

Iboga New Zealand Limited

Dr B

Mrs C

**A Report by the
Health and Disability Commissioner**

(Case 13HDC00966)



Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Table of Contents

Executive summary.....	1
Complaint and investigation	3
Information gathered during investigation.....	3
Relevant standards	15
Opinion: Introduction.....	18
Opinion: Dr B.....	19
Opinion: Mrs C — Breach.....	25
Opinion: Iboga New Zealand Limited — Breach.....	26
Recommendations	28
Follow-up actions.....	29
Appendix A — Independent advice to the Commissioner	30
Appendix B — Independent advice to the Commissioner.....	49

Executive summary

1. Mrs A, aged 45 years at the time of these events, had a history of opiate drug use.
2. In 2013, Mrs A consulted a clinic for assistance with her drug addiction. The clinic offered treatment with the psychoactive substance ibogaine. Dr B was the medical director of the clinic, and Mrs C was the “iboga assistant”.
3. Ibogaine is an unapproved medicine under the Medicines Act, and has been listed as a prescription-only medicine by Medsafe since 2010. There is a paucity of data supporting the use of ibogaine in scientific literature. However, it has been linked to sudden cardiac death following ingestion.
4. In 2013, Mrs A was booked with the clinic for ibogaine treatment. Prior to travelling to the clinic, Mrs A completed a questionnaire, and had blood tests and an electrocardiogram (ECG) as part of the assessment for her suitability for treatment. She was also advised to stop taking the antidepressant venlafaxine. There is reference to Mrs C providing Mrs A an information sheet about ibogaine treatment, but Mrs A never signed a consent form for treatment.
5. Mrs A missed her scheduled flight on the day she was scheduled to start treatment, so she took the next available flight and arrived at the clinic at 9am the following day (Day 1)¹.
6. At approximately 8pm on Day 1, Dr B met with Mrs A. He carried out an examination and assessed her as being suitable for treatment. Dr B told HDC that he assessed Mrs A for her suitability for treatment based on her answers to the questionnaire, blood test findings, ECG, and findings of the physical examination. Dr B did not document this assessment.
7. On Day 3, ibogaine treatment was commenced with an initial dose administered at 7.50am. Further doses were then administered at 8.50am, 5.45pm, 7.25pm and 8.40pm on Day 3, and 7am on Day 4.
8. At 9am on Day 4, Mrs A’s blood pressure was recorded as 97/80mmHg. No further blood pressure readings were recorded.
9. At 12 noon on Day 4, Dr B left to go overseas, leaving sole responsibility for ongoing monitoring of Mrs A with Mrs C.
10. At 1pm on Day 4, Mrs C recorded that Mrs A was: “Lying still. Facing bathroom.” At 2pm she is recorded to be: “Lying still. On side, peaceful.” At 3pm she is recorded to be: “Lying still. Arm raised over head.” At 4pm she is recorded to be: “Lying still. Turned heater on and she didn’t stir.” At 7pm the record states: “Sleeping. [Mrs A’s husband] rang.” At “11pm approximately” Mrs C recorded only “last check —”.

¹ Relevant dates are referred to as Days 1-5.

11. On Day 5 at 6am, Mrs C found that Mrs A was dead. She had not moved since 3pm on Day 4, and was lying on her side with her arm over her head.

Decision

12. In prescribing ibogaine for the treatment of drug addictions, Dr B was prescribing an unapproved medicine for experimental use and, accordingly, Dr B should have acted in a more cautionary manner.
13. Dr B breached Right 6(1) of the Code of Health and Disability Services Consumers' Rights (the Code)² for failing to provide Mrs A with adequate information about the risks and side effects of ibogaine, or about the experimental nature of its use to treat drug addiction. Furthermore, Dr B also breached Right 7(6)³ for failing to obtain Mrs A's written informed consent for treatment, which was required because of the experimental nature of the treatment.
14. Dr B departed from the ibogaine treatment protocol, and did not monitor Mrs A adequately. Dr B therefore breached Right 4(1) of the Code.⁴
15. Dr B also failed to keep comprehensive and accurate records and, as such, failed to comply with professional standards and breached Right 4(2) of the Code.⁵
16. Mrs C breached Right 4(1) for failing to monitor Mrs A adequately. Concern is also raised about Mrs C's immediate response when she found Mrs A dead.
17. Iboga New Zealand Limited did not operate safely, and failed to provide Mrs A with services with reasonable care and skill, in breach of Right 4(1) of the Code.

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

³ Right 7(6) states: "Where informed consent to a health care procedure is required, it must be in writing if —

- (a) The consumer is to participate in any research; or
- (b) The procedure is experimental; or
- (c) The consumer will be under general anaesthetic; or
- (d) There is a significant risk of adverse effects on the consumer."

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

⁵ 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."

Complaint and investigation

18. The Commissioner received a complaint regarding the services provided to Mrs A. The following issues were identified for investigation:

- *Whether the care provided to Mrs A by Dr B in 2013 was appropriate.*
- *Whether the care provided to Mrs A by Mrs C in 2013 was appropriate.*
- *Whether the care provided to Mrs A by Iboga New Zealand Limited (operating as the clinic) during 2013 was appropriate.*

19. An investigation was commenced on 20 June 2014.

20. The parties directly involved in the investigation were:

Dr B	General practitioner, provider
Mrs C	Provider
Iboga New Zealand Ltd	Provider

21. Information was reviewed from the above parties and from:

Dr D	Researcher
The Coroner	
New Zealand Police	
Medical Council of New Zealand	
MedSafe	

22. Independent expert advice was obtained from general practitioner Dr David Maplesden (**Appendix A**) and general practitioner Dr George Tripe (**Appendix B**).

Information gathered during investigation

Background

23. Mrs A, aged 45 years at the time of these events, had used various drugs since she was a teenager.

24. At the time of these events, Mrs A was taking intravenous drugs.

The clinic

25. In 2013 Mrs A contacted the clinic, owned by Iboga New Zealand Limited, for assistance with her drug addiction. At the time of these events the clinic offered treatment of drug addictions with the psychoactive substance ibogaine. General practitioner (GP) Dr B and Mrs C are the sole shareholders and directors of Iboga New Zealand Limited. Dr B was the clinic's medical director, and Mrs C worked as the "iboga assistant".

26. This opinion relates to the events surrounding Mrs A's death following her treatment with ibogaine at the clinic on Day 3 and Day 4.

Ibogaine

27. Medsafe⁶ provided HDC with the following information about ibogaine.
28. Ibogaine is a naturally occurring indole alkaloid derived from the roots of the rain forest shrub *Tabernanthe iboga*. It is used in low doses by the indigenous peoples of western Africa to combat fatigue, hunger and thirst, and in higher doses as a sacrament in religious rituals.
29. The use of ibogaine for the treatment of drug dependence is based on anecdotal reports from American and European addicts' self-help groups, that it decreases the signs of opiate withdrawal and reduces drug craving for cocaine and heroin for extended time periods. Ibogaine has diverse effects on the central nervous system, and the pharmacological targets underlying the physiological and psychological actions of ibogaine are not completely understood.
30. In 2007, Medsafe formed the view that, given ibogaine's potential therapeutic use in treating addiction, and the need for this treatment to be under supervision, there was a case for classifying ibogaine and its metabolite, noribogaine, as prescription medicines. This would limit attempts at self-treatment and prevent its development for recreational use as a "party pill".
31. In November 2009, ibogaine was considered by Medsafe's medicine classification committee and, subsequently, in 2010, ibogaine and noribogaine were listed as prescription-only medicines. This means that they can be accessed only by prescription from authorised prescribers acting within their scope of practice.
32. In terms of the Medicines Act 1981, any product containing either of these substances would be considered an "unapproved medicine". Unapproved medicines are medicines that have not been approved by the Ministry of Health for marketing, and are not regulated by Medsafe. Sections 25 and 29 of the Medicines Act contain exemptions that allow medical practitioners to obtain and administer unapproved medicines for treatment of a patient under the practitioner's care. The Medicines Act imposes special reporting requirements regarding how unapproved medicines are imported and supplied.
33. Medsafe advised HDC that ibogaine was imported and supplied to Dr B in accordance with the requirements of the Medicines Act.

Evidence of ibogaine's safety and efficacy

34. There is a paucity of data for ibogaine available in the scientific literature.⁷ No randomised controlled clinical trials in humans appear to have been undertaken,

⁶ Medsafe is the New Zealand Medicines and Medical Devices Safety Authority. It is responsible for the regulation of medicines and medical devices in New Zealand.

although there have been open label case series.⁸ It has been hypothesised that ibogaine may cause sudden cardiac death in humans, up to several days after ingestion.

35. In an article published in 2006,⁹ neurophysicist Kenneth Alper reviewed the available autopsy, toxicological, and investigative reports of all known fatalities outside of West Central Africa temporally related to the use of ibogaine from 1990 until 2008. The article examines 19 individuals who were known to have died within 1.5–76 hours of taking ibogaine. The article states that the clinical and post-mortem evidence did not suggest a characteristic syndrome of neurotoxicity.¹⁰
36. The article concludes that pre-existing medical co-morbidities (mainly cardiovascular) and/or one or more commonly abused substances explained or contributed to death in 12 of the 14 cases for which adequate post-mortem data was available. Other apparent risk factors include seizures associated with withdrawal from alcohol and benzodiazepines,¹¹ and the uninformed use of ethnopharmacological¹² forms of ibogaine.

Dr D

37. Dr D is an anthropologist with a professional interest in drug use as a cultural practice.¹³ He is the lead investigator in a New Zealand study observing outcomes and long-term efficacy for people who have been treated with ibogaine for opioid dependence. The study is an observational study¹⁴ conducted through the University of Otago, and follows patients for 12 months after their treatment with ibogaine. The study has multiregional ethics committee approval.
38. Dr D contacted Dr B in late 2011 and advised him of his, at that stage, proposed study. He asked if Dr B would like to involve any of his patients in the study. Dr D said that the clinic referred two of their clients to participate in his research. However, none of their clients were involved in Dr D's research in 2013.
39. Dr D told HDC that in 2013 he was looking for more participants for the study, and he decided to contact Dr B again, to ask whether he had anyone he would consider referring to the study. Dr D said that Dr B and Mrs C told him that they would be

⁷ See Maas U and Strubelt S (2006). Fatalities after taking ibogaine in addiction treatment could be related to sudden cardiac death caused by autonomic dysfunction. *Med Hypotheses*, 67(4), 960–4.

⁸ A type of clinical trial in which both researcher and participants know which treatment is being administered.

⁹ Alper, KR, Stajić, M, and Gill, JR (2012). Fatalities Temporally Associated with the Ingestion of Ibogaine. *Journal of Forensic Sciences*, Vol. 57(2), 398–412.

¹⁰ The exposure to natural or artificial toxic substances, which are called neurotoxins, that alter the normal activity of the nervous system in such a way as to cause damage to nervous tissue.

¹¹ A type of psychoactive drug.

¹² Substances used medicinally, especially folk remedies, by different ethnic or cultural groups.

¹³ Dr D has a PhD, he is not a medical doctor.

¹⁴ An observational study involves research undertaken by observation only. The researcher is not involved, and has no control over, the treatment being provided.

treating someone (Mrs A) and invited Dr D to come to meet her in person, which Dr D agreed to.

40. Dr B said that he checked whether Mrs A would be interested in participating in the study, and then put her directly in touch with Dr D.

Dr B

41. At the time of these events, Dr B was a vocationally registered GP and rural hospital medicine practitioner.¹⁵ He told HDC that he became interested in ibogaine in the 1990s and, in November 2010, he and Mrs C attended the second international conference of ibogaine providers, in Barcelona, Spain.
42. Dr B said that after the Barcelona conference he and Mrs C developed a set of protocols for ibogaine treatment and, in February 2011, they commenced providing ibogaine treatment at the clinic for the treatment of drug addiction.
43. Dr B stated that by 2012 the clinic had treated 38 cases with ibogaine, none of which resulted in an adverse outcome. He said that in October 2012 he and Mrs C attended the international ibogaine providers' conference in Vancouver, Canada, at which presenters raised concerns about fatalities and "near misses" associated with ibogaine's possible QT prolonging effect,¹⁶ and its potential for inducing fatal tachyarrhythmia.¹⁷
44. Dr B stated that by 2013 he had treated approximately 54 clients with ibogaine or iboga alkaloids, with no adverse outcomes.

Mrs C

45. Mrs C told HDC that she is studying addictions practice, and is in the process of becoming a professional member of the Addiction Practitioners' Association Aotearoa-New Zealand (DAPAANZ).¹⁸ She said that in 2013 she was studying towards a diploma in herbal medicine, and was a student member of the New Zealand Association of Medical Herbalists. Mrs C advised that she had been involved in over 50 ibogaine treatments at the clinic over a period of three years.
46. Mrs C stated that her role as "iboga assistant" included liaising with the client, providing information about the treatment, obtaining a completed pre-treatment questionnaire, ECG¹⁹ and blood results and providing them to Dr B, and making the arrangements for the treatment. Once the client arrived to undergo the treatment, her role included orientation of the client and completing a comprehensive assessment of

¹⁵ Dr B has not held a New Zealand practising certificate since mid 2014. Currently he is overseas.

¹⁶ The QT interval is a measure of the time between the start of the Q wave and the end of the T wave in the heart's electrical cycle. A lengthened QT interval is a marker for the potential of ventricular tachyarrhythmias and a risk factor for sudden death.

¹⁷ A heart rate over 100 beats per minute is categorised as tachycardia. Tachycardia can be a normal adaptation to certain conditions (eg, exercise) or can occur inappropriately, and is then called tachyarrhythmia.

¹⁸ Mrs C is not registered as a member of DAPAANZ.

¹⁹ Records the electrical activity of the heart.

the client. Once treatment began, the client's vital signs were monitored every 30 minutes for the first four hours, hourly for the next four hours, and two-hourly thereafter. Mrs C said that she assisted with the observations, took notes, and recorded the observations of the client.

