Osteopath, Mr B Osteopathy Clinic

A Report by the Deputy Health and Disability Commissioner

(Case 16HDC01803)



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Executive summary

- 1. Mrs A had an accident in 2006, which resulted in incomplete tetraplegia. In early 2016, Mrs A sustained a lumbar sprain and had a further lower back injury two months later. She sought treatment of her recent injuries from an osteopath, Mr B.
- 2. At the first consultation, Mrs A explained that she had a spinal cord stimulator and a baclofen pump in situ. She also offered to show Mr B X-rays of her spine to demonstrate the positioning of her indwelling devices and to show the extent of her scoliosis and pelvic obliquity, but Mr B declined.
- The first four treatments proceeded without incident; however, within an hour of the fifth treatment session, Mrs A developed severe pain in her right sacroiliac joint and lumbar spine. When she telephoned Mr B to report her increasing pain of a type that she had not experienced previously, and that had not resolved with analgesia Mr B recommended acupuncture treatment and advised Mrs A to apply ice to the affected area. Mrs A told HDC that she continues to experience pain, and that she has experienced a marked decrease in mobility.

Findings

4. It was found that Mr B placed insufficient emphasis on the provision of safe and appropriate care. He did not undertake research to remedy his gap in clinical knowledge regarding treatment of consumers with tetraplegia, and did not view Mrs A's X-rays when presented with the opportunity. Mr B's treatment and clinical documentation failed to meet the standard required of an osteopath, and he did not refer Mrs A to her GP or to the hospital when she complained of increasing pain following treatment. For all these reasons, it was held that Mr B failed to provide services to Mrs A with reasonable care and skill, and therefore breached Right 4(1) of the Code. Adverse comment was made about the osteopathy clinic's lack of written policies and procedures.

Recommendations

- 5. It was recommended that Mr B audit his documentation, arrange for regular mentoring, and provide a written apology to Mrs A.
- 6. It was also recommended that the Osteopathic Council consider whether a review of Mr B's competence is warranted.

Complaint and investigation

- 7. The Commissioner received a complaint from Mrs A about the services provided to her by Mr B. An investigation was commenced and the following issues were identified for investigation:
 - Whether Mr B provided Mrs A with an appropriate standard of care in 2016.
 - Whether the osteopathy clinic provided Mrs A with an appropriate standard of care in 2016.
- 8. This report is the opinion of Meenal Duggal, Deputy Commissioner, and is made in accordance with the power delegated to her by the Commissioner.
- 9. The parties directly involved in the investigation were:

Mrs A Consumer/complainant
Mr B Osteopath/provider

Osteopathy clinic (the clinic)/provider

10. Information was reviewed from:

Dr C General practitioner/provider

District Health Board Provider

Accident Compensation Corporation

Independent expert advice was obtained from Dr Sharon Awatere, an osteopath (**Appendix** A).

Information gathered during investigation

Background

12. In 2006, Mrs A had an accident and sustained a spinal cord injury (C4/5¹ fracture dislocation with a burst fracture at C5), causing incomplete tetraplegia.² She underwent a corpectomy³ and anterior C4–6 fusion. To manage her spasticity,⁴ Mrs A has a spinal cord stimulator⁵ and baclofen pump⁶ in situ.

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¹ The midsection of the cervical spine, near the base of the neck.

² Partial paralysis of all four limbs (there is some level of function, voluntary movement, or sensation).

³ A surgical procedure to remove a vertebral body, usually done as a way of decompressing the spinal cord and nerves.

⁴ Increased tension in muscle.

⁵ A surgically placed device that delivers small electrical impulses to the spinal cord to interrupt pain signals to the brain.

⁶ A surgically implanted pump that continuously delivers baclofen into the spinal canal to treat stiff muscles.

- 13. Mrs A told HDC that the battery of the spinal cord stimulator sits subcutaneously⁷ over her anterior right ribcage, with the lead from the battery running around the lateral side of the rib cage and into the spinal canal. The electrode plate is implanted at T10.⁸ In relation to her other indwelling device, Mrs A stated that the baclofen pump reservoir is situated subcutaneously in the lower right abdomen, with the catheter running around the right side of the waist and into the intrathecal⁹ space of the spinal canal at L3.¹⁰
- 14. On 26 February 2016, Mrs A sustained a lumbar sprain. Her back pain improved intermittently with physiotherapy.
- 15. On 28 April 2016, Mrs A was jolted whilst being mobilised in her wheelchair, resulting in further injury to her lower back. Mrs A attended an osteopath, Mr B, on 11 May 2016, 18 May 2016, 25 May 2016, 1 June 2016, and 8 June 2016 for treatment of her recent injuries.
- 16. This report focuses on the care Mr B provided to Mrs A on 11 May 2016 and 8 June 2016.

