.

I am a past secretary of the New Zealand Dermatological Society, a current shared vice-chair of the Council of the Royal Australian College of Physicians, and a dermatology advisor for the New Zealand Medical Council.

I regularly see patients with acne and treat them with isotretinoin.

Question 1

1. Whether the failure of [Dr B] to ensure [Ms A] was not pregnant (via a negative serum HCG or high sensitivity urinary HCG) prior to commencing isotretinoin represents departure from the expected standards of care.

la. What is the standard of care/accepted practice?

The standard of care is for all women of childbearing potential to have a pregnancy test prior to taking isotretinoin.

References:

Medsafe Prescriber Update 23(3): 35–36 August 2002

'Before starting isotretinoin treatment, all female patients of childbearing potential should have a pregnancy test, preferably but not essentially performed on blood since it is more accurate at an earlier stage of pregnancy.'

Medsafe Publication Isotretinoin Indications in Teratogenicity Prescriber Update 30(2):7 May 2009

'As a result of its teratogenicity isotretinoin is contraindicated in women of childbearing potential unless an extensive list of conditions for prescribing are met. For further information on the conditions associated with prescribing

isotretinoin please see the product data sheets at www.medsafe.govt.nz/Medicines/infoSearch.asp.'

3. Three data sheets are available and three consumer medical information sheets are available making a total of six documents on the Medsafe website.

3a Data sheet. 'Isotretinoin is contraindicated in women of childbearing potential unless the female patient meets all the following conditions:

… she has a negative pregnancy test within two weeks prior to beginning therapy. Monthly repetition of pregnancy testing is recommended.'

3b The Consumer Medical Information

'Before you take oratane

When you must not take oratane

Do not take oratane capsules if

1. You are pregnant or for at least one month before you intend to become pregnant. If you fall pregnant while taking oratane capsules there is an extremely high risk of having a baby that is severely deformed.'

lb. Has there been a departure from the standard of care or accepted practice. In my opinion this is a significant departure.

lc. The view of peers.

It is my opinion that my peers would consider this to be a significant departure from the standard of care or accepted practice.

ld. Recommendations for improvement.

From reading the statements that [Dr B] has made:

'I have made the following recent changes to my practice with regard to the prescribing of isotretinoin in women of childbearing potential;

All women have a pretreatment blood pregnancy test regardless.

Application for health funding authority approval to prescribe isotretinoin will be delayed until the results of these test results are to hand.'

I agree with the changes to practice that [Dr B] has recommended implementing and I believe that these will bring her practice in to the recommended standard of care.

Note: One of the above references talks about monthly tests while female patients of childbearing potential are taking isotretinoin, this is a standard of care in North

America but it is not usual practice in the United Kingdom, Australia or New Zealand. However, a pretreatment pregnancy test is the standard of care in all of the above locations.

Question 2

2. Whether the failure of [Dr B] to ensure [Ms A] was using reliable contraception prior to her commencing isotretinoin represents a departure from the expected standards of care.

2a. What is the standard of care/accepted practice?

The standard of care/accepted practice is for patients to have two forms of contraception while on isotretinoin and preferably for one of these forms of contraception to be hormonal.

References:

From the patient data sheet referred to by Medsafe, reference above 'she must use effective contraception without any interruption for one month before beginning isotretinoin therapy, during therapy and for one month following discontinuation of therapy. Use of two complementary forms of contraception, including the barrier method, should be used.'

Also 'she must fully understand the precautions and confirm her understanding and willingness to comply with reliable contraceptive measures as explained to her.'

From 'advice on the safe introduction and continued use of isotretinoin in acne in the UK 2010 British Journal of Dermatology Volume 162, pages 1172–1179 Goodfield et al.' 'Ideally the main form of contraception should be hormonal — either the combined oral contraceptive pill or injectable or implantable hormonal therapy should be used.' … 'female patients are advised to use at least one but ideally two methods of contraception for one month before starting treatment, including a barrier method and to continue to use effective contraception throughout the treatment and for at least one month after cessation of treatment, even in patients with amenorrhea.'

'All female patients must sign a form indicating that they fully understand the risks of pregnancy, that they are not currently pregnant, that they have been using appropriate contraception for one month before starting treatment and that the responsibilities of the patient and physician have been discussed.' And from 'Avoiding teratogenicity with isotretinoin Medsafe', referred to above 'one month before starting isotretinoin commence the woman on contraception, ideally on hormonal such as either a combined oral contraceptive pill or an injectable implantable hormonal contraceptive. Intra-uterine devices are also an option. The progesterone-only pill may be less reliable in women taking isotretinoin.'