Policies and procedures

47. Iboga New Zealand Limited provided HDC with a one-page document, "the clinic Policies and Procedures", which provides a summary of the clinic's process for screening patients, and in providing the treatment. That document provides: "Written information sent some weeks before treatment regarding treatment protocols, potential risk (including death), and disclaimer to be signed." The protocol for treatment, as set out in the clinic Policies and Procedures document, provides that a test dose of 200–400mg of ibogaine hydrochloride be given, then 600mg ibogaine one to two hours later, and then a further 200–600mg two hours later, depending on sensitivity and response. This equates to a total of three treatments over four hours. The protocol does not make any mention of possible further doses.
48. The protocol requires continuous observation of the patient for the first eight hours of treatment with ibogaine, including taking hourly pulse and oxygen saturation readings. The protocol then requires "[r]educed observations depending on response after 8 hours to 2 hourly then 4 hourly". It does not state how long the two-hourly and four-hourly observations should continue. The protocol requires a doctor trained in ibogaine detoxification to be present on the premises for the first 24 hours of treatment.
49. The protocol for treatment includes: "Preceding SOWS scale (subjective opiate withdrawal scale) to make sure the patient is in withdrawal before treatment."²⁰

Pre-treatment involvement with Mrs A

Initial contact with Mrs A

50. Dr B stated that initially Mrs A contacted the clinic by telephone. He said that Mrs A told the clinic that she had been reading about ibogaine and wanted to try the treatment in order to recover from her longstanding addiction.
51. Dr B provided HDC with email correspondence between Mrs A and Mrs C. Mrs C said that, in addition to the emails, she spoke to Mrs A by telephone four times in the lead-up to her treatment, although there is no record of these telephone conversations.
52. Mrs A referred to a telephone conversation with Mrs C in an email. Mrs A wrote: "As I've said I have been reading up on Iboga and would REALLY like to give it a go!" Mrs C sent a questionnaire to Mrs A for her to complete and return, and instructed her to have an ECG and blood tests. The questionnaire asks questions around the patient's addiction, including what he or she is addicted to, and how often he or she has used

²⁰ The Subjective Opiate Withdrawal Scale provides for self-assessment by patients of the severity of their withdrawal symptoms. The patient places a score from 0–4 for each item in a list of 16. The possible range is 0–64. The higher the score the more uncomfortable the patient is, which means that he or she is experiencing various symptoms of withdrawal.

drugs in the last month. The questionnaire also covers the patient's medical and mental health history.

53. Mrs A returned the questionnaire by email to Mrs C. The covering email stated:
“[A]nyway I definitely have not changed my mind about doing this! I have a doctor's appointment on Monday, they will send me to the hospital for those blood tests ...”
54. On the questionnaire, Mrs A documented her drug use history, and noted that over the last month she had been using morphine, but she does not state how much or how often.
55. In an email, Mrs C told Mrs A that the cost of the treatment would be \$6,500 plus GST, and outlined the potential dates for the treatment. Mrs C asked:
“How long have you been on effexor [venlafaxine]²¹ and have you ever tried to come off that in the past. We would need you to be off that prior to treatment which would mean your weaning off it soon if you want the [earliest available] date we will get back to you with a clear plan for that.”
56. Mrs A replied: “If the choice is between in 9 days time and [later] I'd rather do it sooner than later!! I don't know if it is possible to come off the effexor that fast! I'm currently on 3x37.5mgs a day, but I'm willing to give it a try. If you have any advice on how I can do that ...”
57. In response to the provisional opinion, Mrs C said that after discussing Mrs A's response with Dr B, he developed a plan for Mrs A to wean herself off venlafaxine by halving the dose two weeks before the treatment was due to commence, and stopping it one week before treatment. Mrs C said that Dr B advised her of this plan verbally, and that it was her intention to communicate the plan to Mrs A. Dr B agreed that he provided Mrs C with advice about how Mrs A should wean herself off venlafaxine, and that any communication between Mrs C and Mrs A was Mrs C “merely following [his] instructions”.
58. Mrs C emailed Mrs A suggesting that she telephone her. Mrs C told HDC that she contacted Mrs A by telephone to discuss the plan to wean her off venlafaxine, but that during this conversation Mrs A advised that she had already taken herself off it. Dr B told HDC that Mrs A “took herself off effexor [venlafaxine] of her own accord, despite our recommendation that she follow a plan”. The only reference to Mrs A stopping venlafaxine (other than in the emails outlined above) is in Mrs C's documented summary of her assessment of Mrs A, which was written retrospectively. That summary states: “She [Mrs A] had taken herself off effexor [venlafaxine] in the last month.”

²¹ A selective serotonin and norepinephrine reuptake inhibitor used for treating depression. The Medsafe Data Sheet states: “Discontinuation effects are well known to occur with antidepressants, and it is therefore recommended that the dosage is tapered gradually and the patient monitored.”

59. Mrs A sent an email to Mrs C with a copy of her blood test results and ECG, stating that the nurse who performed the ECG said that she could not interpret it, but had pointed out that the print-out of the reading said “ECG abnormal”. In that email, Mrs A stated that she had booked her tickets to travel to the clinic.
60. Mrs C told HDC that she printed out the completed questionnaire, ECG and blood test results, and gave a hard copy to Dr B for his review. She said that Dr B reviewed this information and confirmed verbally to her that treatment of Mrs A was not contraindicated, and that Mrs A could be booked in for treatment. There is no documentation in relation to Dr B’s review or interpretation of these results, nor is there any record of what advice he gave Mrs C.
61. Mrs C said that she spoke to Mrs A on the telephone about ensuring that the “triggers” in relation to drug use were removed from her home environment before she left for treatment, so that upon return home she would be in a safe environment. No notes of this conversation were provided to HDC.
62. None of the email correspondence between Mrs A and Mrs C mentions the risks of ibogaine treatment, or that deaths had been associated with its use.

Suitability for treatment

63. Dr B told HDC that his assessment of Mrs A as an appropriate client for ibogaine treatment was based on her answers to the questionnaire, the history she provided, her blood test findings (which in Dr B’s opinion were mostly within normal limits), the ECG, and his clinical examination, which (according to Dr B) focused mostly on the health of her heart and lungs (see below).
64. With regard to the ECG, Dr B stated that the computerised interpretation “was a worry” as it detailed multiple abnormalities. He stated:

“Because of this I had to have a very careful look at this, and, as a rural hospital emergency physician, experienced in the treatment of acute MI²² and arrhythmias, I was confident that this ECG was within normal limits.”

65. Dr B said that although the computerised trace included the comment “premature Ventricular complexes, and premature supraventricular complexes”, in his view, there was no evidence of those on the ECG, and that interpretation was based on a baseline artifact in Lead V3. With regard to the statement on the ECG trace: “Probable inferior infarct, QS in III, with Q in II, minor repolarisation disturbance secondary to infarct, flat or low negative T in AVF, with negative T in III”, Dr B stated:

“There was indeed a QS and negative T wave in lead III and flattened T wave segment in AVF but there were no significant Q waves in II or AVF, the T waves in Lead II were upright with a good repolarisation voltage, so, in combination with the fact there was no history of significant chest pain I felt these changes were not significant and the ECG was within normal limits.”

²² Myocardial infarction is the medical term for a heart attack.

66. There is no documented record of Dr B's interpretation of the ECG or blood test results. The only reference to these tests in the records was documented by Mrs C retrospectively, and states: "ECG result was normal and Blood screens were all clear."

Patient Informed Consent Form

67. Dr B stated that prior to treatment every client is "mailed a copy of [the clinic's] treatment protocols, together with a detailed information sheet and consent form, to be signed by each client in advance of their treatment".
68. There is no evidence that these documents were sent to Mrs A, other than an email from Mrs C to Mrs A which stated: "I have attached an info sheet for you to read through. If you have any questions then please ring or email me." It is unclear whether this is a reference to a consent form or the information sheet.
69. Dr B provided HDC with an unsigned one-page "Patient Informed Consent Form" (the Consent Form). The Consent Form outlines what ibogaine is and what its side effects are. It outlines the requirements for treatment, in particular, stating:

"I also agree that I have not used any illicit substances or drugs 12 hours prior to treatment, 24 hours for methadone, and 5 days for methamphetamine or alcohol."

70. It states that the patient will be "monitored for at least the first 24 hours after taking Ibogaine". The Consent Form also includes the following statement:

"The risks involved in this study are those incurred by taking Ibogaine, which, although registered for prescription by medical practitioners in New Zealand, is still a Schedule 4 unapproved medicine. The state of science related to Ibogaine is still in its infancy, and not many studies have been done on it as a treatment. It is however, well proven in many thousands of cases in many different countries to be safe in the doses that will be given in this case. No studies have been done on the long term side effects of Ibogaine, but there have been no reported or experienced long term side effects from ingesting Ibogaine."

71. The only reference to the risks of ibogaine treatment in the Consent Form is a statement: "I have been informed that taking Ibogaine with any other drugs may be harmful, and in the worst circumstances may lead to death."
72. In relation to the Consent Form's reference to participation in a "study", Dr B stated that in October 2012, at the international ibogaine providers' conference in Vancouver, he presented a summary of the cases he had treated with ibogaine. However, he provided no evidence of undertaking a research study of ibogaine.
73. Dr B told HDC that Mrs A was provided with a copy of the Consent Form, "but the actual signing of it was overlooked".

Contact with general practitioner

74. There is no record of Dr B having consulted Mrs A's GP prior to Mrs A's treatment. Dr D told HDC that he asked Dr B whether he had been in contact with Mrs A's other health providers, and Dr B responded that he had not been able to contact her doctor.

Day 1 — Mrs A arrives at the clinic

75. Mrs A missed her flight, so she arrived at 9am the day after treatment was scheduled to start.
76. Dr D told HDC that he travelled on the same flight as Mrs A. He said that he had been contacted by Dr B and told that Mrs A had missed her flight and been rescheduled on the same flight as him. Dr D said that he identified Mrs A prior to boarding the plane, and introduced himself. He said that he noted that "[s]he appeared very drug affected and fell asleep almost immediately on the plane". Dr D said that when they arrived at the clinic he suggested to Mrs C that she should check Mrs A's bags for concealed drugs, given her condition on the plane.
77. Mrs C said that, after arriving at the clinic, Mrs A rested for approximately four hours. Mrs C met with Mrs A, after her rest, at about 2pm on Day 1 for an assessment. The meeting took approximately two hours, and they discussed Mrs A's issues, lifestyle, and possible changes to her lifestyle after treatment.
78. Mrs C recorded her observations from this assessment in a document headed "Comprehensive Assessment and Treatment Notes". However, this record was made some two months after the assessment, and was compiled from handwritten notes made by Mrs C at the time and her recollection of her conversation with Mrs A. Mrs C also documented Mrs A's vital observations on a separate record entitled "Clinical Treatment Notes",²³ including her height and weight, that she was a heavy smoker, and her blood pressure was 128/69mmHg.²⁴

Sevredol

79. On Day 1 at 2pm, according to the Clinical Treatment Notes, Mrs C administered 100mg of Sevredol to Mrs A.²⁵ Further Sevredol was administered at 8pm (100mg) and 10pm (120mg).
80. Dr B stated that Sevredol was given to help "stabilise" Mrs A, and said that he "determined the doses she needed based on [his] clinical assessment, and her SOWS [Subjective Opiate Withdrawal Score], and the doses were noted by Mrs C in the 'Clinical Treatment Notes'". However, as set out below, Dr B did not assess Mrs A until 8pm on Day 1, well after the first dose of Sevredol was administered.

Consultation with Dr B

81. At approximately 8pm, Dr B met with Mrs A for two hours. He told HDC that he took Mrs A's medical history and performed an examination during this assessment. There is no documentation of this assessment.

²³ This record appears to have been made contemporaneously by Mrs C.

²⁴ Normal blood pressure is considered to be between 100/60 and 140/85mmHg.

²⁵ A type of morphine used for severe pain relief.

Day 2

Further consultation with Dr B — 8am

82. Mrs A slept overnight, and Dr B reviewed her again at 8am the following morning. Dr B said that he auscultated Mrs A's heart and lungs. There is no documentation of this assessment or of Dr B's management plan with respect to the proposed ibogaine dosage regimen. The only mention of the assessment is in the Clinical Treatment Notes, which state that Mrs A was "[c]hecked by [Dr B]". Dr B told HDC that he would have documented his findings only if anything abnormal or unexpected was uncovered.
83. Dr B told HDC that the lack of comprehensive documentation was "mostly due to the fact that [Mrs A's] late arrival meant that the day I had put aside which would have allowed me to give her my undivided attention was no longer available". Dr B also said that once Mrs A's treatment had commenced he also had his hospital commitments, which put "the onus of the recording of the treatment onto the Iboga Assistant [Mrs C]". Dr B said that the process in place at the clinic at the time of Mrs A's treatment was that clinical observations and vital observations (pulse, blood pressure, etc) were recorded by Mrs C.
84. The records show that 100mg of Sevredol was administered at 8am.

Consultation with Dr D — 9am

85. As Mrs A had agreed to participate in Dr D's research study, Dr D met with her at 9am and spent approximately two hours discussing the study with her. Dr D told HDC that they discussed the research protocol. He could not recall any discussion about the risks of ibogaine, as he was seeking consent to her participation in his observational study, not consent to treatment. It was agreed that she would participate in the study after her treatment. They then went through some assessments of her drug dependence and her mood. Mrs A signed a consent form to participate in Dr D's research, a copy of which was provided to HDC. This consent form is quite different from the Consent Form for treatment with ibogaine, as it relates only to participation in the study.

Further assessment by Dr B — 4pm

86. Mrs C then took Mrs A, Dr D, and three other people²⁶ to local hot springs at about midday, returning at 4pm. Dr B stated that he met with Mrs A again for another discussion at about 4pm. Again, the only record of this consultation is a note in the Clinical Treatment Notes, which states: "Talked with [Dr B] pre treatment."
87. Dr D said that at about 5pm Mrs C took him to the airport. He understood that Mrs A was going to be treated that evening.
88. Dr B stated that on the evening of Day 2 Mrs A's SOWS score was too low to commence treatment (that is, she was not in sufficient withdrawal).²⁷ The decision was therefore made to reassess Mrs A in the morning. The Clinical Treatment Notes

²⁶ It is unclear who these people were.

²⁷ Mrs A's SOWS level is recorded as being 9 at 6pm, and 11 at 7pm.

at 7pm state: “Decided to treat in the am as SOWS scores too low. [Dr B] decided to treat in am when scores should be higher.”

89. The records show that further Sevredol was administered at 12pm (100mg) and 7pm (120mg).

Day 3 — treatment commences

90. When Mrs A was assessed again at 7am on Day 3 her SOWS score was 21. Dr B told HDC that this was still low, and so the decision was made to wait another 45 minutes. The Clinical Treatment Notes at 7am state: “Score still a bit low. Waited 45 mins. [Dr B] said to wait. Worked out treatment plan with [Dr B].” Dr B stated that at 7.45am Mrs A’s SOWS score was sufficiently high to start treatment (29.5).
91. At 7.50am, Mrs A was given a test dose of ibogaine, recorded as “HCL 2 x 200mg”, and her observations were taken (oxygen saturation 99%, blood pressure 128/69mmHg and pulse rate 71 beats per minute (bpm)²⁸). Narrative observations are recorded approximately every 20–30 minutes until 1pm. They are then recorded hourly until 5pm.
92. Mrs A’s “flood dose” of ibogaine was given at 8.50am (HCL 3 x 200mg). At 10.50am, her blood pressure is recorded as 98/69mmHg, and at 1.02pm as 98/70mmHg. At 4.11pm, her blood pressure was 124/86mmHg and her pulse rate 86bpm.
93. Further ibogaine doses were given at 5.45pm (HCL 2 x 200mg), 7.25pm (HCL 1 x 200mg) and 8.40pm (HCL 1 x 200mg). There are no further recordings of vital signs for that day.