Initial osteopathy consultation — 11 May 2016

- 17. Mr B told HDC that Mrs A presented with lumbar discomfort, severe lumbar scoliosis, ¹¹ and pelvic obliquity. ¹² Mr B stated that he obtained Mrs A's medical history during the initial consultation. He recalls that Mrs A spoke about the impact of her disability, the medications she was taking and the side effects of those medications, including constipation and muscle weakness, and that she was no longer able to weight bear with the aid of a walking frame. Mr B told HDC that he had treated a tetraplegic patient previously but, unlike Mrs A, that patient did not have severe scoliosis or an intrathecal pump fitted.
- 18. Mrs A told HDC that Mr B did not ask her any direct questions about her medical history, but she recalled detailing the injuries she had sustained earlier in the year, the impact of those injuries, how she came to be a wheelchair user, and the location of her indwelling devices. Mrs A stated that Mr B's recollection of the consultation is not entirely correct, and that at the time she was able to weight bear with the assistance of a walking frame, but for a shorter period than previously. She also said that she did not discuss all her medications with Mr B on that occasion and that she would have offered to email him the list if he had enquired.
- 19. Mr B recorded the following details in his practice management software:

"Mechanism: pulled on a hosepipe

Past Medical History (General Health): tetraplegic

Medications: pump in abdomen for painkilling drugs into spinal cord"

20. Mr B explained that Mrs A had related the various medications she was taking and their purpose, but he recorded only the pump, as "it was the most important". Mr B stated that he

¹² Malalignment of the pelvic girdle.



⁷ Under the skin.

⁸ One of the vertebrae at the bottom of the thoracic (middle) region of the spine, in the lower part of the ribcage.

⁹ Space under the middle membrane covering the spinal cord.

¹⁰ The middle of the five lumbar vertebrae in the lower back portion of the spine.

¹¹ A side-to-side curve in the lower spine.

had not seen a baclofen pump previously and relied on the information from Mrs A about where it was inserted and its benefits. There are specific text boxes in the practice management system for entries on sport, weekly activity, diet and fluids, surgery, social factors, fitness, accidents, road traffic accidents, pregnancies and birth, fractures, injury, medical intervention, and family history; however, these were not filled in. Mr B said:

"I could and should have spent a lot more time filling in the relevant information on this page ... I kept the notes down to the bare minimum. I believe that even though I was aware of the details, it was an error of judgment not to have recorded much more detail."

- Mr B observed that Mrs A's lower ribs did not move laterally when she inhaled, which restricted her diaphragm. He said that he planned to ease Mrs A's discomfort by freeing the 12th rib to release the diaphragm. The treatment notes indicate a differential diagnosis of "S5Y3 sprain rib cage right side".
- 22. Mrs A said that she offered to show Mr B X-rays of her spine to demonstrate the positioning of her indwelling devices and to show the extent of the scoliosis and pelvic obliquity, but Mr B declined as he could see the extent of Mrs A's scoliosis clearly and was aware of the pump's position. Mr B explained that he did not need to view the imaging as he had no intention of treating Mrs A anywhere near the baclofen pump, which he said was "clearly visible" under the right abdominal wall.
- 23. Mrs A stated that, while the baclofen pump reservoir is clearly visible, the subcutaneous catheter cannot be seen and is not palpable.
- Mr B told HDC that he should have viewed the X-rays, as it would have given him a visual clue as to what techniques would possibly have a negative impact on the intrathecal pump insertion, and it would also have increased his understanding of the severity of the scoliosis. Mr B considers that he should have viewed the X-rays at least before performing the extra techniques at the fifth treatment session.
- 25. Mrs A expressed no concerns to HDC about the treatment Mr B provided to her on 11 May 2016 or on the subsequent three consultations.