2b. There has been a departure from the standard of care or accepted practice. There are clear written guidelines for the standard of care in this situation. However, from [Dr B's] description, she had already had some discussion a few

years earlier about appropriate forms of contraception and had referred the patient back to her general practitioner. In addition, [Dr B] states that she gave this patient a thirty four page booklet with written guidelines about using the medication which include very clear statements in a number of areas about the requirements for contraception. So while there has been a departure from the accepted standard of care in this case, there are mitigating factors and given the circumstances, this would be considered to be a mild departure from the standard of care.

How would it be viewed by your peers.

In this case [Dr B] noted that she had discussed with this patient that she was using condoms for contraception and that she had been using them reliably for some time. There doesn't appear to be any indication during the 2015 consultation that a discussion about more effective forms of contraception than condoms, such as the combined oral contraceptive pill or an IUD had taken place and there does not seem to have been a referral for this patient to see her general practitioner to discuss this issue further.

I note that [Dr B] does seem to have documented a discussion and a referral back to this patient's general practitioner in 2011, however the consultations in question took place five years later. To my knowledge, most dermatologists in New Zealand would consider one reliable form of contraception such as an IUD or the combined oral contraceptive pill to be satisfactory contraception. It is my opinion that barrier contraception alone would not be considered to be as reliable a form of contraception. As noted in the previous section, the fact that this patient was given detailed written information which would clarify this situation for a patient, means it is likely my peers would consider this to be a mild departure from the standard of care or accepted practice.

Recommendations for improvement

It appears that [Dr B] would agree with the above comments as in her letter she has said 'the following already existing components of my practice are now re-emphasised by me, documented in the consultation notes and reinforced with written material.

All women of childbearing potential if sexually active are required to be on a secure form of contraception. This is usually a combination of oral contraception and barrier method. If they have not previously been prescribed the oral contraceptive, or are unable to tolerate this, they will be referred back to their family doctor for contraceptive advice.

All women of childbearing potential who say they are not sexually active are advised of the consequences of a pregnancy, and the need for effective contraception if their circumstances change.

I advise of the need to consider a termination of pregnancy if a pregnancy should occur.

I re-emphasise the need to delay commencing the medicine until the first day of their menstrual cycle.'

Question 3

3. Whether [Dr B's] clinical documentation with respect to recording [Ms A's] contraception management on 7 July 2015 and the steps taken to exclude the possibility of current pregnancy, meet expected standards of care.

3a I am informed that [Dr B] has a computerised practice, that she takes handwritten notes during the consultation and that the content of these notes is then dictated or typed in to a letter to the patient's general practitioner which then becomes part of the patient's permanent medical records. Once this has been done the handwritten notes taken during the consultation are shredded. This is not my current method of keeping medical records but I understand that it is a method that is used by a number of specialist clinicians in New Zealand. If a letter to the general practitioner is to be used in such a way to keep a record of a medical consultation then the letter should reflect what happened during the consultation and I am assuming that this is the case here. The letter dated 7th July 2015 indicates that [Dr B] did have a discussion about contraception with this patient, 'she does have a partner but she doesn't have sexual intercourse frequently and when she does, she uses a condom.' Nothing is said in relation to possible warnings that may have been given in relation to pregnancy, printed information that may have been given to this patient regarding taking isotretinoin and precautions that need to be taken and there is no record of a written consent form having been signed by the patient regarding the need to avoid pregnancy and to use contraception while taking isotretinoin.

In [Dr B's] letter to the complaints assessor dated 30th August 2016 a more detailed description of the discussion is recounted including the statement that [Ms A] was given a printed information booklet.

[Dr B] states that she gave [Ms A] a booklet titled 'Oratane Isotretinoin, Acne Treatment Programme Information'. This is a detailed thirty four page booklet with a separate section on contraception titled 'VERY IMPORTANT'. Without retyping the two and a half pages of this, this detailed information states that patients are responsible for their own contraception. It explains why contraception is so important and it says that 'the most effective form of birth control or contraception is "the pill" (oral contraceptive) plus the barrier method (condom or diaphragm).' In addition there is a one page summary which can be used as a separate signable consent form on page thirty four of the booklet where the top five paragraphs are all describing in careful detail, the necessity and the requirements for contraception. I don't believe this form is signed but to my eye, the information appears to be clearly laid out and it stresses all the important facts. The fact that this was given to the patient, in my mind significantly mitigates the briefness of documentation regarding contraception in the 2015 consultation.