Day 4 — treatment continues

94. Mrs A’s last dose of ibogaine was given at 7am (HCL 2 x 200mg) on Day 4, at which time her blood pressure was 96/75mmHg. At 7am on Day 4, Mrs A was also administered two diazepam²⁹ 5mg tablets.
95. On Day 4 at 9am, Mrs A’s blood pressure is recorded as 97/80mmHg. Thereafter, no vital signs were recorded.
96. Mrs C stated: “[F]rom [Day 2–Day 4] I continued to ensure the client was comfortable, undertook the ongoing observations, and maintained the notes on my laptop. I regularly updated and liaised with [Dr B] about [Mrs A’s] condition.” Dr B told HDC that, during treatment, he was “present on some of the occasions when [oxygen saturations] and pulse and BP were recorded”.
97. The records indicate that Mrs A was smoking regularly throughout the treatment.

²⁸ A normal resting heart rate for adults ranges from 60 to 100bpm.

²⁹ A benzodiazepine used to treat anxiety and withdrawal symptoms.

Dr B departs — midday

98. At 12 noon on Day 4, the records state: “Lying still. Facing window. Checked by Dr. Breathing pink sleeping — prior to leaving clinic.” Dr B then left to travel overseas and sole responsibility for monitoring Mrs A was passed to Mrs C.
99. There is no evidence to indicate that Mrs A was informed of Dr B’s planned departure, or of the fact that, owing to the late start of her treatment, he would not be present during the monitoring stage of her treatment.

Monitoring

100. At 1pm Mrs C recorded that Mrs A was “[l]ying still. Facing bathroom.” At 2pm Mrs A is recorded to be “[l]ying still. On side, peaceful.” At 3pm Mrs A is recorded to be “[l]ying still. Arm raised over head.” At 4pm she is recorded to be “[l]ying still. Turned heater on and she didn’t stir.” At 7pm the record states: “Sleeping. [Mrs A’s husband] rang.” At “11pm approximately” Mrs C recorded: “[L]ast check —”
101. Mrs C told the Police that the last time she checked Mrs A was at 7pm on Day 4, and that Mrs A had not moved since 3pm. However, she told HDC: “There were no concerns at the 11pm check.”
102. Dr B stated:

“[Mrs A] was intensively monitored for 24 hours after treatment was first initiated, as per our protocol. During this period, observations and clinical recordings were within normal and expected ranges. Because of this [Mrs A] was assessed as fine to be left sleeping unobserved for her second night.”

103. As stated above, the Consent Form states that the patient will be “monitored for at least the first 24 hours **after** taking Ibogaine” (emphasis added).

Day 5 — Mrs A found dead

104. When interviewed by the Police, Mrs C stated that at 6am on Day 5, she went into Mrs A’s room to turn off the heater, and found Mrs A dead. Mrs C told the Police that Mrs A was “found deceased in same position as yesterday afternoon”. The Police report stated that, when found, Mrs A was “lying on her side with her arm over her head and ... had been in bed since 11am, [Day 4]. Hadn’t moved since 1500 hours that day.” Mrs C recorded in the notes that, at 6am, “client was cold to touch”.
105. Mrs C recorded: “I immediately rang [Dr B] who was on route [overseas]. I then rang 111.” She then rang a number of local friends, including one who made a statement to the Police. The friend said that he heard a siren at 6–6.30am and, about 10 minutes later, Mrs C called him and told him that one of their clients had died. In his statement to the Police, the friend said that he and his wife arrived at the clinic before the Police. The friend stated: “At some point we were allowed to go into the room where [Mrs A] was and she just looked like she was sleeping. I walked over to look at her face but she just looked like she was sleeping on her side.”

106. The Clinical Treatment Notes (completed by Mrs C) and the Police report both state that the Fire Service arrived at the clinic first, followed by the ambulance and the Police.

Subsequent events

107. Iboga New Zealand Limited told HDC that it has not carried out an investigation or review of the “adverse event” (Mrs A’s death), as it is awaiting the Coroner’s report. However, the day following Mrs A’s death, the company resolved that no further ibogaine treatments would be commenced on new clients, pending the outcome of the Coroner’s report on Mrs A’s death. There is also a statement to this effect on the clinic website. The company stated that a full review of the adverse event will be undertaken upon completion of the Coroner’s inquiry.
108. The Coroner provided HDC with the toxicology results, which indicate that Mrs A had significantly high acetone levels with a blood level of 60mg/L (average in adults 0.15 to 15.4mg/L), which are most commonly caused by uncontrolled diabetes or a prolonged period of fasting.
109. Mrs A’s ibogaine level was approximately 0.06mg/L, although there was insufficient blood for an accurate estimate. A toxicologist commented that “ibogaine has a short half-life so levels in the blood will drop rapidly”. She added that post-mortem ibogaine levels of 0.73 and 0.36mg/L have been associated with deaths following ingestion of the drug. Low levels of diazepam were also found, which is consistent with the dose administered during Mrs A’s treatment.
110. The post mortem report concluded that “[o]n the basis of the lack of any significant cardiac pathology or history, and lack of any other definable cause of death there remains a strong possibility that this woman’s death is related to ibogaine ingestion, and most probably related to a cardiac arrhythmia.”

Relevant standards

111. The Medical Council of New Zealand publication *Good Prescribing Practice* (April 2010) provides:

“Prescribing unapproved medicines

1.1 You may prescribe unapproved or provide medicines for a purpose for which they have not been approved but, if you decide to do so, you should take responsibility for overseeing the patient’s care, including monitoring and any follow-up treatment. You may also like to discuss the patient’s treatment with a senior colleague. You should also inform the patient:

- whether there are any other options available
- of any risks, side effects, costs or benefits

- that the medicine being prescribed is for an unapproved use
 - that details relating to the supply of the unapproved medicine will be supplied to the Director-General of Health.”
112. The Medical Council of New Zealand’s “Statement on Complementary and Alternative Medicine” (March 2011) provides definitions of Complementary and Alternative Medicines, including the World Health Organization definition:
- “Complementary and alternative medicine (CAM) refers to a broad set of healthcare practises that are not part of a country’s own tradition and not integrated into the dominant healthcare system. Other terms sometimes used to describe these health cares include ‘natural medicine’, ‘non conventional medicine’ and ‘holistic medicine’.”
113. With regard to doctors who practise CAM, the statement refers to a Medical Practitioners Disciplinary Tribunal decision,³⁰ which states:
- “There is an onus on the practitioner to inform the patient not only of the nature of the alternative treatment offered but also the extent to which that is consistent with conventional theories of medicine and has or does not have, the support of the majority of practitioners.
- ...
- Careful attention to the process of informed consent is particularly important when the proposed treatment is expensive or in any way innovative, and you should advise patients when scientific support for treatment is lacking.”
114. The statement endorses the same Tribunal decision’s statement that “[t]he Tribunal recognises the persons who suffer from chronic complaints or conditions for which no simple cure is available are often willing to undergo any treatment which is proffered as a cure. As such they are more readily exploited.”
115. The Medical Council of New Zealand “Statement on Complementary and Alternative Medicine” further states:
- “17. With **assessing** patients you must:
- (a) perform a pertinent history and physical examination of patients, sufficient to make, or confirm, a generally recognised diagnosis, and in this meet the standard of practice expected of the profession.
 - (b) reach a diagnosis by using a diagnostic system demonstrated by appropriate research methodologies to have a high level of accuracy and proven benefits to patients.

³⁰ *Director of Proceedings v Dr R W Gorringer*, MPDT Decision No: 237/02/89D.

- (c) advise patients of the evidence based and conventional treatment options, their risks, benefits and efficacy, as reflected by current knowledge.
- (d) document all of the above in accordance with sound practice.

18. In **treating** patients and engaging in health promotion you must:

- (a) ensure that the treatment is efficacious, safe and cost effective.
- (b) have current knowledge and skills in your area of practice.
- (c) be competent in the practices you employ.
- (d) act honestly and in your patient's best interest according to the fundamental ethics of the profession.
- (e) provide sufficient information to allow patients to make informed choices, and to refer to, or consult with, others when patients request it, when you require assistance or when the standard of practice requires it (where there is no reason to believe such a referral would expose the patient to harm there is no barrier to making a referral to a CAM practitioner or to utilising a CAM treatment).
- (f) not misrepresent information or opinion. Patients must be made aware of the likely effectiveness of a given therapy according to recognised peer-reviewed publications, notwithstanding your individual beliefs.
- (g) obtain informed consent to any proposed treatment."

116. The New Zealand Medical Association "Code of Ethics" provides:

"49. Boundaries between formalised clinical research and various types of innovation have become blurred to an increasing extent. Doctors retain the right to recommend, and any patient has the right to receive, any new drug or treatment which, in the doctor's considered judgement, offers hope of saving life, re-establishing health or alleviating suffering. Doctors are advised to document carefully the basis for any such decisions and also record the patient's perception and basis for a decision. In all such cases the doctors must fully inform the patient about the drug or treatment, including the fact that such treatment is new or unorthodox, if that is so.

50. In situations where a doctor is undertaking an innovative or unusual treatment on his or her own initiative, he or she should consult suitably qualified colleagues before discussing it with, or offering it to, patients. Doctors should carefully consider whether such treatments should be subject to formal research protocols."

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

“Introduction

Records form an integral part of any medical practice; they help to ensure good care for patients and also become critical in any future dispute or investigation.

01 Maintaining patient records

(a) You must keep clear and accurate patient records that report:

relevant clinical findings

decisions made

information given to patients

any drugs or other treatment prescribed.

(b) Make these records at the same time as the events you are recording or as soon as possible afterwards.”

Opinion: Introduction

118. At the time of these events, Dr B was a vocationally registered general practitioner and rural hospital medicine practitioner who had developed an interest in treating drug addiction with ibogaine. Ibogaine is an unapproved medicine in terms of the Medicines Act 1981.
 119. Dr B began offering ibogaine treatment in February 2011 through the clinic, which he operated with Mrs C. By June 2013, Dr B had treated approximately 54 clients with ibogaine or iboga alkaloids.
 120. On Days 3 and 4, the clinic treated Mrs A with ibogaine, following which she was found dead at 6am on Day 5. Mrs A was the first fatality the clinic or Dr B and Mrs C had experienced with the use of ibogaine.
 121. This report considers a number of aspects around the care and treatment of Mrs A with ibogaine, as well as the adequacy of the systems in place at the clinic for the provision of such treatment.
 122. It is not my role to establish what caused Mrs A’s death. That is the role of the Coroner. Accordingly, my findings should not be interpreted as having any implication as to the cause of Mrs A’s death.
-

Opinion: Dr B

Information and consent — Breach

123. Right 7(1) of the Code provides that services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent. The Code also provides in Right 7(6):

“Where informed consent to a health care procedure is required, it must be in writing if —

- (a) The consumer is to participate in any research;
- (b) The procedure is experimental.”

Was the prescription of ibogaine experimental treatment?

124. It is therefore important in terms of the informed consent process whether or not the prescription of ibogaine in these circumstances amounted to an experimental procedure. Previously I have considered the meaning of experimental procedure when considering whether the prescription of ketamine for treatment of treatment-resistant depression constituted an “experimental procedure”.³¹
125. In that case I concluded that, when considering whether or not a particular treatment is experimental, “the essential issue is whether there is a body of evidence that supports the treatment or procedure being safe and efficacious”.³²
126. One of my experts in that case, psychiatrist Associate Professor Wayne Miles, advised that there would be a range of views in relation to the point at which the evidence base regarding the safety and efficacy of a particular medication would be considered sufficient to support prescribing for a specific clinical indication. He stated:
- “I suspect the majority would want evidence that the treatment has been used in humans safely and also have a modest degree of reported evidence that it does have a desired effect in the condition under question.”
127. Associate Professor Miles advised that a conservative position would require randomised controlled trial (RCT) evidence, but many clinicians would be prepared to contemplate less. In his view, safety data in humans is essential, and there would need to be either case reports attesting to benefit or a strong theoretical/physiological argument for the product having the potential to produce benefits.
128. In the case of ibogaine, there is scant evidence of its safety and efficacy. I note that there have been no reported randomised controlled clinical trials in humans relating to the use of ibogaine, although there have been open label case series. However, it has been hypothesised that ibogaine may cause sudden cardiac death up to seven days after treatment. There is anecdotal evidence that some consumers have gained benefit from taking ibogaine, but there have been deaths of consumers who have taken

³¹ Opinion 11HDC01072 (9 July 2013).

³² Ibid page 30.

ibogaine. I note that the Consent Form itself recognises that “the state of science relating to Ibogaine is still in its infancy”, and that “not many studies have been done on it as a treatment”. In my view, there is insufficient robust, clinical evidence that ibogaine is either safe or efficacious and, accordingly, I find that Dr B was prescribing an unapproved medicine for an experimental use.

Information about treatment and consent

129. I have been provided with no evidence that Dr B had any direct contact with Mrs A prior to her arrival. The information given to Mrs A about the treatment was provided by way of telephone conversation and email exchanges between Mrs A and Mrs C.
130. The emails suggest that Mrs A had been reading about ibogaine and had formed the view that it might be appropriate to treat her longstanding drug addiction. There is no record of the accuracy, source or content of the material Mrs A had been reading, or whether it included any information about the previous adverse events related to ibogaine. I note that this Office has previously stated:³³
- “It is unwise to assume that a patient has been adequately informed by way of internet research, as the information obtained may be inaccurate or the patient may not have understood it.”
131. Dr B has supplied the email trail between Mrs A and Mrs C, and also an unsigned one-page Consent Form as evidence of the informed consent process followed with Mrs A. Mrs C emailed an “info sheet” to Mrs A. The email trail did not include the attachment. It is unclear whether this was the Consent Form, or another document. Dr B said that the Consent Form was provided to Mrs A, “but the actual signing of it was overlooked”.
132. I am not satisfied that Mrs A was ever supplied with the Consent Form. However, regardless of whether the Consent Form was, in fact, provided to Mrs A, I have some concerns about its content. The form states: “I have been informed that taking Ibogaine with any other drugs may be harmful, and in the worst circumstances may lead to death”, and undertakes that the patient will be “monitored for at least the first 24 hours after taking Ibogaine”.
133. Although there was no suggestion from the records that Mrs A was taking part in a research study conducted by Dr B, the Consent Form also states that “the risks involved in this study are those incurred by taking Ibogaine”, and then that ibogaine is a Schedule 4 unapproved drug. The form advises that “the state of science relating to Ibogaine is still in its infancy”, and that “not many studies have been done on it as a treatment”. The form goes on to state: “[I]t is, however, well proven in many thousands of cases, in many different countries to be safe in the doses that will be given in this case. No studies have been done on the long term side effects of Ibogaine, but there have been no reported or experienced long term side effects from ingesting Ibogaine.”

³³ Opinion 08HDC20258 (11 November 2009).