Fifth treatment session — 8 June 2016

Mr B stated that because Mrs A reported that she had not experienced any real improvement in her symptoms, he suggested that he work on her scoliotic posture to try to increase the space between the 12th rib and the iliac crest¹³ in order to help her to sit more upright and comfortably in her wheelchair. According to the notes taken on 8 June 2016, this included mobilisation of the lumbar spine and the sacroiliac joint. He said that Mrs A agreed to the new approach in treatment. However, Mr B acknowledges that the suggestion would have been very agreeable to Mrs A, and the potential for a significant improvement in her comfort would have influenced her decision to give consent.

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¹³ Top part of the hip bone.

The joint that connects the hip bones to the sacrum (the bone between the lumbar spine and the tailbone). The sacroiliac joints primarily absorb shock between the upper body and the pelvis and legs.

- 27. Mrs A told HDC that she has no recollection of Mr B stating that his treatment would improve her scoliosis, and that such a suggestion would have prompted a number of questions, as she had found previous attempts to treat it very painful.
- 28. Mr B ticked the check boxes in the practice management system labelled "treatment plan discussed", "warnings regarding treatments discussed", and "verbal consent to treatment gained".
- 29. Mrs A said that she was not informed of the possible risks, but consented to the treatment as she trusted Mr B, and he seemed confident that he would be able to help her. Mr B acknowledged in retrospect that he did not provide Mrs A with sufficient information to obtain her informed consent. He stated:

"As the outcome of the treatment given was not certain i.e. there was insufficient evidence to prove that it was the right approach for a tetraplegic client, nor did I know the possibility of Autonomic Dysreflexia or offer an alternative option, such as Cranial-Sacral therapy, then all the criteria for informed consent were not met."

- 30. Mr B described to HDC the treatment he provided as follows:
 - a) While Mrs A was supine,¹⁵ he placed his hands under the right quadratus lumborum muscle¹⁶ and then attempted to stretch the muscle and mobilise the lumbar spine by separating his hands. He held the stretch for a few seconds before releasing, and repeated the procedure approximately 10 times.
 - b) Mr B supported Mrs A's right leg and flexed it to 45 degrees to mobilise the right sacroiliac joint. He sat on the treatment table on Mrs A's right-hand side, so that her right foot touched his right thigh, and then placed his right hand on Mrs A's right knee to keep her leg straight. Mr B put his left hand under Mrs A's right posterior superior iliac spine, and proceeded to move Mrs A's knee downwards towards her right foot with his right hand. When Mr B felt the sacroiliac open slightly, he encouraged the opening with his left hand by pulling caudally towards Mrs A's feet. This technique was repeated approximately 10 times.
 - c) Mr B assisted Mrs A to lie on her right-hand side so that he could stretch her left quadratus lumborum. As she switched from her supine position, Mr B bent Mrs A's knees to 45 degrees flexion¹⁸ and supported her legs. Mrs A lay slightly diagonally and had her back to Mr B. While ensuring that her lumbar spine was neutral, Mr B supported Mrs A's left leg with his right hand under the medial left thigh and had his left hand support the medial lower leg. He straightened her left leg and lowered the left leg towards the treatment table until the left knee came into contact with the table. Mrs A's left lower leg was slightly over the edge and in line with her body. Mr B stood behind Mrs A, placed his left hand on Mrs A's left lateral aspect of the iliac crest, contacting the left gluteus medius, and then placed the heel of his right hand on the left

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¹⁵ Lying on the back.

¹⁶ Located in the lower part of the back. It contributes to the movement and stabilisation of the spine and pelvis.

¹⁷ Towards the posterior part of the body.

¹⁸ A bending movement around a joint that decreases the angle between the bones of the limb at the joint.

quadratus lumborum, just lateral to the left lumbar erector spinae. With slight pressure, he moved his right hand superior and laterally to passively stretch the quadratus lumborum. The left hand supported the left iliac crest and gently moved the iliac crest towards Mrs A's feet. The stretch was repeated between 7–10 times.