3b. In my opinion the record keeping in this case represents a mild departure from the standard of care or accepted practice. I do not have a problem with the letter

being used to summarise a clinical consultation but if the letter is to be used as a replacement for the clinical notes taken during the time of the consultation then the letter must comprehensively reflect the content of the consultation and that does not seem to have been the case here.

While the clinical documentation in this case is lacking, the detailed printed booklet as indicated above, does make up for some of the lack of documentation.

Comment: I agree with the changes to practice that [Dr B] has recommended implementing and I believe that these will bring her practice up to the recommended standard of care.

3c. I believe my peers would agree with the above statements and consider this to be a mild departure from clinical practice.

3d. Recommendations for future improvement:

There are a variety of ways that this could be achieved. It might be possible to scan the paper notes taken during the consultation in to the patient's file electronically. Another approach might be to dictate a more comprehensive letter if this is to be used in place of the contemporaneous notes.

I would make the suggestion that [Dr B] may wish to consider the use of a written consent form, which could then be retained in paper form or scanned in to her computerised notes electronically.

Question 4

4. Any other aspect of [Ms A's] management as described by [Dr B] or indicated by the clinical documentation.

[Dr B] presents as a conscientious and careful dermatologist who has prescribed isotretinoin appropriately. In this case, the clinical situation has unfolded over a number of years and this has made the care of the patient disjointed. Some of the issues relating to documentation, particularly as regards the 2015 consultations, if taken in isolation, are a cause for concern and these have been described previously.

[Dr B] has written a considered letter describing the situation and how it came about. She has already implemented a number of significant changes in her practice which would greatly reduce the possibility of a situation like this happening again. I would suggest that [Dr B] considers the use of a patient consent form and either keeps more comprehensive clinical records, or dictates a more detailed letter to the patient's general practitioner.

Signed 

Dated 9/11/16. "

On 18 May 2017, the following further expert advice was obtained from Dr Strack:

> "I have answered your questions labelled 1 to 4 starting with question 2 as this reinforces the comments I will make in reply to the other questions.
>
> Question 2: Other than Medsafe guidelines referenced in your original article, are there any relevant standards which may apply to this case?
>
> Yes there are several well respected references in this field. I can supply some of these in electronic copy if needed.
>
> 2a British Journal of Dermatology 2010 162, pp 1172–1179 Advice on the Safe Reduction of Continued Use of Isotretinoin in Acne in the UK 2010 Godfield et al page 1174 paragraph numbered 4 'All female patients must sign a form indicating that they fully understand the risks of pregnancy …'. The article shows a fairly strict set of guidelines and also includes a reference to the need for a pregnancy test 'All female patients of childbearing potential should have a medically supervised pregnancy test', this is the next paragraph down from the above reference.
>
> Exceptions to this are made for women who are not sexually active, or who can not get pregnant, for example women who have had a hysterectomy.
>
> 2b BPAC New Zealand Prescribing Advice Reference www.bpac.org.nz/2017/isotretinoin.aspx 'testing to exclude pregnancy preferably a serum HCG test is recommended'. BPAC also has a published consent form for patients to sign.
>
> 2c North American Guidelines
>
> In North America a system called 'iPledge' has been operating for more than ten years. This requires a written consent form and monthly pregnancy tests to be taken prior to treatment, during the course of treatment and for one month afterwards.
>
> 2d Manufacturer's Information.
>
> The booklet which [Dr B] gave to this patient on the inside of the back page has a foldout which is a consent form explaining the need for females to avoid pregnancy and issues related to mood change.
>
> 2e Recommendation from New Zealand Dermatologists
>
> Dr Amanda Oakley 'How to Prescribe Isotretinoin' GPCME Rotorua June 12th 2010 Slide 47 of 83 slides shows a consent form for patients to sign and slide 44 of 83 slides shows a recommendation for beta HCG or blood pregnancy test to be checked prior to treatment. This talk is readily accessible with a web search of 'Oakley isotretinoin GPCME'.
>
> 2f New Zealand Dermatologists ii

Talk 'Isotretinoin Prescribing' Martin Keefe Consultant Dermatologist, Christchurch Hospital and Bridge Street Dermatology, Nelson. Slide 40/50 'Ask patients to sign an isotretinoin consent form …' and slide 39/50 'HCG (pregnancy test) recommended as a pre-treatment blood test'.