134. In my view, this information is misleading. It confines the risk of death to the circumstance in which a consumer combines ibogaine with other drugs, and provides reassurance that ibogaine is safe, with no information about the risks and international evidence of previous adverse events, which Dr B has acknowledged he was aware of at the time of Mrs A's treatment.
135. The Medical Council of New Zealand's *Good Prescribing Practice* states that when prescribing unapproved medicines, the doctor should inform the patient:
- “• Whether there are any other options available.
 - Of any risks, side effects, costs or benefits.
 - That the medicine is being prescribed for an unapproved use.
 - That details relating to the supply of the unapproved medicine will be supplied to the Director-General of Health.”
136. In my view, only one of these requirements is met by the content of the Consent Form — that ibogaine was being prescribed for an unapproved use. I consider that the information in the Consent Form unduly focused on the benefits of treatment with ibogaine, and did not give balanced information about the risks. Furthermore, the Consent Form does not explain that details relating to the supply of ibogaine would be supplied to the Director-General of Health.

Conclusion

137. As stated above, having made the finding that Dr B's use of ibogaine was experimental, the requirements in accordance with Right 7(6) of the Code apply, that is, informed consent must be given in writing. In my view, there are some circumstances in which this may be satisfied by way of email communications. However, I am not satisfied that this occurred in this case. In particular, I do not consider that, at the time of her email correspondence with Mrs C, Mrs A was sufficiently informed to be in a position to give informed consent to her treatment with ibogaine.
138. Furthermore, even if Dr B did provide Mrs A with the Consent Form, she was not provided with all the information she should have been about being prescribed an unapproved medication. A reasonable consumer in Mrs A's circumstances would expect to be fully and accurately informed about the risks and side effects of ibogaine, and the experimental nature of its use. In my view, Dr B failed to provide Mrs A with such information and, accordingly, breached Right 6(1) of the Code. Furthermore, Mrs A did not give written informed consent to the treatment, and so Dr B also breached Right 7(6) of the Code.

Decision to treat — No breach

139. My independent expert advisor, GP Dr David Maplesden, advised me that “as there is a paucity of robust evidence for appropriate use of Ibogaine in terms of pre treatment screening, dosing regimes, monitoring etc, it is not possible to describe Dr B's management of Mrs A against ‘expected’ or ‘accepted’ standards, other than those

standards applying to use of unapproved medicines in New Zealand”. Accordingly, in assessing the standard of care provided by Dr B, I am guided by the general advice provided by my experts, and by the policies and procedures the clinic had in place at the time.

140. Mrs C sent a questionnaire to Mrs A for her to complete and return, which she did. The questionnaire includes information about Mrs A’s recent drug usage.
141. Mrs A emailed her medical test results, including a print-out of an ECG, noting that the nurse who conducted the ECG said that she could not interpret it, but had pointed out that the printed result said “ECG abnormal”. Mrs C said that she printed the completed questionnaire, ECG and blood test results, and gave copies to Dr B for his review.
142. Dr B said that his assessment of Mrs A as an appropriate client for ibogaine treatment was based on her answers to the questionnaire, the history provided, her blood test findings (which were mostly within normal limits), the ECG, and his clinical examination.
143. With regard to the ECG, Dr B stated that the computerised interpretation “was a worry” as it detailed multiple abnormalities. He stated that as a rural hospital emergency physician he is experienced in the treatment of heart attacks and arrhythmias and, having reviewed the ECG printout himself, he was confident that it was within normal limits. Dr B said that he was further reassured by the clinical examination he conducted on Day 1, which (according to Dr B) focused mainly on the health of Mrs A’s heart and lungs. This physical assessment was not documented.
144. My independent expert advisor, GP Dr George Tripe, considered that the ECG findings were insignificant, and that it was reasonable to classify it as “unremarkable”. Dr Tripe advised: “I would report this ECG as normal sinus rhythm with minor sinus arrhythmia. I would accept the QRS complexes, ST segments and T waves as within normal limits.”
145. I note that the New Zealand Medical Association Code of Ethics provides that in situations where a doctor is undertaking an innovative or unusual treatment he should consult suitably qualified colleagues before offering it to patients. However, I also note Dr Tripe’s advice that, given that it would be unlikely that any cardiologist would have experience or knowledge of ibogaine, there would have been limited value in consulting a specialist in relation to the ECG in the context of ibogaine treatment. However, in my view, consulting Mrs A’s GP prior to treatment would have been sensible. I note that Dr B did not do this.
146. Dr Tripe noted that Mrs A’s blood tests showed minor changes in the liver function tests, and slightly reduced albumin, but that these were a probable consequence of past drug use and poor diet. Dr Tripe said that the treatment priority in these circumstances would be to stop the drug use.

147. Overall, guided by Dr Tripe's advice, I accept that, with regard to the ECG and blood test results, Dr B's decision to accept Mrs A as a suitable candidate for ibogaine treatment was reasonable in the circumstances.

Standard of care — Breach

Venlafaxine

148. During initial discussions with Mrs A about potential ibogaine treatment, Mrs C told Mrs A that she would need to cease taking venlafaxine prior to treatment. The Medsafe Data Sheet for venlafaxine states: "Discontinuation effects are well known to occur with antidepressants, and it is therefore recommended that the dosage is tapered gradually and the patient monitored."
149. Mrs C told Mrs A that a plan to wean off venlafaxine would be provided. According to Mrs C, while Dr B did develop a plan for Mrs A to wean off venlafaxine, when she came to communicate it to Mrs A she had already ceased taking it. As noted by Dr Tripe, one of the common behaviours of drug users is a tendency to disregard medical advice. Providing Mrs A with a documented plan in relation to weaning from venlafaxine and the need to be monitored appropriately during this process was therefore very important. However, I accept that Mrs A ceased venlafaxine on her own accord before a plan could be communicated to her.
150. The clinic's protocol for treatment, as set out in the Policies and Procedures document, provided that a test dose of 200–400mg of ibogaine hydrochloride be given, followed by a "flood dose" of 600mg ibogaine one to two hours later, and then a further 200–600mg two hours later, depending on sensitivity and response. This equates to three treatments over four hours. However, Mrs A received six doses of ibogaine over approximately 24 hours between 7.50am on Day 3 and 7am on Day 4. There is no record of the rationale for this departure from the treatment protocol.

Monitoring

151. The Consent Form states that the patient will be "monitored for at least the first 24 hours after taking Ibogaine". The Policies and Procedures document also states that monitoring is required after ibogaine administration. The protocol specifies continuous observation for the first eight hours (including hourly pulse and oxygen saturations), and then reduced observations after eight hours to two hourly, then four hourly with no specified time period. A doctor trained in ibogaine detoxification is to be present "for the first 24 hours".
152. It is evident that the monitoring protocol was not complied with. Dr B administered the test dose of ibogaine at 7.50am on Day 3, after which Mrs A's observations were taken. At that time her oxygen saturation was 99%, blood pressure 128/69mmHg, and her pulse rate 71bpm. Mrs A was given a "flood dose" of ibogaine at 8.50am. No observations were recorded at this point. At 10.50am her blood pressure had dropped to 98/69mmHg and, at 1.02pm, it was 98/70mmHg. However, by 4.11pm her blood pressure was 124/86mmHg and her pulse rate was 86bpm. Further ibogaine doses were given at 5.45pm, 7.25pm and 8.40pm. However, no further vital signs were recorded that day. Mrs A's last dose of ibogaine was given at 7am on Day 4, at which

time her blood pressure was 96/75mmHg. The final blood pressure recording was at 9am, and was 97/80mmHg.

153. The protocol also required a doctor trained in ibogaine detoxification to be present “for the first 24 hours”. Dr B stated that once Mrs A’s treatment commenced, he had hospital commitments, so he put “the onus of the recording of the treatments onto the iboga assistant (Mrs C), although [he] was at all times available by telephone and never more than a few minutes away if needed”.
154. Dr B stated that he was present at some of the occasions when the vital signs were recorded. Mrs C said that she undertook the ongoing observations and maintained the notes, and she updated and liaised with Dr B regularly about Mrs A’s condition.
155. At 12 noon on Day 4, Dr B checked Mrs A. The record states that she was sleeping. No vital signs are recorded. Dr B then left to go overseas, and the sole responsibility for monitoring Mrs A was passed to Mrs C.
156. In my view, Dr B’s monitoring of Mrs A was regrettably lax. If Mrs A’s late arrival meant that Dr B was unable to monitor her adequately during and after the treatment, he should not have commenced the treatment. It was Dr B’s responsibility to oversee the required monitoring and ensure that Mrs A’s vital signs and other physical signs were monitored regularly (as required by the protocol) and were recorded.
157. I do not consider it was appropriate for Dr B to leave five hours after Mrs A received her last treatment, and for him to pass the responsibility for monitoring his patient to someone who had no medical training. I note that the Medical Council of New Zealand publication *Good Prescribing Practice* states that the doctor should take the responsibility for overseeing the patient’s care, including monitoring and any follow-up treatment, when prescribing unapproved medicines.

Conclusion

158. Dr B departed from the ibogaine treatment protocol, and did not monitor Mrs A adequately. In my view, Dr B failed to provide services to Mrs A with reasonable care and skill and, accordingly, breached Right 4(1) of the Code.

Records — Breach

159. Dr B provided HDC with limited records of the care provided to Mrs A. The records provided to HDC contain no documentation of the physical assessments undertaken by Dr B on Day 1 or Day 2, although he stated that he auscultated Mrs A’s heart and lungs, and would have recorded findings if anything abnormal or unexpected had been disclosed. He did not document his interpretation of the ECG or the blood test results, even though there were abnormalities in the results. He also failed to document Mrs A’s management plan with respect to the proposed ibogaine dosage regimen, including the rationale for the timing of the doses and the amounts he administered (which were not in accordance with the process or dosages set out in the clinic’s treatment protocol).

160. Furthermore, Dr B did not ensure that the “Comprehensive Assessment Notes” completed by Mrs C were completed contemporaneously. These were not completed until two months after Mrs A’s death, and were taken from Mrs C’s contemporaneous handwritten notes, her recollection of her conversation with Mrs A when she first arrived, and “a brief recording of that conversation”.
161. Dr B acknowledged that the documentation fell below his usual standards. He stated that this was because of Mrs A’s late arrival, meaning that the day he had put aside for her treatment was no longer available, and because once treatment commenced he had commitments at the hospital. These are not valid excuses.
162. Dr Maplesden advised that the standard of documentation fell below expected standards at least to a moderate degree. As I have noted previously, the importance of good record-keeping (including comprehensive consultation notes) cannot be overstated.³⁴ In my view, Dr B should be mindful of his professional obligation³⁵ to keep comprehensive and accurate records. For failing to maintain adequate records I find that Dr B failed to comply with professional standards and, accordingly, breached Right 4(2) of the Code.

Opinion: Mrs C — Breach

163. Mrs C is not a trained health professional. However, by her own account she had been involved in over 50 ibogaine treatments over a period of three years. Mrs C stated that as the “iboga assistant”, her role included liaising with the client, providing information about the treatment, obtaining the completed questionnaire, ECG and blood results and providing them to Dr B, and making the arrangements for the treatment. Once the client arrived to undergo the treatment, her role included orientation of the client and completing a comprehensive assessment of the client. During the treatment, the client’s vital signs were monitored every 30 minutes for the first four hours, hourly for the next four hours, and two hourly thereafter. She assisted with the observations, took notes, and recorded the observations of the client.
164. I have concerns about Mrs C’s involvement in the care provided to Mrs A, particularly in relation to monitoring.
165. Mrs C was aware of the requirements set out in the clinic’s Policies and Procedures document, including continuous observation for the first eight hours, including hourly pulse and oxygen saturations, and then reduced observations after eight hours to two hourly, then four hourly. The Policies and Procedures document also requires a doctor trained in ibogaine detoxification to be present on the premises for the first 24 hours.

³⁴ Opinions 10HDC00610 (29 February 2012 at page 10) and 13HDC00031 (20 March 2014) at page 9.

³⁵ *Patient A v Nelson Marlborough District Health Board* (HC) BLE CIV-2003-406 — 14, 15 March 2001.

166. Mrs C took Mrs A's observations because Dr B had hospital commitments once Mrs A's treatment commenced. In my view, Mrs C should have recognised that it was inappropriate for her to have the sole responsibility for monitoring Mrs A while Dr B was attending to his hospital commitments and then travelling overseas.
167. On Day 3, Mrs A's vital signs were recorded on several occasions, with the last record of vital signs at 4.11pm (when Mrs A's blood pressure was 124/86mmHg and her pulse rate 86bpm). Although further ibogaine doses were given at 5.45pm, 7.25pm and 8.40pm, no further vital signs were recorded that day. Mrs A was given a final dose of ibogaine at 7am on Day 4, and her blood pressure at that time was 96/75mmHg. A final blood pressure recording was taken at 9am (97/80mmHg) and, thereafter, no further vital signs are recorded. This is clearly less than the requirements of the protocol.
168. From midday on Day 4, when Dr B left, the monitoring conducted appears to have amounted to only visually checking Mrs A. From 2pm, such records as exist indicate that she was lying still throughout this period. At 3pm, she was recorded to be "lying still. Arm raised over head". At "11pm approximately" Mrs C recorded "last check —".
169. It is unclear whether Mrs A was checked at 11pm, as Mrs C told the Police that the last time she checked Mrs A was 7pm on Day 4. In any event, when Mrs C checked Mrs A at 6am on Day 5, she was dead. Mrs C told the Police that Mrs A was "found deceased in same position as yesterday afternoon", lying on her side with her arm over her head. Mrs C also told the Police that Mrs A had not moved since 3pm on Day 4. In my view, Mrs C's monitoring of Mrs A was insufficient, and should have included (as a minimum) checking her breathing and pulse at each check.
170. When Mrs C discovered Mrs A was not breathing, she did not immediately commence CPR or telephone emergency services. She stated that her first action was to ring Dr B. Although I accept that it is more likely than not that Mrs A had been dead for some time, I consider that Mrs C's focus should have been on commencing immediate resuscitation and calling for emergency assistance rather than contacting Dr B.
171. Overall, I find that the services Mrs C provided to Mrs A were not provided with reasonable care and skill and, accordingly, I find that Mrs C breached Right 4(1) of the Code.

Opinion: Iboga New Zealand Limited — Breach

172. Iboga New Zealand Limited was responsible for ensuring that the clinic had robust systems in place to provide an appropriate standard of care to its clients. It was also responsible for taking reasonably practicable steps to ensure that its staff understood, and were compliant with, its policies, procedures and guidelines.