- d) Mr B assisted Mrs A to lie supine again, and raised Mrs A's right lower leg to 30 degrees. He had his left hand under the left calf supporting the left leg whilst his right hand contacted the sole aspect of the right foot. Mr B asked Mrs A to straighten her right leg while he resisted with his right hand. This was repeated 7–10 times.
- 31. Mr B stated that the movements were slow and gentle.
- In contrast, Mrs A described the treatment as more vigorous than what she had received previously from Mr B and other health providers. She recalled that her treatment on that day involved:
 - "• Multiple large rotations of my right hip, starting with my leg held at a 90 degree bend at the hip and knee and then rotated in a clockwise direction repetitively
 - [Proprioceptive neuromuscular facilitation¹⁹] stretching of my right leg and right side of my lower back
 - Extensive stretches taking my right knee over towards my left shoulder
 - Repetitive pulling down motions on the right hand side of my pelvis and sacroiliac area with my right knee and hip in a flexed position
 - While lying on my left side, 'mobilisation of my lumbar facet joints' which included extension of my spine towards the side of the bed and lowering my legs over the side of the bed while performing manipulations on my lumbar spine with [Mr B's] hand."
- 33. Mrs A stated that she could not have been placed on her right side as she has not been able to lie on her right side since 2006, owing to a right-sided shoulder injury she sustained at the same time as her spinal cord injury.
- Mr B denied that Mrs A was placed in a left-hand side lying position with both legs bent over the edge. He stated that he did not apply any "thrusts" to Mrs A's back or the right ilium, nor did he lift her right leg up and force it towards her left shoulder or perform any rotational techniques to the lumbar spine. Mr B stated that he was aware that mobilising the lumbar spine in any rotational direction is not appropriate when treating someone with tetraplegia, regardless of whether they have an intrathecal pump in situ or not.

Subsequent events

Mrs A stated that within an hour of the osteopathic treatment she developed severe pain in her right sacroiliac joint and lumbar spine, which radiated around her whole lower back, down into her pelvis, and up into the base of her rib cage.

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¹⁹ A technique that involves pulling a muscle into a stretch position before flexing it — used to increase flexibility and range of motion.

- 36. On the afternoon of 8 June 2016, Mrs A telephoned Mr B and informed him that despite having taken paracetamol, ibuprofen, and OxyNorm, she had increasing pain of a kind she had not experienced previously, particularly around the area of the baclofen pump. Mrs A also expressed concern that she was developing autonomic dysreflexia. She said that Mr B offered to see her in the afternoon and arrange for acupuncture treatment to relieve her pain, and advised her to apply an ice pack to the area of concern. Mrs A said that she applied the ice pack but declined the offer of acupuncture as she felt that she needed to go home and lie down.
- Mr B told HDC that he assumed that Mrs A had had a reaction to the muscular work on the left quadratus lumborum and the active resistance exercises. He said that Mrs A did not report any symptoms that would have indicated a risk of dysreflexia, such as irregular or racing heartbeat, headache, dizziness, anxiety, or confusion. He stated that Mrs A had been sore for two days following her session on 1 June 2016, and he assumed that her discomfort would last a similar amount of time. He said that he asked Mrs A to call back if her pain did not resolve the next day, but to his knowledge she did not call the clinic again.
- 38. Mrs A reported that over the next few days she continued to experience severe pain and muscle spasms on both sides of her mid-lower back, and the right-hand side of her waist and abdomen.
- On 10 June 2016, Mrs A consulted her general practitioner, Dr C, regarding her symptoms. Dr C documented that Mrs A had been experiencing more frequent dysreflexia over the past few weeks, and that this was likely caused by a combination of menstruation, a healing pressure sore, and recent lower back strain. Dr C also recorded Mrs A's complaint that she had had increased lower back pain, stiffness, and more dysreflexia since her last osteopathy session. On examination, Dr C noted that Mrs A had a tender lumbar spine, particularly over the right sacroiliac joint; however, the baclofen pump appeared undisturbed. Dr C recommended trialling extra gabapentin, and conservative management for muscular pain, such as applying a heat/cold pack, acupuncture, and Voltaren. She advised Mrs A to seek immediate medical attention if her dysreflexia did not resolve with gabapentin and OxyNorm.
- 40. On 12 June 2016, Mrs A received acupuncture treatment, but this did not provide any noticeable relief, and on the following day she was referred to hospital for pain management. Mrs A was discharged on 27 June 2016. Her discharge summary stated:
 - "You have had a significant increase in the pain in your lower back and we feel this may have been related to the osteopathic manipulating you had, fortunately no concerning causes for this pain were found on your scan."
- 41. Mrs A told HDC that her pain has still not resolved, and she has experienced a marked decrease in mobility, resulting in the need for 24-hour care per day. She said that, prior to this, she required only seven hours of carer support each day.