Question 2 Summary

There is a widespread agreement amongst published talks given by senior New Zealand Dermatologists and published guidelines including BPAC and overseas sources from North America and United Kingdom that a serum or blood pregnancy test and a written consent form are the appropriate standards of care prior to prescribing isotretinoin for women of childbearing potential. In addition to the above, [Dr B] herself in her recommendations has indicated that she will adopt these two points as part of her ongoing practice.

Question 1: Whether the additional information provided causes you to make a further comment or amend your original advice. If so, please explain why.

[Dr B] has sought collegial support and this has been provided in the way of a one page letter from [Dr D]. [Dr D] is a well respected and senior New Zealand based dermatologist. He is also the author of some of the Medsafe references which I used in my first submission. In the written guidelines which he has published through Medsafe dated August 2002 he recommends that a pregnancy test, not necessarily a blood test, should be taken prior to starting treatment and that 'regular pregnancy tests should be undertaken during treatment with isotretinoin'.

[Dr D] states that 'less than half my female patients have routine pregnancy testing'. [Dr D] also comments that pregnancy rates on isotretinoin may be lower in New Zealand than in North America. This is not proven and there is published data to suggest that the rate of pregnancy on isotretinoin is higher than has been published in the past (Moody et al New Zealand Medical Journal 2011 v124).

[Dr D] also says 'it is unclear what dosage level the teratogeneric risk of isotretinoin disappears'. I agree with this statement but as far as I am aware the scientific research has not been done in this area. So I am sure [Dr D] would agree for now any prescription of oral isotretinoin in pregnancy is contraindicated.

While I disagree with some of [Dr D's] statements, I accept that he is a competent and well respected dermatologist and that his views may well be shared by some of our peers.

In view of the above submission I would like to change my original reply to Section lc 'The view of peers'. I would like to downgrade this from labelling it a significant departure to the following statement.

'It is my opinion that my peers would consider this to be a moderate departure from the standards of care of accepted practice.'

This seems like an appropriate place in the report to reflect on my original answer to Section lb. All references that I have quoted maintain the need for a pregnancy test prior to starting treatment in women of childbearing potential. In addition, all of these references recommend that this is a blood or serum test with the exception of [Dr D's] 2002 reference where he says that blood/serum or other pregnancy testing is acceptable.

It is still my opinion that the lack of a serum HCG pregnancy test prior to commencing isotretinoin represented a significant departure from the expected standard of care in this case.

Question 3: The accepted practice around obtaining written consent before commencement of Oratane historically at the time of events then and now.

The above references given in my answer to question 2 all mentioned or documented the appropriateness of a written consent form with the exception of [Dr D's] 2002 reference which didn't specifically address this issue one way or the other.

'Coles Medical Practice in New Zealand 2013' Chapter 10 Informed Consent, Page 99 'It is not necessary to have a signed consent form for every treatment, this would be impractical, for example for every prescription written in general practice. However, the more invasive the procedure or the more risks it involves, the more prudent it is to have the patient sign a consent form.' The two references that I place the most weight on in this area would be the talks given by dermatologists where the need for a consent form is indicated. And as noted above, [Dr B] herself has said that going forwards, she wishes to use a written consent form for female patients prior to them starting isotretinoin. I do not think that the indications or the guidelines regarding the need for consent forms in this clinical situation have changed in New Zealand over many years. [Dr D] mentions that to the best of his knowledge 'the majority of prescribers no longer obtain written informed consent'. He may well be correct however I think the high risk of congenital abnormalities and cognitive impairment from the use of isotretinoin easily justifies the need for a written consent form on a routine basis in this clinical setting. I am not aware of any published guideline that says the consent forms are unnecessary in this setting.

Question 4: I think I have addressed most issues in my initial communication. I agree with the action plan that [Dr B] has put in place to prevent this situation from occurring in her practice in future and I commend her on an appropriate and well thought out response to this upsetting event.

Yours sincerely

Matthew Strack
18 May 2017"