173. Several serious deficiencies in Mrs A's care have been identified in this report. I consider that failures by Iboga New Zealand Limited at an organisational level contributed to these deficiencies.
174. Iboga New Zealand Limited provided HDC with the document "[Clinic] Policies and Procedures". That document provides: "Written information sent some weeks before treatment regarding treatment protocols, potential risk (including death), and disclaimer to be signed." However, there is no robust evidence that information was sent, and it is clear that no disclaimer was signed.
175. The protocol for treatment, as set out in the above document, states that a test dose of 200–400mg of ibogaine hydrochloride was to be given, followed by 600mg one to two hours later, and then a further 200–600mg two hours later (depending on sensitivity and response). This equates to three treatments over four hours, and no more than 1600mg in total. However, Mrs A received six doses of ibogaine over approximately 24 hours between 7.50am on Day 3 and 7am on Day 4. The total dose of ibogaine she was administered was 2200mg. There is no record of the rationale for this departure from the treatment protocol.
176. The protocol requires continuous observation of the patient for the first eight hours of treatment with ibogaine, including hourly pulse and oxygen saturations. The protocol then requires "[r]educed observations depending on response after 8 hours to 2 hourly then 4 hourly". It does not state the period for which the two-hourly and four-hourly observations should continue. Furthermore, the protocol requires that a doctor trained in ibogaine detoxification is present on the premises for the first 24 hours of treatment. However, Dr B was not present on the premises continuously for the first 24 hours, and much of the monitoring was undertaken by Mrs C.
177. Iboga New Zealand Ltd's protocols do not specify who is to perform various functions (such as conducting observations during treatment), nor does it stipulate any requirement to document either observations or the treatment. For such a complex and intensive treatment, the documented policies and procedures were minimal, and amounted to only one page.
178. What protocols were in place were not complied with in a number of respects, including: the provision of information about the risks of ibogaine treatment; the dosage; the time over which the treatment was provided; the observations; and the Consent Form. Furthermore, there was no documentation in relation to Dr B's assessments or proposed treatment plan. In addition, Mrs C did not record any observations after 4.11pm. Clinical documentation is also an important part of ensuring continuity of care and to ensure any concerns are identified at the earliest possible opportunity. The failure by Dr B and Mrs C to document their treatment and assessments is indicative of wider systems issues, and contributes to my view that Iboga New Zealand Limited did not operate a safe clinic.

179. The lack of comprehensive protocols and failure to comply with what protocols were in place give the overwhelming impression that it was a sloppy operation with little regard for professional standards. Iboga New Zealand Limited did not provide services to Mrs A with reasonable care and skill and, accordingly, breached Right 4(1) of the Code.
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Recommendations

180. Dr B and Mrs C have agreed to the following recommendations as set out in my provisional report:
- a) Each to prepare a separate formal written apology to Mrs A's family. The apologies are to be sent to HDC for forwarding, within three weeks of the date of this opinion.
 - b) Before resuming practice in New Zealand, Dr B has agreed to undertake further training with regard to his informed consent processes and documentation, and provide evidence to HDC and the Medical Council of New Zealand of this training having been undertaken.
 - c) Before commencing further use of ibogaine in New Zealand, Dr B has agreed to:
 - i. Enter into a collegial arrangement with a senior doctor specialising in addiction treatment and ensure that each case is discussed with that colleague before commencing treatment.
 - ii. Review his informed consent process to ensure that before commencing treatment with ibogaine all clients are provided with balanced information about ibogaine, and are fully informed of the risks of the treatment, including the risk of death.
 - iii. Ensure that he takes responsibility for all monitoring of clients before and after ibogaine treatment.
 - iv. Develop a process he will use to ensure that all elements of the Medical Council of New Zealand publication *Good Prescribing Practice* are considered and recorded when using unapproved medications.
 - v. Arrange for this process to be reviewed by a clinician approved by the Medical Council of New Zealand, and provide a report from the reviewer to HDC.
181. I recommend that the Medical Council of New Zealand consider undertaking a competence review of Dr B in the event that he reappplies to practise in New Zealand.

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182. Before commencing further use of ibogaine, Iboga New Zealand Limited has agreed to take the following steps and report to HDC on the actions taken:
- a) Obtain a review by an independent addictions practitioner of its documentation, including its website, Consent Form, and processes and protocols.
 - b) Ensure that its processes and protocols comply with professional standards, and that training is provided to all practitioners employed by Iboga New Zealand Limited.
 - c) Consider using cardiac monitoring during and following treatment for a period suggested by a cardiologist.
 - d) Review its treatment protocols with a view to strengthening the monitoring requirements during and in the days immediately following treatment with ibogaine.
 - e) Ensure that all clients give written informed consent to treatment with ibogaine, following a detailed information provision process.
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Follow-up actions

183. A copy of this report with details identifying the parties removed, except the name of Iboga New Zealand Ltd and the experts who advised in this case, will be sent to the Medical Council of New Zealand and the overseas Medical Council, and they will be advised of Dr B's name.
184. A copy of this report with details identifying the parties removed, except the name of Iboga New Zealand Ltd and the experts who advised in this case, will be sent to the Addiction Practitioners' Association Aotearoa-New Zealand (DAPAANZ), Medsafe, and the Health Quality & Safety Commission.
185. A copy of this report with details identifying the parties removed, except the name of Iboga New Zealand Ltd and the experts who advised in this case, will be sent to the District Health Board, which will be advised of Dr B's and Mrs C's names.
186. A copy of this report will be sent to the Coroner and the New Zealand Police.
187. A copy of this report with details identifying the parties removed, except the name of Iboga New Zealand Ltd and the experts who advised in this case, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A — Independent advice to the Commissioner

The following expert advice was obtained from general practitioner Dr David Maplesden:

‘BRIEF CLINICAL ADVICE

1. Thank you for providing this file for advice. [Dr B] administered a client, [Mrs A], with the unapproved medication ibogaine, [in 2013] as treatment for opioid drug addiction. [Mrs A] was found dead approximately 39 hours after commencement of the treatment having been last seen alive and well some seven hours beforehand. I have reviewed the available information: letters from NZ Drug Foundation and Medical Council of New Zealand requesting further investigation of the circumstances of this case; responses from [Dr B] to HDC; [the clinic’s] Policies and Procedures document; [the clinic’s] documentation relating to [Mrs A’s] treatment including consent documentation; correspondence from Medsafe per [Group Manager]; ESR toxicology report on [Mrs A] dated [...]; NZ Police documentation.

(i) I have been asked to comment on the following issues: The clinical appropriateness of prescribing ibogaine as a treatment for drug addiction; [Mrs A’s] suitability as a candidate for ibogaine treatment (including comment on the pre-treatment ECG assessment); the consent process followed in this case in relation to ibogaine treatment; the standard of documentation kept by [Dr B]. These questions will be addressed generally in the discussion that follows and specifically in the concluding section.

(ii) In his initial response to HDC, [Dr B] has outlined his experience with ibogaine therapy which was preceded by significant experience with herbal treatments including therapeutic use of rongoa. Training in relation to ibogaine dated from 2009 when he attended a local forum on the drug, with extensive training on therapeutic use of the drug undertaken during a conference in Spain in 2010. [Dr B and Mrs C] began treating patients with ibogaine from February 2011 having developed treatment and monitoring protocols based on their training in Spain and the ibogaine ‘manual’ (cited as reference 4) developed by some of the individual researchers of the drug. [Dr B] remained actively involved with the international ibogaine therapists ‘network’ and attended another conference in Canada in 2012 where he presented his experiences with the drug (38 patients treated at that stage, most successfully and no morbidity/mortality associated with the drug). At this conference the association of ibogaine use with prolongation of the QT interval and subsequent potentially fatal (and perhaps fatal) arrhythmias was discussed, and [Dr B] was involved with developing appropriate resuscitation equipment standards for clinics offering ibogaine therapy. At the time of [Mrs A’s] death, [Dr B] had treated 54 patients with ibogaine without incident.

(iii) [Mrs A (age 45 years) had a long history of multi-drug addiction]. She had researched ibogaine on the internet and approached [Dr B] for the therapy. She confirmed her intention for treatment by way of completing a screening

questionnaire, and screening blood tests and ECG were performed and did not show any contraindications to treatment. She had stopped her antidepressant venlafaxine prior to treatment. Further immediate re-treatment assessment [was scheduled] but [Mrs A] missed her plane and arrived [the following morning, on Day 1. During that day [Mrs A] rested and underwent assessment by [Mrs C] who was completing a qualification in addiction counselling and assisted [Dr B] with management of ibogaine clients. Later that evening [Dr B] assessed [Mrs A] including physical examination and review of her medical history. He reassessed her on the morning of [Day 2] and she was then assessed by [Dr D] who was undertaking a research project into the long-term efficacy of ibogaine (see section 6) — [Mrs A] had apparently agreed to take part in this research. [Dr B] reassessed [Mrs A] on the evening of [Day 2] but her Subjective Opiate Withdrawal Scale (SOWS) score was too low to commence treatment. SOWS test was repeated at 0700hrs [Day 3] (still too low) and at 0745hrs when it was sufficiently high to commence treatment. A test dose of ibogaine (400mg) was given at 0750hrs and was tolerated. Therapeutic doses were given at 0850hrs (600mg), 1745hrs (400mg), 1925hrs (200mg), 2040hrs (200mg) on [Day 3] and a final dose at 0700hrs [Day 4] (400mg + 10mg diazepam) according to [Mrs A's] reported withdrawal symptoms. [Mrs A] *was intensively monitored for 24 hours after treatment was first initiated, as per our protocol. During this period observations and clinical recordings were within normal and expected ranges. Because of this, [Mrs A] was assessed as fine to be left sleeping unobserved for her second night.* [Mrs A] was last checked at 2300hrs [Day 4] and was found deceased in her bed at the clinic at 0600hrs [Day 5].

(iv) Following this incident, any further ibogaine treatments at [Dr B's] facility were suspended until the outcome of investigations into [Mrs A's] death. [Dr B] has notified colleagues in the international ibogaine 'community' *and learnt in detail of several other fatalities similar to ours which I had not previously been aware of.* If he recommences treatments, [Dr B] is considering continuous cardiac monitoring of clients as undertaken by one overseas colleague.

(v) I have reviewed [the clinic's] Policies and Procedures. These appear consistent with some aspects of the 'medical model' of ibogaine therapy described in the ibogaine 'manual' (see below). However, as there is paucity of robust evidence for appropriate use of ibogaine in terms of pre-treatment screening, dosing regimes, monitoring etc it is not possible to describe [Dr B's] management of [Mrs A] against 'expected' or 'accepted' standards, other than those standards applying to use of unapproved medicines in New Zealand. On review of [Mrs A's] clinical file, I see [this implies] she had received extensive input from 'mainstream' addiction management services at some stage in the past. There appears to have been extensive and appropriate pre-treatment assessment of [Mrs A's] mental health and cognitive status together with her medical history and addiction history (report from [Mrs C] compiled retrospectively from handwritten notes obtained on [Day 1]). The consent form provided (unsigned — [Dr B] states this was *overlooked* although [Mrs A] had read the consent form) was extensive and included reference to potential mortality from ibogaine and its unapproved status

in New Zealand. Pre-treatment counselling included reference to various web-sites, those sites containing extensive information on the drug including inclusion and exclusion criteria. In e-mail traffic between [Mrs A] and [Mrs C] it is apparent [Mrs A] had considered ibogaine treatment in some detail and was very keen to proceed with treatment. My conclusion is that it is very likely [Mrs A] was adequately informed regarding relevant aspects of ibogaine therapy, including the status of the drug in New Zealand and internationally including very limited evidence base for its use, and the small risk of death. However, it was a significant omission to fail to gain her signature on the consent to treatment form, and the consent form signed for participation in [Dr D's] research was no substitute for this.

(vi) Screening medical history and assessment results have been reviewed. [Mrs A] was obese and was a heavy smoker (40+ per day). There was no apparent family history of heart disease and no personal history of diabetes. Assuming a normal lipid profile and no diabetes, this placed her in a mild risk group for a cardiovascular event. She had a history of hepatitis-C (unclear whether she had ever received treatment for this, or if she was currently symptomatic). There is no documented record of the physical assessments undertaken by [Dr B] on [Day 1] or [Day 2] although he states in his response that he auscultated [Mrs A's] heart and lungs and *would have recorded findings if anything abnormal or unexpected was disclosed*. In all the clinical documentation examined I can find only a single documented recording of blood pressure and pulse as noted below, and no additional physical examination findings. The clinical record completed by [Mrs C] includes the comments *ECG results were normal and blood screens were all clear*. In fact blood tests showed mild elevation of the liver enzymes GGT and ALT with normal blood count and thyroid function. There is no record of renal function. [The clinic's] website lists, under exclusion criteria, *Indication of impaired liver function*. However, there is discussion later on the site indicating clinics overseas have successfully treated patients with hepatitis-C who have elevation in liver enzymes up to 400% of upper limit of normal without incident. In my opinion, there should have been documentation noting the abnormal liver function and that this issue had been discussed specifically with [Mrs A] prior to treatment. However, in the absence of robust 'guidelines' for use of ibogaine, it is not possible to say that continuing with therapy when there was evidence of mild liver dysfunction in a hepatitis-C sufferer departed from 'accepted' or 'expected' standards of practice.

(vii) Screening ECG had been performed [prior] to [Mrs A's] travel to [the clinic]. I note [Mrs A] did not report any symptoms suggestive of ischaemic heart disease or arrhythmia and had no significant past cardiac history. The computerised ECG report stated *sinus rhythm, premature ventricular complexes, premature supraventricular complexes, possible inferior infarct, QS in III with Q in II, minor inferior repolarisation disturbance secondary to infarct, flat or low negative T in aVF with negative T in III. Abnormal ECG*. In his response, [Dr B] states he has significant training and experience in reading ECGs as part of his rural hospital medicine specialist training. He discounted the rhythm abnormalities reported as

being due to misreporting of an artefactual disturbance in lead V3, and felt that the possible ischaemic changes noted (Q and T wave abnormalities) were not extensive and, in the absence of any history suggestive of ischaemic heart disease, were unlikely to be significant. On reviewing the ECG trace (poor quality copy only) I agree there is no evidence of rhythm disturbance. QTc interval was 428ms which is within the expected range (<450 ms for females). The T wave inversion seen can be normal (lead III and aVR). The Q wave interpretation might be more fraught. A recent review article on Q-waves¹ stated: *clinicians should be aware of three principles with respect to Q waves: 1) not all Q waves are pathologic; 2) not all pathologic Q waves are due to myocardial infarction caused by fixed coronary artery occlusion; and 3) there is no firm consensus on the criteria for the diagnosis of pathologic Q waves*

...

