Commissioner's Opinion
01HDC02649

Ms A

Thank you for your response to my provisional opinion. Your comments have been considered and changes made to my report where relevant, but you have not provided me with any new information that has persuaded me to alter my view. In my opinion you overstated the benefits of IHT and led Ms A to believe that it was scientifically proven to treat CFS. Accordingly, you breached Right 6(1)(b) of the Code of Health and Disability Services Consumers' Rights.

My final opinion is as follows:

The complaint was that:

In December 1998, general practitioner [Dr B] treated [Ms A] inappropriately as follows:

- *Provided Interval Hypoxic Training ("IHT") to [Ms A] to treat her Chronic Fatigue Syndrome ("CFS").*
- *Informed Ms A that IHT was scientifically proven to treat CFS when it was not.*
- *Did not monitor [Ms A]'s oxygen levels during the IHT treatments.*

During the course of this investigation I obtained information from you and Ms A. I reviewed your consultation records. I obtained expert advice from a general practitioner with specialist qualifications in sports medicine, Dr C.

Facts Gathered During Investigation

Ms A first consulted you at your practice on 7 December 1998. Ms A had heard about Interval Hypoxic Training ("IHT") from a friend and thought it might help her CFS. Ms A informed me that she had learned to manage her illness and was very careful not to try any unproven remedies to treat her condition.

Ms A stated that you told her IHT had been used successfully to treat CFS many times before, and that there was a large body of research supporting the use of the treatment.

Your notes record that you explained to Ms A that IHT is used to enhance the physical performance of athletes. The purpose of the IHT was to improve Ms A's severely depleted energy levels and not a treatment for CFS itself. This was based on a large body of Eastern European scientific literature, mainly Russian. You advised me that you carefully explained to her that there was no evidence that IHT could cure her CFS, but that, given the physiological adaptations that occur with altitude exposure and the safety of IHT, there could be an improvement in her severe fatigue symptoms. This is recorded in your notes. At the time you also provided Ms A with an information sheet titled "Hypoxia: Non-Specific Interval Training". This sheet was written by Dr D, who introduced IHT to New Zealand. A copy is attached.

Your lawyer advised me that you did not give Ms A the information sheet. However, Ms A is adamant that you gave her the sheet. I note that you informed me that "the

information provided in the consent process was what had been given to me from Dr D", who wrote the sheet which Ms A claims you gave her. I am satisfied on the balance of probabilities that Ms A's recollection is correct, and that you did provide her with the information sheet.

You purchased the IHT unit in 1998 in order to offer it to the athletic community. I note that you sold your IHT equipment late in 1999 to a facility specialising in sports training and at present are living overseas.

You informed me that IHT is a form of physical conditioning and training, akin to altitude training. IHT involves passive altitude (hypoxic) air exposure and is a way of improving oxygen delivery and utilisation by body cells. A typical course involves 15 to 30 one-hour exposures over three weeks. Each one-hour application consists of alternating five minute hypoxic exposure with five minutes of normal air exposure. The blood oxygen levels return to normal within 30 seconds of room air exposure. Blood oxygen saturation levels are monitored by use of an oxygen pulsimeter attached to the finger of the client.

Prior to acceptance for IHT training the client's medical history and current health status is checked to exclude contraindications such as anaemia, heart disease, chronic obstructive airways disease, epilepsy, pregnancy etc. A blood test is undertaken to exclude anaemia. You informed me that any adverse symptoms experienced by clients are similar to those experienced when people climb to altitude: increase in breathing and pulse rates, sometimes dizziness, and light-headedness.

Ms A claims that you were not present and did not monitor her oxygen levels during treatments. Your notes record that you did, apart from one occasion when the equipment was unavailable. My advisor noted that you were in an adjacent room and considered you provided Ms A with a reasonable level of supervision.

My advisor stated that your notes were of an appropriate standard.

After the session on 7 December 1998 Ms A next consulted you on 19 January 1999 and your notes record that she was feeling improved, with reduced fatigue. Ms A then had 13 further sessions with her last session on 12 February 1999.

About 48 hours after her last treatment Ms A said she felt dreadful, "as if she was dying". Ms A believes these symptoms were attributable to IHT. Your notes record that on 24 February 1999 Ms A consulted you stating that she had an increase in her dizzy symptoms, headache when bending forward, nausea and numbness in her hands and feet. Examination revealed no abnormalities.

My advisor informed me that CFS presents a constellation of symptoms and it would be difficult to separate out which symptoms were true side effects of IHT or symptoms relating to CFS.

Ms A returned on 27 February 1999 to discuss her blood test results. She was concerned about a possible Vitamin B12 deficiency. You gave her a Vitamin B12 injection intramuscularly. This was the last time you saw Ms A.