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²⁰ An acute disease that commonly occurs in patients with spinal cord injury, with symptoms ranging from headaches, sweating, hot flashes, and involuntary bristling of hairs, to irregular heartbeat and high systolic blood pressure, which may lead to cerebral haemorrhage, convulsions, and death.

Further information

42. Mr B told HDC that he does not believe that the treatment he provided could have resulted in a soft tissue injury, as this would require "a lot of force". However, he stated:

"The fact that I did the massage and stretching on the left quadratus lumborum when [Mrs A] was in a right side lying position could have placed [a] stretch on the ureter and the kidney possibly leading to bladder irritation and on to dysreflexia."

- 43. Mrs A stated that she was put in a left lying position rather than on her right side, and maintained that she did not have her left quadratus lumborum stretched. She also denied experiencing any bladder irritation. She therefore disagreed with Mr B's explanation above.
- 44. Mr B acknowledged that he ought to have increased his knowledge of tetraplegia and baclofen pumps before treating Mrs A. He said that he has since spent a lot of time researching intrathecal pumps and, as a result, is now aware that autonomic dysreflexia is a risk for anyone with a spinal cord injury above the sixth thoracic level. He said:

"Tetraplegia would naturally lead to atrophy of the musculature and with baclofen being a muscle relaxant which is constantly drip feeding into the spinal cord, I now realise that the atrophy of [Mrs A's] muscles would unlikely change with massaging or stretching muscles ... my attempt to try and regain some strength in the right leg with gentle resistant exercises would have very limited results, if any. I now believe that I put too much 'input' i.e. stimuli through the central nervous system."

- 45. Mr B stated that he does not consider tetraplegia to be an absolute contraindication to mobilisation, but he conceded that, in hindsight, it may have been more prudent to utilise cranial-sacral therapy or not to treat at all.
- 46. At the time of these events, the clinic did not have any written policies, protocols, or procedures.
- 47. Mr B said that he has made a number of changes to his practice, including:
 - a) He has increased his consultation time from 30 minutes to 40 minutes, in order to improve his standard of notetaking without compromising treatment.
 - b) He will ensure that he reviews all relevant X-rays and scans and specialist notes, and obtains the patient's informed consent before commencing treatment.
 - c) The clinic now has a policies and procedures manual in place, which includes sections on informed consent, external communications, onward referral, and medical note-taking.
 - d) If presented with a condition with which he is unfamiliar, he will research its implications as to whether there are any contraindications to osteopathic treatment.
 - e) He now has regular clinical and practice management discussions with an osteopathic colleague about the problems encountered when running his own clinic.

f) He will hold weekly meetings with all practitioners at the clinic to discuss various patients, approaches to treatment plans, referrals, and any problems staff have encountered. The purpose of these meetings is to provide the opportunity for reflection and ongoing education.

Responses to provisional opinion

- 48. Mrs A was provided with an opportunity to respond to the "information gathered" section of my provisional opinion. Her comments have been incorporated into this report, where appropriate.
- 49. Mr B and the clinic were provided with an opportunity to respond to my provisional opinion. Mr B and the clinic had no comments to make.

Opinion: Mr B — breach

- 50. Mrs A had an accident in 2006, resulting in a C4/5 fracture dislocation with a burst fracture at C5. Following this, Mrs A developed incomplete tetraplegia. She has a spinal cord stimulator and a baclofen pump in situ.
- Mrs A sustained a lumbar sprain in February 2016 and had a further lower back injury two months later. She sought treatment of her recent injuries from Mr B.
- On 11 May 2016, Mrs A attended her first appointment with Mr B. Mrs A offered to show Mr B X-rays of her spine, but he declined on the basis that he could see her scoliosis clearly and he did not plan to treat her anywhere near her baclofen pump, which was "clearly visible". Mrs A told HDC that while the baclofen pump reservoir is visible, the catheter cannot be seen and is not palpable.
- Mrs A expressed no concerns to HDC about the treatment Mr B provided to her on 11 May 2016 or on the subsequent three consultations. However, Mrs A complained that the treatment she received from Mr B on 8 June 2016 was more vigorous than what had been provided previously, and that she developed severe pain in her right sacroiliac joint and lumbar spine within an hour of treatment. When Mrs A telephoned Mr B in the afternoon to report her increasing pain of a type that she had not experienced previously, and that had not resolved with paracetamol, ibuprofen, and OxyNorm Mr B recommended acupuncture treatment and advised Mrs A to apply ice to the affected area. Mrs A told HDC that she continues to experience pain, and that she has experienced a marked decrease in mobility, resulting in the need for increased carer support.
- 54. While Mrs A and Mr B disagree on the particulars of the treatment provided on 8 June 2016, both their accounts and the clinical notes refer to mobilisation of the lumbar spine.
- 55. My consideration below concerns the standard of care Mr B provided to Mrs A. It is not my role to make findings of causation, and my report should not be interpreted as drawing any inferences about whether or not Mrs A sustained a treatment injury.