(viii) Treatment and monitoring records have been reviewed. These are mainly narrative observations with the only clinical observations recorded being 0750hrs [Day 3], BP 128/69, P 71 and oxygen saturations 99%. Unless there is a record of clinical observations not provided to HDC, the nature of the observations undertaken was not consistent with the Clinic procedures document which stated *Continuous observation for the first 8 hours, including hourly pulse and Oxygen saturations ...* Narrative observations are recorded every 20–30 minutes until 1300hr then hourly until 1700hrs on [Day 3]. [Mrs A] was reviewed for further doses of medication until 2040hrs as described in section 1(iii) although no clinical observations are recorded following these subsequent doses. Final documented review on [Day 3] was 2130hrs. Next documented review was 0700hrs [Day 4] when a further 200mg of ibogaine + 10mg diazepam was administered. [Mrs A] was then reviewed hourly until 1600 hrs, lying still but having changed position at these reviews. At 1500hrs she was *lying still. Arm raised over head.* At 1600hrs *Lying still. Turned heater on and she didn't stir.* At next review 1900hrs *Sleeping...* There is no comment recorded beside the next recorded time of 2300hrs. In her police statement dated [Day 5] [Mrs C] has recounted visiting [Mrs A's] room at 0600hrs that day *to turn her heater off. I noticed she was in the same position, with her arm over her head, as I had left her last night. I touched her and she was cold despite being in a hot room.* It is unclear whether [Mrs C] can confirm [Mrs A] was actually breathing and alive after 1500hrs on [Day 4] (although she confirms she did check on her at the times stated) when [Mrs A's] resting position described in that entry appears similar to the position she was found in the following morning. A Police *Initial Report for Coroner* states that [Mrs C] had found [Mrs A] *in the same position as yesterday afternoon ... Had been in bed since 1100hrs [Day 4]. Hadn't moved since 1500hrs that day.* The standard of assessment and monitoring documentation falls short of that outlined in the Clinic procedure document with respect to recording of vital signs. However, failure to document the observations does not mean observations were not undertaken.

¹ Goldberger A. Pathogenesis and diagnosis of Q waves on the electrocardiogram. Uptodate. Last updated April 2013. www.uptodate.com

...

(ix) I am not aware of any autopsy findings or whether a cause of death has been established. The toxicology results reviewed indicated [Mrs A] was significantly acetotic. She was not known to be diabetic but had evidently had very limited food intake, and had been vomiting, in the day or so before her death which could cause such a picture. Ibogaine level was approximately 0.06 mg/L although there was insufficient blood for an accurate estimate. The pathologist comments that *Ibogaine has a short half-life* [although its metabolite noribogaine has a much longer half-life] *so levels in the blood will drop rapidly. Post-mortem drug levels of 0.73 and 0.36mg/L have been associated with deaths following ingestion of the drug.* [Mrs A's] estimated ibogaine level was somewhat lower than those described in association with fatalities. Low levels of diazepam were also found consistent with the dose administered during treatment.

2. Ibogaine background

A review of the available literature indicates ibogaine has been used for decades in a largely unregulated manner for treatment of drug addiction and there are multiple small observational studies on humans attesting to its effectiveness for this purpose, together with a significant amount of animal data². One of the better summaries reviewed was an unpublished but well referenced thesis³ which included the following referenced observations:

(i) *Ibogaine is classified as a Schedule 1 drug in the United States. It is also illegal in Australia, Belgium, Denmark, France, Sweden, and Switzerland, but it is unscheduled in many other countries. This does not necessarily confer a legal status in other countries, but laws vary around the world. Reports indicate ibogaine is not often used as a recreational drug like other hallucinogens. Status of the drug in New Zealand is discussed in section 3.*

(ii) *Promotional websites direct customers to programs for opioid detoxification using ibogaine. These programs offer detoxification sessions in countries where ibogaine is a legal substance. There are four proposed models for ibogaine administration. The medical model is administered by a licensed physician in a country where ibogaine holds legal status, such as Mexico, Panama, or St. Kitts. This model emulates current conventional medical standards in addiction treatment and the main difference is using a drug that has little conclusive evidence for an addiction protocol. [This model would most closely approximate the use of the drug by Dr B.] The lay provider model is similar to the medical*

² Review articles consulted include:

- a. Maciulaitis R et al. Ibogaine, an anti-addictive drug: pharmacology and time to go further in development. A narrative review. *Hum Exp Toxicol.* 2008; 27:181–194.
- b. Alper K. Ibogaine: A Review. *Alkaloids Chem Biol.* 2001;56:1–38
- c. Alper K, Lots of H. The use of ibogaine in the treatment of addictions. In: Winkelman M, Roberts T eds. *Psychedelic Medicine.* Westport, CT. Praegar/Greenwood Publishing Group; 2007:43–66

³ Amadon N et Roecker A. Ibogaine as an Alternative and Efficacious Treatment for Heroin Addiction. Available at: https://www.onu.edu/files/amadon-ibogaine_article.pdf

model, but the provider does not hold any medical credentials. These providers are viewed as 'guides' and use informal protocols that have been developed by various countries, such as the United States or the Netherlands. These manuals are available for download online and include directions for dosage, monitoring, and how to address any adverse events that may occur while the patient is on the hallucinogenic trip. The third model is the activist or self-help model, in which the lay provider participates with an activist or evangelical, usually to gain acceptance of the use of ibogaine by a certain group. The final model is the religious or ceremonial model, which involves a lay provider at a Bwiti shrine or other ceremonial context.

(iii) According to one of the lay provider manuals, a single oral treatment of 6 to 19 mg/kg can effectively precipitate and maintain abstinence from drug abuse for approximately 6 months.

(iv) *The manual for ibogaine therapy⁴ is fairly complete considering it has not been approved by a credible medical association ... The manual lists inclusion and exclusion criteria to ensure patient safety⁵. Each patient must obtain an electrocardiogram prior to initiation of therapy and pulse and blood pressure should be recorded at regular intervals for a 24 hour period. Neurological and psychological assessments are also suggested and the manual includes scales for withdrawal symptoms.* On reviewing the 'manual' cited above, I feel although the publication purports to be a manual, it appears rather to represent experiences of the authors and other contributors and many of the comments within it are not explicit but give a variety of options for management, including anecdotal reports from contributors.

(v) *Ibogaine use is associated with a few serious adverse drug events. The most pronounced of these are cardiac rhythm abnormalities ... Risk factors including prior myocardial infarction, pulmonary embolism or mixed drug overdoses may predispose a patient to cardiac abnormalities with ibogaine administration. These cardiac events are also noted more frequently with the alkaloid extract and dried root bark as opposed to the powder that is used to make tablets and capsules. The severity of cardiac adverse events necessitates the use of an EKG throughout a patient's treatment with ibogaine, as specified in protocols. Many of the exclusion criteria for treatment focus on cardiac diseases the patient may have. The possibility of neurological adverse effects remains uncertain. Although treatment*

⁴ Lots of HS, Wachtel B. Manual for ibogaine therapy: screening, safety, monitoring and aftercare (Second Revision 2003). Available from: <http://www.ibogaine.desk.nl/manual.html>

⁵ See Appendix 1 for extracts from this manual.

with ibogaine is underreported, there are a few reported cases where treatment adversely resulted in the death of the patient (see also section below)⁶.

3. Ibogaine toxicity and monitoring

(i) There are multiple recent references in Medline listed medical journals to concern regarding the adverse cardiac effects of ibogaine, particularly in relation to prolongation of the QT interval leading to potentially fatal arrhythmias with some deaths attributed to such arrhythmias. These were mostly case reports or retrospective reviews with small numbers, and the true frequency of adverse effects including fatalities is unknown because of the significant ‘subculture’ use of the drug in an unregulated fashion. Some comments from the literature reviewed include: *Nineteen individuals (15 men, four women between 24 and 54 years old) are known to have died within 1.5–76 h of taking ibogaine ... In this series of 19 cases, advanced pre-existing medical comorbidities, which were mainly cardiovascular, and/or one or more commonly abused substances explained or contributed to the death in 12 of the 14 cases for which adequate post-mortem data were available. Significant factors in this series appear to include pre-existing medical, particularly cardiovascular disease, possible PE, drug use during treatment, seizures associated with withdrawal from alcohol and benzodiazepines, and the uninformed use of ethnopharmacological forms of ibogaine*⁷; *We present three cases in which toxic side effects were noted. We used the Naranjo scale to estimate the probability of a causal relationship between these effects and ibogaine. Findings in these three cases are suggestive of a causal relationship between the use of ibogaine and serious respiratory and cardiac problems (including lengthening of the QT interval). In our opinion it is of great importance that clinicians are aware of these potentially serious side effects and realise that widespread online marketing practices will give many more people access to ibogaine*⁸; *At the doses currently used, ibogaine can lead to serious cardiac-rhythm abnormalities. The use and possible future trials of the drug should be permitted only under strict medical observation and continuous electrocardiographic monitoring*⁹; Further recent case studies reported on potentially fatal arrhythmias associated with therapeutic ibogaine use^{10,11}.

⁶ The ibogaine ‘manual’ referred to also contains the comments: To date, there is no published data from a controlled clinical trial that has assessed the safety of ibogaine in the treatment of drug addictions. Information from the anecdotal reports indicates there is a mild transient increase in blood pressure and a minimal effect on pulse and respiration. To date, there is no published data from a controlled clinical trial that was conducted to assess the preliminary efficacy of ibogaine in the treatment of drug addictions. The initial observations of effects of ibogaine was a narrative account of the results of taking ibogaine in the mid 1960s by seven heroin addicts, five of whom several days later reported no signs of withdrawal, abstinence, and no desire to take heroin.

⁷ Alper K, Staiic M, Gill J. Fatalities temporally associated with the ingestion of ibogaine. *J Forens Sci.* 2012; 57(2):308–412

⁸ Paling F et al. Life-threatening complications of ibogaine: three case reports. *Neth J Med.* 2012;70:422–424

⁹ Hoelen D, Spiering W, Valk G. Long-QT syndrome induced by the antiaddiction drug ibogaine. [N Engl J Med. 2009;360\(3\):308–9.](#)

¹⁰ Asua I. Growing menace of ibogaine toxicity. *Br. J. Anaesth.* (2013) 111 (6): 1029–1030

(ii) Two of the most well-known ‘pioneers’ of ibogaine research and use made the following observation regarding monitoring during ‘medical model’ therapy with the drug¹²: *The standard of care varies greatly across the settings in which ibogaine is administered. In the medical model, the most intensive approaches can include a pretreatment Holter monitor to evaluate the presence of arrhythmias by recording continuous EKG (electrocardiogram) for 24 hours or longer, and 12-lead EKG. Additional evaluative procedures such as an echocardiogram are performed for patients with a question of a prior history of endocarditis, an infection that often affects the valves of the heart, and is relatively common in intravenous drug users. Monitoring and safety procedures during the treatment can include EKG and vital signs, and pulse oximetry monitoring (a method of measuring blood oxygenation). Other procedures utilized in the medical model may include the routine provision of intravenous access, the presence on-site of an emergency physician with ACLS (advanced cardiac life support) certification, and a registered nurse in the room with the patient continuously during the treatment.*

(iii) It is well documented that heroin users are at substantially greater risk of premature mortality than their general population peers. Longitudinal studies indicate yearly mortality rates of between 1% and 3% among heroin users. The excess mortality risk among heroin users have been estimated to be between 6 and 20 times higher than in the general population of the same age and gender¹³. A New Zealand study on opioid related mortality noted *There were 92 poisoning deaths involving opioids in New Zealand during 2001 and 2002. Morphine was the most frequently reported opioid reported in poisoning deaths, but there were almost as many methadone-related deaths. Methadone and morphine deaths were predominantly considered to be unintentional with 28 of the 31 methadone deaths and 24 of 33 morphine deaths coded as Unintentional*¹⁴. A recent UK study commented *Opiate users have a high risk of death and contribute substantially to adult mortality. Systematic reviews estimate annual death rates of about 1%*¹⁵.

(iv) It is difficult to gain an accurate picture of mortality rates associated with ibogaine use given the largely unregulated nature of such use meaning both number of patients being treated and number of deaths, may be significantly under-reported. The ‘official’ UK based ibogaine website¹⁶ includes the following information: *There is an inherent level of risk with ibogaine treatment. Twelve people are known to have died in connection with taking ibogaine or other iboga*

¹¹ Pleskovic A et al. Ibogaine-associated ventricular tachyarrhythmias. *Clin Toxicol (Phila)*. 2012 Feb;50(2):157.

¹² Alper K, Lotsof H. The use of ibogaine in the treatment of addictions. In: Winkelman M, Roberts T eds. *Psychedelic Medicine*. Westport, CT. Praegar/Greenwood Publishing Group; 2007:43–66

¹³ Bargagli A et al. A Systematic Review of Observational Studies on Treatment of Opioid Dependence. 2007. Department of Epidemiology, ASL RM E, Rome. Available at: http://www.who.int/substance_abuse/activities/observational_studies_treatment.pdf.

¹⁴ Reith DF, Fountain J, Tilyard M. Opioid poisoning deaths in New Zealand (2001–2002). *NZMJ*. 2005;118(1209)

¹⁵ Cornish R et al. Risk of death during and after opiate substitution treatment in primary care: prospective observational study in UK General Practice Research Database. *BMJ* 2010;341:c5475

¹⁶ See: http://www.ibogaine.co.uk/info.htm#_UyPpQ_mSyhI

alkaloids. In actuality, the figure is likely higher, given that ibogaine is frequently administered in surroundings where people may be reluctant to contact the authorities in the event of something going wrong. Statistically, a ballpark figure for deaths during treatment is probably of the order of 1 in 300. (This is based on 12 recorded deaths having occurred within 3611 recorded treatments, outside of Africa, as of March 2007). While the reliability of this data may be questionable, it appears the mortality rate associated with ibogaine administration may not be dissimilar to that associated with opioid use (including methadone substitution therapy) as noted by the Medsafe committee in 2009 (see 4(ii)), although would contribute to overall opioid associated mortality. However, a mortality rate of 1 in 300 associated with a prescribed drug taken ‘as directed’ (noting much of the excess opioid related mortality is due to overdose) does seem exceptionally high and I suspect would be a barrier to commercial development of the drug if the rates proposed are accurate.

4. Ibogaine classification in New Zealand

In November 2009, Medsafe resolved to classify ibogaine as a prescription only medicine and this status was formalised in 2010. However, the drug is not approved for use in New Zealand and does not appear on the current Pharmaceutical Schedule, and it does not have a formal Medsafe ‘data sheet’. This does not mean it is unable to be used in this country, but as an unapproved prescription only medication, its use is governed by various legislation which is discussed further in section 4. In making the decision to classify ibogaine as a prescription only medicine, Medsafe recorded the following discussion¹⁷:

(i) Ibogaine is a naturally occurring indole alkaloid derived from the roots of the rain forest shrub Tabernanthe iboga. It is used in low doses by the indigenous peoples of western Africa to combat fatigue, hunger and thirst, and in higher doses as a sacrament in religious rituals. The use of ibogaine for the treatment of drug dependence had been based on anecdotal reports from American and European addict self-help groups that it decreased the signs of opiate withdrawal and reduced drug craving for cocaine and heroin for extended time periods. Although ibogaine has diverse effects on the central nervous system (CNS), the pharmacological targets underlying the physiological and psychological actions of ibogaine are not completely understood.