Names have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

Ms A believes that IHT is not scientifically proven to treat CFS. My advisor informed me that IHT is scientifically proven to improve the aerobic sporting performance of élite athletes. However, its role in the treatment of disease is much less well documented. My advisor read additional material which attests to the benefit of IHT in clinical medicine. It is not a recognised or scientifically proven treatment for CFS.

Code of Health and Disability Services Consumers' Rights

The following Rights in the Code of Health and Disability Services Consumers' Rights are applicable to this complaint:

RIGHT 4
Right to Services of an Appropriate Standard

1) *Every consumer has the right to have services provided with reasonable care and skill.*

RIGHT 6
Right to be Fully Informed

1) *Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including –*
    a) *An explanation of his or her condition; and*
    b) *An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option. ...*

Commissioner's Opinion

In my opinion you did not breach Right 4(1) of the Code of Health and Disability Services Consumers' Rights, but you did breach Right 6(1)(b) of the Code.

Right 4(1)

Alleged failure to monitor Ms A's oxygen levels
Under Right 4(1) of the Code, Ms A had the right to have services provided by you with reasonable care and skill. Dr C advised me that you generally met the expected standards of care for a general practitioner when you provided IHT to Ms A.

Dr C informed me that, while not absolutely essential, it was highly desirable to monitor oxygen levels with an oximeter during each IHT treatment, particularly when using it to manage disease as opposed to a training adjunct for healthy athletes. Your notes reflect that you monitored Ms A's oxygen levels during the treatment apart from one occasion when the oximeter was unavailable.

Accordingly, in my opinion you did not breach Right 4(1) of the Code in relation to the quality of care you provided Ms A.

Right 6(1)(b)

Informed Ms A that IHT was scientifically proven
The efficacy of IHT is not in issue here. I do not have the power to review the efficacy of any treatment. The Code governs the standard of treatment and of the information disclosed prior to treatment, but not the efficacy of the treatment. There is nothing to prevent people providing or seeking out any form of treatment they wish. The crucial issue in this case was what you told Ms A prior to providing IHT treatment.

Under Right 6(1)(b) of the Code, Ms A had the right to all the information that a reasonable consumer, in her circumstances, would expect to receive, including an assessment of the expected risks, side effects, benefits and costs of each option. She was entitled to be given information about the safety and efficacy of any proposed therapy. This included accurate information about the benefits of proposed treatments.

Ms A has CFS. My advisor noted that the information sheet – which I am satisfied you provided to Ms A prior to receiving IHT – was very strongly supportive of IHT being beneficial for a wide range of medical conditions including CFS. My advisor had reservations that some of the information in the advice sheet provided to Ms A prior to treatment overstated the benefits of IHT. My advisor considered that some of the information appeared more promotional than informative. For example, a wide range of diseases was quoted, with effectiveness recorded as a percentage. Under the heading 'Medicine, Traditional, Rehabilitation, Preventative, Prophylaxis, Treatment' positive effects of 80 to 95% were reported. This heading included stress related disorders such as CFS, depression, neurosis, low energy etc.

My advisor was not aware of any validation of these percentages from appropriately conducted research published in peer review journals. Certainly there was no validation referred to for these figures in the information sheet.

My advisor was concerned that an unrealistic expectation of treatment benefits could be built up from reading this advice sheet. Also my advisor noted that anaemia is inappropriately included in the list of conditions amenable to treatment by IHT. My advisor considered that the written advice sheet should have been written in more appropriate terms to distinguish between evidence-based treatment (based on one or more randomised controlled trials) and those conditions with a lesser evidence base.

I accept that you also gave a great deal of oral information to Ms A at her initial visit in December 1999, and explained the bodily symptoms she might experience during IHT sessions. However, in my opinion the lasting impression given to Ms A, in particular by the information sheet which you gave her to take away, was that IHT had significantly proven benefits as a treatment for CFS.

In my opinion you overstated the benefits of IHT. You did not meet the standard of accurate information about benefits about a proposed treatment that a reasonable consumer in Ms A's circumstances would expect to receive. Accordingly, in my opinion, you breached Right 6(1)(b) of the Code.

Actions

I recommend that you take the following actions:

- Apologise in writing to Ms A for breaching the Code. This apology is to be sent to my Office and will be forwarded to Ms A.

- Ensure that should you provide IHT treatment in the future, you review the oral and written information provided to patients, to ensure that it is accurate and more informative than promotional.

I have sent a copy of my final opinion to the Medical Council of New Zealand for its information. I also propose to send an anonymised copy of my final opinion to the Royal New Zealand College of General Practitioners, and the Royal Australasian College of Sport Physicians, for educational purposes.

I look forward to receiving your written apology to Ms A, and confirmation that you will meet my recommendation about any future provision of IHT treatment, by 16 January 2002. The file will then be closed.

Names have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.