Documentation

- Mr B told HDC that he took Mrs A's medical history at the initial consultation, and that Mrs A had detailed the impact of her disability, the medications she was taking, and the side effects of those medications, including constipation and muscle weakness to the extent that she was no longer able to weight bear with the aid of a walking frame. Mrs A stated that Mr B's recollection was not entirely correct, and that at the time she remained able to weight bear with a walking frame but for a shorter period than previously. Mrs A stated that Mr B did not ask her any direct questions, but she did recall talking about her recent injuries, the impact of those injuries, and how she became a wheelchair user. She also stated that she told Mr B about her indwelling devices and where they were located.
- 57. The following details were recorded in the practice management system:

"Mechanism: pulled on a hosepipe

Past Medical History (General Health): tetraplegic

Medications: pump in abdomen for painkilling drugs into spinal cord"

- 58. Although there are specific text boxes for entries on sport, weekly activity, diet and fluids, surgery, social factors, fitness, accidents, road traffic accidents, pregnancies and birth, fractures, injury, medical intervention, and family history, these were not filled in.
- 59. Mr B explained that even though Mrs A named the various medications she was taking and what they were for, he recorded only the pump, as "it was the most important". He said: "I kept the notes down to the bare minimum. I believe that even though I was aware of the details, it was an error of judgment not to have recorded much more detail."
- 60. My expert advisor, osteopath Dr Sharon Awatere, advised:

"The accepted practice is to keep accurate patient records that clearly document the presence and absence of relevant signs, symptoms, clinical information and medications prescribed, as well as options discussed, decisions made and the reasons for them, information given to the patient, and the proposed management plan."

- Or Awatere noted that Mr B's clinical notes were brief, and showed gaps in the gathering, organising, and recording of a focused personal health record. She commented that Mr B's notes do not show:
 - "• the site, radiation, character, intensity, duration, frequency, aggravating/relieving/non-affecting factors in relation to the presenting complaint.
 - a baseline assessment of 3–5 important activities the patient is unable to do on a day to day basis.
 - [Mrs A's] general health, energy levels, height, weight, and whether this is constant.
 - [Mrs A's] medical history and negative findings relative to negating the presence of dysreflexia.
 - Family and social factors.
 - [Mrs A's] expectation of treatment.

- Sufficient exploration of working hypotheses or prognoses.
- Possible findings indicative of the diagnosis of rib sprain."
- of Dr Awatere also noted that Mr B did not document the examination findings that led to the diagnosis of a rib sprain, and that there is no documentation of Mrs A's telephone call with Mr B on the afternoon of 8 June 2016. Dr Awatere stated that accepted practice is to clearly document the details of communications, including telephone discussions. She considered that the overall standard of Mr B's documentation, in terms of history taking, level of detail, and synthesis of information, was a departure from the standard of care.
- 63. Dr Awatere stated that the case history taken by Mr B did not reflect the complex nature of Mrs A's presentation or demonstrate potential clinical challenges and uncertainties. Dr Awatere opined: "Obtaining the relevant information supports safety and ensures the osteopath is able to act accordingly."
- I share Dr Awatere's concerns about Mr B's standard of record-keeping. While I accept that Mr B obtained elements of Mrs A's case history, I consider that his records were inadequate and incomplete. There were a number of text boxes in the practice management software on matters pertinent to Mrs A's presentation that had not been completed, and I am critical that the documentation does not show that an adequate examination occurred. The importance of the health record cannot be overstated. It is the primary document for recording care, and, in addition to facilitating continuity of care, is evidence of the rationale behind treatment decisions.

Treatment approach

65. Dr Awatere advised that Mr B's treatment approach had an insufficient focus on safety. She considered that this was exemplified by Mr B's decision not to review Mrs A's radiology. Dr Awatere advised:

"The serious nature of past injuries sustained by [Mrs A] required identification and documentation of the potential risks of treatment. For example, the presence of a fracture-dislocation requires ascertaining the location and severity via imaging, to prevent risk of increasing or precipitating nerve root irritation or compression in possible unstable segments of the spine."