*(ii) The Committee was provided with a table of data which attempted to state what is known regarding ibogaine related fatalities in the public domain. **The figures suggest that the number of deaths due to methadone, the most controlled substance, were a little higher than those associated with ibogaine, which is unregulated.** The most frequently reported use for ibogaine is for the reduction or elimination of addiction to opiates. Ibogaine is reported to alleviate the symptoms of opiate withdrawal. It has also been suggested that ibogaine may be useful in treating dependence to other substances such as alcohol, methamphetamine and nicotine.*

¹⁷ See: <http://www.medsafe.govt.nz/profs/class/mccMin03Nov2009.htm?mid=54883>

(iii) *Given its use for the therapeutic purpose of managing/treating addiction and the need for this treatment to be under supervision, Medsafe believed that there was a case for classifying ibogaine and its metabolite noribogaine as prescription medicines. This would not necessarily restrict the medical use in a therapeutic environment but would limit attempts at self treatment and prevent its development for recreational use as a 'party pill', even though the documented experience of using it is usually not that pleasant.*

(iii) *Due to the potential for therapeutic use of the product, the safety profile and the potential for misuse, Medsafe suggested that the substance ibogaine and its metabolite noribogaine met the criteria for classification under the Medicines Act 1981. This would provide ability to control the import and supply of ibogaine, its metabolite or any products containing each or both of the substances.*

(iv) Some of the newspaper articles in this file (mostly those prior to the death of [Mrs A]) appear to imply that ibogaine was approved for use in New Zealand by virtue of it being listed as a prescription only medicine. This is not the case and the medicine remains unapproved for any specific indication in this country.

4. Unapproved medicine use

(i) The use of unapproved medicines in New Zealand has been clarified in a Medsafe statement most recently revised in April 2013¹⁸. This makes reference to current legislation including the *Code of Health and Disability Services Consumers' Rights*. Various scenarios are outlined to illustrate appropriate procedures when using unapproved drugs. In this case, I feel the procedure outlined in scenario 1 approximates most closely the expected procedure to be undertaken by [Dr B], and I have reproduced that scenario adapted to the situation in question: A patient comes to a medical practitioner's surgery requesting ibogaine therapy to assist with opiate addiction. The patient has researched ibogaine on the internet and knows that [Dr B] offers this service. [Dr B] knows that ibogaine is not approved and that it has been scheduled a prescription only medicine. The practitioner is obliged to use the means available to him to obtain unbiased information on the efficacy and safety of [ibogaine] in the treatment of [opiate addiction], and be assured that it may benefit and not harm the patient. ([Dr B's] response implies he had extensively researched the use of ibogaine, but was aware of its potential to cause fatal arrhythmias at the time he treated [Mrs A].) He is then able to decide whether he wishes on scientific grounds to assist the patient to obtain ibogaine and for her to undergo therapy. He should discuss with the patient the information he has regarding efficacy, safety and status (experimental vs accepted) of ibogaine in treating addictions, as well as the nature of the patient's addiction and other medical and non-medical treatment options. If, after a full and frank discussion, the decision of both the medical practitioner and the patient is to use ibogaine, the practitioner has three further steps to take before obtaining supplies. He should decide whether use of ibogaine for addiction treatment should be regarded as experimental, necessitating signed consent. (In

¹⁸ See: <http://www.medsafe.govt.nz/profs/riss/unapp.asp>

this case there was research being undertaken but it was in regard to assessment of long-term efficacy of the medication rather than use per se.) If it is considered experimental he should agree with the patient on a suitable procedure for monitoring for safety and efficacy. Finally, he should advise the patient that it is a requirement under the Medicines Act for the information about the supply, including the patient's name, to be forwarded to Medsafe and be stored in a database. The practitioner then contacts Company X and requests ibogaine for his patient. If the medicine is procured from Company X, the company must report the supply to the Director-General. Documentation from Medsafe indicates they were aware [Dr B] had been importing ibogaine although it is not clear whether he notified them of client particulars.

(ii) The NZMA Code of Ethics¹⁹ states in section 42: *Advances and innovative approaches to medical practice should be subject to review and promulgation through professional channels (including ethics committees) and medical scientific literature. Doctors should accept responsibility for providing the public with carefully considered, generally accepted opinions when presenting scientific knowledge. In presenting any personal opinion contrary to a generally held viewpoint of the profession, doctors must indicate that such is the case, and present information fairly.* Section 50 states: *In situations where a doctor is undertaking an innovative or unusual treatment on his or her own initiative, he or she should consult suitably qualified colleagues before discussing it with, or offering it to, patients. Doctors should carefully consider whether such treatments should be subject to formal research protocols.*

5. The Medical Council of New Zealand makes the following statements in its publication Good Prescribing Practice (2010)²⁰:

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

(ii) *Take an adequate drug history of the patient, including: any previous adverse reactions to medicines; current medical conditions; and concurrent or recent use of medicines (including non-prescription, complementary and alternative medicines) ...*

(iii) *Ensure that the patient (or other lawful authority) is fully informed and consents to the proposed treatment and that he or she receives appropriate information, in a way they can understand, about the options available; including an assessment of the expected risks, side effects, benefits and costs of each option ...*

¹⁹ Available at: http://www.nzma.org.nz/sites/all/files/Code_of_Ethics.pdf

²⁰ Available at: <http://www.mcnz.org.nz/assets/News-and-Publications/Statements/Good-prescribing-practice.pdf>

(iv) *Prescribe in accordance with accepted practice and any relevant best practice guidelines. Prescribing outside of accepted norms should only occur in special circumstances with the patient's informed consent. In such circumstances, it might be useful to discuss the proposed treatment with a senior colleague before completing the prescription.*

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

(vii) *You may prescribe unapproved medicines or prescribe medicines for a purpose for which they have not been approved but, if you decide to do so, you should take responsibility for overseeing the patient's care, including monitoring and any follow-up treatment. You may also like to discuss the patient's treatment with a senior colleague. You should also inform the patient: whether there are any other options available; of any risks, side effects, costs or benefits; that the medicine being prescribed is for an unapproved use; that details relating to the supply of the unapproved medicine will be supplied to the Director-General of Health. Section 29 of the Medicines Act 1981 requires that certain details relating to the supply of unapproved medicines be passed to the Director-General of Health.*

6. Research

(i) [Mrs A] apparently consented to be involved in research related to the long-term efficacy of ibogaine therapy, undertaken by [Dr D]. The research had Ethics Committee approval and the research protocol is available online.

(ii) [Dr D] spent two hours discussing his research proposal with [Mrs A] and obtained signed consent to enrol [Mrs A] in his research. It appears [Mrs A] made an adequately informed decision to become a subject in the research project.

7. Scope of practice

(i) [Dr B] is registered with the MCNZ in both the Rural Hospital Medicine and the General Practice vocational scopes²¹. The MCNZ description for Rural Hospital Medicine vocational scope is: *Rural hospital medicine is determined by its social context, the rural environment, the demands of which include professional and geographic isolation, limited resources and special cultural and sociological factors. It is invariably practised at a distance from comprehensive specialist medical and surgical services and investigations. A broad generalist set of skills, knowledge and attitudes are needed to deliver optimum patient outcomes in rural hospitals. Unlike rural general practice, rural hospital medicine is orientated to secondary care and is responsive rather than anticipatory and does not continue over time.*

²¹ See <https://www.mcnz.org.nz/get-registered/scopes-of-practice/vocational-registration/types-of-vocational-scope/>

(ii) The MCNZ description for General Practice vocational scope is: *General practice is an academic and scientific discipline with its own educational content, research, evidence base and clinical activity, and a clinical speciality orientated to primary care. It is personal, family, and community-orientated comprehensive primary care that includes diagnosis, continues over time and is anticipatory as well as responsive.*

(iii) Addiction medicine is not currently recognised as a distinct vocational scope in New Zealand although this recognition was granted in Australia at the end of 2009. There is an Australasian Chapter of Addiction Medicine (ACAM) allied to the Royal Australasian College of Physicians (RACP) and the RACP is currently in the process of submitting the Stage 2 application to Medical Council of New Zealand for recognition of addiction medicine as a distinct vocational scope here. The ACAM describes itself as providing *a collegiate home for Addiction Medicine specialists* and their website lists the objectives of the Chapter with links to training and professional development requirements²². [Dr B] does not claim membership of ACAM.

(iii) The current general practice vocational training curriculum²³ has been reviewed and includes a specific Addictions module. Learning goals include: *the general practitioner should be competent in recognising signs and symptoms of addiction, including co-dependency; the GP will demonstrate the ability to recognise and manage acute conditions, such as intoxication, psychosis or withdrawal; the GP will demonstrate the ability to develop skills to help with community detoxification; the GP will demonstrate the ability to develop a working knowledge of the various treatments and programmes available so that appropriate [addictions] care can be planned; the GP will demonstrate the ability to prescribe medications appropriately for various aspects of addiction, for example detoxification, methadone programme.*

(iv) There is an Addiction Practitioners' Association Aotearoa-New Zealand which describes itself as representing the interests of member practitioners working in addiction services, and has a Code of Ethics and registration process²⁴. [Dr B] is not listed as a current registered member of this Association although it appears to support primarily non-physician practitioners. It does not appear that [Mrs C] is listed as a current member of the Association although she was evidently a member in 2012 (her response).

(v) The National Committee for Addiction Treatment New Zealand provided a report on the current status of addiction treatment in New Zealand in a 2011

²² See: <http://www.racp.org.nz/page/australasian-chapter-of-addiction-medicine/about-the-chapter-of-addiction-medicine/>

²³ The Royal New Zealand College of General Practitioners. Curriculum for General Practice: General Practice Education Programme. 2012

²⁴ See: <http://www.dapaanz.org.nz/>

publication²⁵. The report noted: *the addiction workforce in New Zealand is heterogeneous and comprises a range of different disciplines working in a variety of roles and settings. The development of a specialist skilled workforce is therefore essential for the provision of accessible and effective addiction services.*

- *Specialist practitioners who work in specialist addiction services or in addiction programmes within non-addiction-focused organisations. The 2008 National Telephone Survey indicated the specialist addiction workforce was made up of counsellors (58.0 percent), nurses (15.0 percent), social workers (16.0 percent), psychologists (2.0 percent) and medical practitioners (2.0 percent).*
- *Generalist workers who are professionals in other areas of health such as primary care and mental health, or from the Corrections, Education or Social Services sectors. They are required to intervene, helping people deal with the consequences of their addiction-related behaviours and provide screening, brief interventions, lifestyle advice and referral to specialist services.*

There has been significant growth in the professionalism of the specialist workforce over the last 15 years with the establishment of the Addiction Practitioners' Association Aotearoa New Zealand (DAPAANZ) and the increase in numbers of staff gaining postgraduate addiction qualifications. In the future, more people with addiction problems will be managed in primary care and other allied health and community settings. This shift will mean the specialist workforce will require the development of new roles to provide expertise to the generalist workforce. Addiction specialty clinical skills and knowledge remain essential. Working within a specialist addiction service will provide the necessary training for an in-depth understanding of the various addiction service user sub-populations and a unique opportunity for skill development.

(vi) In his response, [Dr B] has outlined in some detail the steps he has taken to gain experience with ibogaine use internationally and in networking with ibogaine providers both nationally and internationally. Specifically, he has described his New Zealand collegial relationships which appear appropriate to this particular area of his practice. He does not appear to be working in professional isolation in this regard, and I think he could be reasonably described as a local 'expert' in ibogaine use (GP with Special Interest or GPSi), and he has been invited to share this expertise at a number of professional speaking engagements. It is acknowledged that ibogaine has yet to gain acceptance as a 'mainstream' anti-addiction therapy and [Dr B] was working in his own private anti-addiction clinic rather than a government sanctioned/supported community-based alcohol and drug service. Nevertheless, he describes being referred patients from some government agencies in addition to patient self-referrals implying a degree of mainstream 'acceptance' of his work. While addiction medicine is not currently recognised as a specific vocational scope of practice by MCNZ, it might have

²⁵ National Committee for Addiction Treatment. *Addiction treatment is everybody's business: Where to from here?* Wellington, 2011. Available from http://www.ncat.org.nz/files/NCAT_20pg_Booklet_web.pdf

been prudent for [Dr B] to have sought registration with a recognised specialist body such as ACAM or DAPAANZ but I do not think the failure to do this precluded him from gaining experience in the use of ibogaine (on a background of experience and interest in natural and herbal remedies) and in using this therapy with the support of [Mrs C] who was in the process of gaining a qualification in addiction counselling. Part of the issue here is whether ibogaine therapy should be regarded as specialist anti-addiction treatment (for which it is not approved, and is not used by 'main stream' anti-addiction providers) or whether it should be regarded as use of a 'natural' remedy (albeit prescription only) to treat a specific medical condition. [Dr B] certainly had extensive experience in use of natural therapies (including use of ibogaine), although his experience in 'mainstream' management of addictions may have been generalist rather than specialist. In my opinion, I think it was reasonable for [Dr B] to be offering ibogaine therapy given his specialist knowledge in that area, and his generalist medical knowledge including ability to interpret blood tests and ECGs and advanced resuscitation.

8. Concluding comments

(i) **The clinical appropriateness of prescribing ibogaine as a treatment for drug addiction:** the status of this drug in terms of historical and current usage internationally has been discussed in the body of this report. It has been used for over twenty years for the treatment of opioid addiction but there remains a very limited evidence base regarding its efficacy (lack of robust controlled trials), and there is evolving evidence regarding potential cardiotoxicity and significant mortality rate associated with use of the drug. Balanced against this is the high mortality rate associated with untreated opioid addiction, and with currently used treatment methods (methadone substitution) which [Mrs A] had previously tried over a prolonged period. Also significant is the status of the drug in countries other than New Zealand, and the 'subculture' that has evolved regarding use of the drug, meaning addicts could access ibogaine therapy from lay providers and in an unsupervised environment in many countries. Any comments on 'appropriateness' of ibogaine therapy and training in administration of the therapy must be made in the context of there being no accepted and robust guidelines on these matters — the 'manual' referred to being more a collection of anecdotal experiences to date with recommendations based on these but openly debated by other providers. It appears to me that [Dr B] made significant efforts to gain as much experience as he could regarding use of ibogaine prior to starting his treatment programme, and that he remained an active participant in the ibogaine provider 'network' to ensure he was keeping abreast of developments and not working in isolation. I believe he was working within his level of expertise and that, overall, a reasonable standard of information was provided to potential clients and there was no attempt made to pass off the therapy as well-researched or accepted standard treatment for addictions. I believe he worked within the Medsafe recommendations regarding use of unapproved medications, other than the major omission regarding [Mrs A] signing the consent to treatment form. While this omission must be regarded as a moderate departure from expected practice, the supporting documentation (particularly e-mails from [Mrs A]) indicated she was a well informed and willing participant in the programme. The Clinic process documents indicate some

thought had been put into appropriate screening, assessment and monitoring of patients based on the published data regarding ibogaine and experiences of other providers obtained during [Dr B's] 'networking'. Supervision was provided by [Dr B] and [Mrs C] (who had also partaken in extensive training regarding the drug) over the first 24-hours, and by [Mrs C] alone after 24-hours when [Dr B] believed risk of adverse reactions had diminished. Taking all of these factors into account, I think it was reasonable for [Dr B] to prescribe ibogaine had the processes he had developed for the Clinic been strictly adhered to. It may be more appropriate in the future for ibogaine to be administered in a more regulated environment but current progress in this regard is hampered by the lack of evidence for efficacy and safety and apparent disinterest from major drug companies in progressing robust research on the drug.