- omplications involving an intrathecal baclofen pump or the presence of dysreflexia. These omissions indicate that Mr B lacked awareness of the nature of tetraplegia and did not appear to appreciate the risk of mobilisation acting as an irritant. Dr Awatere advised that mobilisation of the lumbar spine in the area of the baclofen pump was contraindicated, and that Mrs A's incomplete tetraplegia negated the use of mobilisation, in any event.
- 67. Mr B stated that he does not consider tetraplegia to be an absolute contraindication to mobilisation; however, he acknowledged that he ought to have increased his knowledge of tetraplegia and baclofen pumps before treating Mrs A. Mr B told HDC:

"I now realise that the atrophy of [Mrs A's] muscles would unlikely change with massaging or stretching muscles ... I now believe that I put too much 'input' i.e. stimuli through the central nervous system."

- 68. Mr B also stated that he is now aware that autonomic dysreflexia is a risk for anyone with a spinal cord injury above the sixth thoracic level.
- 69. It is apparent that Mr B lacked awareness of the risks of treating patients with tetraplegia and indwelling devices. This gap in clinical knowledge precluded the provision of safe and appropriate treatment to Mrs A. I am critical that Mr B did not take any steps to improve his understanding of Mrs A's condition before formulating a treatment plan and commencing treatment.

Post-treatment advice

- 70. Dr Awatere considers that Mr B's response to Mrs A's report of increasing pain was inappropriate and inadequate. Dr Awatere stated that it was "inadvisable" to refer Mrs A for acupuncture treatment, and that potentially the application of ice to the skin could have acted as an irritant and further complicated Mrs A's presentation. Dr Awatere advised that Mrs A ought to have been referred to the GP or the hospital as a matter of urgency.
- I agree that Mr B ought to have advised Mrs A to attend her GP or the hospital, particularly given that her pain was reportedly of a kind she had not experienced previously, and it had not resolved with paracetamol, ibuprofen, and OxyNorm. However, Mr B had little experience in treating patients with tetraplegia and lacked knowledge of the complications that may arise from treating such patients. I consider that the advice he provided was outside his area of expertise, and I am critical that he did not appreciate this at the time.

Conclusion

- note Mr B's admission that he was not aware that the treatment he provided would have had little effect on Mrs A's atrophied musculature, and that he did not know about the risk of dysreflexia. I am deeply concerned that Mr B did not undertake research to remedy his gap in clinical knowledge and, when presented with the opportunity to view Mrs A's X-rays, declined to do so. This leads me to conclude that there was insufficient emphasis on the provision of safe and appropriate care.
- 73. I am guided by Dr Awatere's advice that Mr B's treatment and clinical documentation failed to meet the standard required of an osteopath.
- 74. Further, I am critical that Mr B did not refer Mrs A to her GP or to the hospital when she complained of increasing pain following treatment. The advice he provided was outside his expertise.
- 75. On the whole, there appears to have been insufficient consideration of the complexities of Mrs A's presentation and the risks of treatment. For all the reasons above, I find that Mr B failed to provide services to Mrs A with reasonable care and skill and, accordingly, breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights.²¹

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²¹ Right 4(1) of the Code states: "Every consumer has the right to have services provided with reasonable care and skill."

Opinion: The clinic — adverse comment

- 76. Mr B is a director and shareholder of the clinic, and an employee of the company.
- As a healthcare provider, the clinic is responsible for providing services in accordance with the Code. In this case, I consider that the errors that occurred did not indicate broader systems or organisational issues at the clinic. Therefore I consider that the clinic did not breach the Code directly.
- In addition to any direct liability for a breach of the Code, under section 72(2) of the Health and Disability Commissioner Act 1994 (the Act), an employing authority is vicariously liable for any acts or omissions of its employees. A defence is available to the employing authority of an employee under section 72(5) if it can prove that it took such steps as were reasonably practicable to prevent the acts or omissions.
- 79. At the time of the events in question, Mr B was an employee of the clinic. Accordingly, the clinic is an employing authority for the purposes of the Act. As set out above, I have found that Mr B breached Right 4(1) of the Code.
- 80. Policies and procedures can be invaluable in setting out the minimum requirements to ensure the safe and effective provision of care. The clinic did not have any written policies in place at the time of Mrs A's treatment by Mr B.
- I am concerned that the clinic did not have any written policies and procedures. This is particularly important as Mr B was not the sole practitioner at the clinic. Despite this criticism, I consider that Mr B's errors were the result of individual decision-making and his lack of insight regarding Mrs A's complex presentation. In my view, the deficiencies in care cannot be attributed to the company's lack of written policies. Accordingly, I do not find the clinic vicariously liable for Mr B's breach of the Code.