(ii) **[Mrs A's] suitability as a candidate for ibogaine treatment (including comment on the pre-treatment ECG assessment):** [Mrs A] had a longstanding drug addiction that was impacting negatively on her wellbeing and placing her at increased risk of morbidity and mortality. She had used 'mainstream' addiction services previously and these were unsuccessful for her. She informed herself regarding ibogaine prior to approaching [Dr B], and was given further appropriate (under the circumstances) information following the approach. There were no particular features in her health questionnaire that disqualified her from treatment. Her liver function was impaired (see previous discussion) but not to the extent that many providers would recommend withholding treatment. Biochemical screening might have been improved by checking electrolytes (in view of likelihood of vomiting with therapy and association between electrolyte disturbances and dysrhythmias). It seems reasonable also to recommend formal cardiovascular risk assessment prior to treatment so that high risk patients can be identified and perhaps referred for more intensive screening (eg exercise ECG) although there are weaknesses in such screening processes. [Mrs A] was not obviously at high risk of cardiovascular disease although confirmation of her stated negative diabetes status, and lipid profile, might have been helpful in this regard. I have recommended expert advice regarding the ECG interpretation (see section 1(vii)). Assuming the (undocumented) physical assessment of [Mrs A] by [Dr B] was unremarkable, and provided expert advice regarding the ECG is that the abnormalities noted were not clinically significant, it was probably reasonable for [Mrs A] to undergo ibogaine therapy.

(iii) **The consent process followed in this case in relation to ibogaine treatment:** This has been discussed above. I think the process was reasonable except that the consent form went unsigned. If [Dr B] continues to administer ibogaine therapy, he should ensure the information provided to clients, particularly regarding safety of the drug, accurately reflects current reports.

(iv) **The standard of documentation kept by [Dr B]:** I feel the standard of clinical documentation kept in regard to [Dr B's] role in [Mrs A's] management fell below expected levels to at least a moderate degree. He did not document the result of his physical assessment of [Mrs A] on [Day 1] and [Day 2]. He did not document his interpretation of the ECG or blood test results even though there

were abnormalities in these results. He did not document [Mrs A's] management plan with respect to the proposed ibogaine dosage regime including rationale for timing of doses and amounts administered.

(v) There were deficiencies in [Mrs A's] overall monitoring with an evident failure by [Mrs C] to document the frequent pulse and oxygen saturation recordings apparently taken frequently during the early phase of treatment; no observation of any sort was listed for over nine hours from 2130hrs on [Day 3] despite [Mrs A] having received multiple doses of ibogaine up to 2040hrs that day; there appears to be a strong possibility observations from at least 1500hrs on [Day 4] consisted of [Mrs C] 'casting an eye' on [Mrs A] rather than ensuring she was breathing or had a pulse, meaning it has not been possible to determine an accurate date or time of death.

(vi) The improvements suggested by [Dr B] should he recommence administering ibogaine, are mainly related to more intensive cardiac monitoring and appear reasonable. Improvements could be made to screening processes as discussed above, and noting the prolonged half life of noribogaine and risk of accumulation with multiple ibogaine doses it seems appropriate to recommend intensive monitoring for at least 24 hours following the last dose of therapy rather than from the time of first administration.

Appendix 1. Extracts from:

Lotsof HS, Wachtel B. Manual for ibogaine therapy: screening, safety, monitoring and aftercare (Second Revision 2003). Available from:
<http://www.ibogaine.desk.nl/manual.html>

INCLUSION CRITERIA (for ibogaine therapy)

1. *Subject participation must be voluntary and not coerced.*
2. *Subject must sign an Informed Consent that indicates an understanding of the risks and benefits of ibogaine administration.*
3. *Subject must undergo a general medical evaluation by a doctor who will provide a report.*
4. *Subject must supply a copy of their medical history questionnaire (generally required upon the intake visit to a physician).*
5. *Subject must respond to a Beck Depression Inventory questionnaire.*
6. *Subject must obtain an EKG (electrocardiogram) and report.*
7. *Blood tests (recommended blood tests and reference ranges listed)*
8. *Upon subject meeting all other inclusion criteria and not being excluded by exclusion criteria, subject will be administered a 100 mg (total) test dose of ibogaine. Should the subject not have an adverse or atypical response, a full therapeutic dose of ibogaine may be considered. See exclusion criteria #4.*

9. Ibogaine providers following a medical model may require evaluation of cytochrome P450 enzymes activity. Particularly, P450 2D6 (CYP4502D6) plays a significant role in the metabolism of ibogaine to noribogaine, its active metabolite. Testing allows a determination of whether the patient will be a 'poor metabolizer' (PM), 'intermediate metabolizer' (IM), 'extensive metabolizer' (EM) or 'ultra rapid metabolizer' (UM). This testing is now available through commercial laboratories.

EXCLUSION CRITERIA

In order to begin to address the safety of persons being treated with ibogaine, the following indications should exclude treatment with ibogaine ...

1. *Patients with a history of active neurological or psychiatric disorders, such as cerebellar dysfunction, psychosis, bipolar illness, major depression, organic brain disease or dementia, that require treatment.*
2. *Patients who have a Beck Depression Inventory score greater than or equal to twenty-four.*
3. *Patients requiring concomitant medications that may cause adverse ibogaine/other drug interactions (e.g., anti-epileptic drugs, antidepressants, neuroleptics, etc.)*
4. *Patients with a history of sensitivity or adverse reactions to the treatment medication.*
5. *Patients with a history of significant heart disease or a history of myocardial infarction.*
6. *Patients with blood pressure above 170 mm Hg systolic/105 mm Hg diastolic or below 80 mm Hg systolic/60 mm Hg diastolic or a pulse greater than 120 beats per minute or less than 50 beats per minute.*
7. *Patients who have a history of hypertension uncontrolled by conventional medical therapy.*
8. *Patients who have received any drug known to have a well-defined potential for toxicity to a major organ system within the month prior to entering the study.*
9. *Patients who have clinically significant laboratory values outside the limits thus specified by normal laboratory parameters.*
10. *Patients who have any disease of the gastrointestinal system, liver or kidneys, or abnormal condition which compromises a function of these systems and could result in a possibility of altered metabolism or excretion of ibogaine will be excluded. As it is not possible to enumerate the many conditions that might impair absorption, metabolism or excretion, the provider should be guided by evidence such as:*
 - A. *History of major gastrointestinal tract surgery (e.g., gastrectomy, gastrostomy, bowel resections, etc.) or a history or diagnosis of an active peptic ulcer or chronic disease of the gastrointestinal tract, (e.g. ulcerative colitis, regional enteritis, Crohn's disease or gastrointestinal bleeding).*

B. Indication of impaired liver function.

C. Indication of impaired renal function.

11. Patients with active tuberculosis.

12. Pregnancy

After years of review of reports of hundreds of ibogaine patient treatments, the effective dose for the treatment of chemical dependence, including opioid dependence, has been seen to be between 15 mg/kg and 20 mg/kg of ibogaine. It has been reported by some researchers that lower doses are effective but, this has been disputed. Effects of ibogaine generally will make themselves evident within 45 minutes to as long as, three hours after administration. In most cases opioid withdrawal signs will be reduced within 45 minutes of ibogaine administration. Ibogaine is usually administered in place of what would be the next scheduled dose of narcotics. This would provide for an ibogaine administration schedule 8 hours after the last dose of heroin, morphine or demerol and 24 hours after the last dose of methadone. It is expected that the patient would be exhibiting minor withdrawal signs at the time of ibogaine administration ... The use of a multi-dose regimen of ibogaine, over time, particularly for methadone, is in keeping with literature in the field [a 1984 study is cited].

Whether in a hospital or outside of a medical environment the patient's safety can be best provided for by continuously observing the patient. A nursing assistant or other trained person should observe the patient continuously for 48 hours or longer if the patient response to ibogaine requires it. During this period pulse and blood pressure should be monitored at regular intervals and at any time that patients indicate discomfort or the observer has concern. The regular intervals may be as short as 30 minutes for the first four hours or until blood pressure and pulse are stable and then at time points of 1 hour to 4 hours thereafter.

Observers should have training in cardiopulmonary resuscitation and be prepared to call a hospital or emergency medical services should the patient's pulse drop below 50 beats per minute ... Two useful surveys that should be included in ibogaine therapy are the Objective Opiate Withdrawal Scale (SOWS) and the Subjective Opiate Withdrawal Scale (SOWS) ...

Assessments [during treatment]

Cardiovascular — Apply ambulatory pulse and blood pressure apparatus that is programmed to obtain and record digital quantities q 30 min for a 24 h period. Apply device just before dosing.

Neurological — Observe for the onset (that is time from the administration of ibogaine) for drug-related changes in neurological functioning (e.g., the onset of changes in speech patterns, nausea and vomiting)

Psychological — Observe and record what patients spontaneously say, Record the onset and duration of the somnolent phase.”

Appendix B — Independent advice to the Commissioner

The following expert advice was obtained from general practitioner Dr George Tripe, who has experience in the rural hospital setting. Dr Tripe was asked to provide advice specifically on Dr B's interpretation of the ECG and the decision to treat Mrs A taking into account her clinical presentation.

“I have been asked to comment on the treatment [Mrs A] received from [Dr B] [in 2013] — commenting particularly on the electronically produced warnings on the report of the ECG.

1. Interpretation of ECG

The ECG is a poor quality fax of the original — much is lost in the electronic transmission of ECGs making them difficult to read. Some of the abnormalities reported on the electronic tracing require a leap of faith to appreciate on the faxed copy.

The electronic reports states there are:

- premature ventricular complexes — I can see P waves followed by QRS complexes. In the rhythm strip on the bottom of the page there is some variability of the cardiac rate (the regularity of the P waves) but no true PVBs that I can see. (One QRS complex has dropped well below the baseline in V3 but this, I would suspect, is something amiss with the recording machine rather than an electrical conduction issue in the patient's heart.) In the latter part of the tracing the baseline does fluctuate and is rather unclear — this is something we quite often see with electrical interference and I attach no significance to it.
- There is comment about a QS abnormality in III — certainly I cannot see any R wave — I am not aware of that being significant.
- A ‘Q’ is described in II — it is difficult to see and I would not attach any significance.
- A repolarisation disturbance is noted in AVF with a flat T wave and an inverted T in III — these do not mean anything to me.

The reported ECG changes do not ring any alarm bells for me. In the absence of relevant clinical history or findings I would not be doing anything about them — in some circumstances I might have an old ECG tracing to compare — but not here.

I would report this ECG as normal sinus rhythm with minor sinus arrhythmia. I would accept the QRS complexes, ST segments and T waves as within normal limits.

Where there has been a sudden death I would consider the possibility of a prolonged QT syndrome — something I know little about. I did research a ‘standard’ QT in this case — as far as I could ascertain the QTc reported as 428 milliseconds is within normal limits.

In the accompanying blood test results there are minor changes in the liver function tests (LFTs) with a slightly reduced albumin. There are no electrolyte or creatinine/urea results as a measure of renal function.

I would accept the abnormal LFTs and reduced albumin as a probable consequence of past drug use and poor diet — the treatment priority I would see as being to get the patient off the drugs she has reportedly been using — heroin, morphine, methadone — and expect the abnormal LFTs would, with time, improve.

2. appropriateness of commencing Ibogaine in the light of ECG and blood test results.

I have no experience in the use of Ibogaine and had not previously heard of the drug. I personally would be most reluctant to use a drug like Ibogaine that I had no experience with or that respected peers had not recommended to me. My lack of experience aside, I do not see any reasons in the ECG or blood reports presented to not use a drug I might have had previous success with.

3. It would be nice to think that [Dr B] might have consulted a specialist in relation to the ECG and administration of Ibogaine; but I doubt if he would have found any specialist in a position to give him useful advice. To give useful advice one has to have knowledge and preferably experience — I doubt if any cardiology expert in NZ has had experience or much knowledge of Ibogaine.

Consultation about the ECG changes reported on the electronic report/print out might have contributed something but unlikely in my view other than caution about using a drug not accepted by mainstream medicine — particularly one that has reportedly been associated with arrhythmias.

4. [Dr B] might have checked the patient's electrolytes though I don't know how long that might have delayed starting treatment (does [the district] have facilities for prompt/reliable electrolyte testing?) — and delay is often unacceptable to drug users seeking treatment.

5. The way [Mrs A] stopped her Effexor is not ideal — but again one must be mindful of the less than optimal behaviours of drug users and their disregard of medical advice that does not suit their immediate aspirations.

6. Treating drug seekers and users is always difficult. They often have other issues such as personality and/or behavioural disorders — if they didn't they would be unlikely to be drug addicts.

Drug addicts tend to be very demanding and not very respectful of medical advice that does not meet their immediate expectations. [Dr B] has obviously treated and helped a number of drug addicts for which one must respect and admire him. He has been using a medication not accepted by the mainstream of a conservative

profession and, as such, would be unlikely to find support and advice amongst colleagues.

I understand that [Dr B] had, after attending conferences on the topic, developed protocols for Ibogaine treatment. I have not seen those protocols but, even if I had seen them, I do not have the knowledge to comment on the value of them in protecting/safeguarding the patient against the recognized risks and side effects of Ibogaine. Apparently the recognized risks of Ibogaine are around cardiovascular disease and seizures — I would hope that [Dr B] was aware of this and what the cardiovascular risks were and how they might be identified.

The final dose of Ibogaine was administered at 8.50 pm [Day 3] (treatment having been started that day) and [Mrs A] was found dead at 6 am [Day 5]. The protocol described would indicate regular monitoring of the patient — there is no comment on recordings made or the state of the patient between the last dose of medication and her being found dead over 30 hours later. I do wonder what observations might have been made and recorded in this time.

SUMMARY.

Whilst I would not be comfortable attempting to treat drug addicts with Ibogaine myself I accept that there are colleagues who have researched the drugs and are prepared to treat these people in this way, and I respect them for this. Unfortunately, because there are few doctors doing this, it leaves those who are relatively unsupported and vulnerable to criticism and sanction should things go wrong.

With my knowledge of ECGs I would not have considered the ECG on [Mrs A] a contra-indication to her being treated with Ibogaine.

In responding to the specific questions asked of me:

1. It was reasonable to classify the ECG as unremarkable.
2. It was not inappropriate for [Dr B] to commence Ibogaine treatment.
3. I doubt if [Dr B] could have ‘usefully’ consulted a specialist about the ECG
4. I doubt if further testing would have changed [Dr B’s] view of the suitability of treatment with Ibogaine for his patient.
5. The sudden cessation of Efexor, whilst not the preferred way and not ideal, was probably inevitable with this patient.
6. To reiterate my comments above:

I do wonder about the monitoring of the patient after the last dose.

I do have some concerns about the lack of support for practitioners practising outside of mainstream accepted practice.”