Recommendations

- 82. I recommend that Mr B:
 - a) Arrange for an independent peer to conduct an audit of his documentation over the last three months to ensure that it is sufficiently comprehensive in relation to case histories and examination findings. The results of the audit, and details of any remedial action taken, should be provided to HDC within three months of the date of this report.
 - b) Arrange for regular mentoring from a senior colleague, and provide written confirmation that this has occurred. This should be provided to HDC within three months of the date of this report.
 - c) Provide a written apology to Mrs A for his breach of the Code. The apology is to be sent to HDC within three weeks of the date of this report.
- 83. I recommend that the Osteopathic Council consider whether a review of Mr B's competence is required.

Follow-up actions

- A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Osteopathic Council, and it will be advised of Mr B's name.
- A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Health Quality & Safety Commission and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

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Appendix A: Independent advice to the Commissioner

The following expert advice was obtained from Dr Sharon Awatere:

"I have been asked to provide an opinion to the Commissioner on this case. I have read, and agree to follow the Commissioner's Guidelines for Independent Advisors.

Qualifications of Advisor

I am a registered practitioner, with a current Annual Practicing Certificate and hold a Bachelor of Science degree in Osteopathy, and a Master of Health Science (Public Health), and a PhD (Candidature in Public Health). I am also registered in Traditional Chinese Medicine (TCM) Acupuncturist with the New Zealand Register of Acupuncturists and hold a current Annual Practicing Certificate. I have worked on the Osteopathic Council of New Zealand's (OCNZ) Competence Review Committee for three years. I am a preceptor/mentor as part of the OCNZ's Overseas Assessment Competent Authority Pathway: The Registration Competency Programme.

Sources of Information Reviewed

In preparing this report, I have reviewed the following sources of information provided by the Commissioner:

Letter of complaint dated ..., from the Nationwide Health and Disability Advocacy Service, including response from [Mr B] dated 12 September 2016;

Clinical records ('Response and Assessment Notes') from [Mr B] covering the period 11 May 2016 to 8 June 2016;

Correspondence from [Mrs A], received 9 March 2017;

Notes from [the] District Health Board.

In addition to the above sources, the Capabilities for Osteopathic Practice (published by the Osteopathy Council of New Zealand¹), have been reviewed.

Background

Following [an] accident in 2006, [Mrs A] was left with a C4–5 fracture-dislocation, burst fracture C5, C5 ASIA C spinal cord injury², C5 corpectomy and anterior C4–6 fusion, resulting in incomplete tetraplegia³. She also has a Baclofen pump inserted at L3 and a spinal cord stimulator in situ⁴.

6 September 2018

¹ Capabilities of osteopathic practice can be found at this link:

http://www.osteopathiccouncil.org.nz/images/stories/pdf/new/Capabilities_April52013.pdf

 $^{^2}$ ASIA refers to the American Spinal Injury Association (ASIA) Classification, as ASIA C = Some sensory and motor preservation. Otherwise A = no function; B = sensory only, D = useful motor function, E = normal. In Mrs A's case the diagnosis made of ASIA C means that motor function is preserved below the neurologic level of C5 and most of the muscles below the neurologic level have a muscle grade of less than three out of five. This is a functional score. (Ego, Koval, & Zuckerman, 2012).

³ A corpectomy is a surgical procedure that involves removing all or part of the vertebral body usually as a way to decompress the spinal cord and nerves. Incomplete tetraplegia refers to involvement of all four limbs, which in the levels involving C1–4 means levels of paralysis in the arms, hands, trunk and legs; the patient

The Commissioner's office has sought my advice to enable the Commissioner to determine whether from the information available, there are concerns about the care provided by [Mr B], which require formal investigation. In particular, to address the issue of [Mrs A] having expressed concern about the appropriateness of treatment she received from [Mr B] on four occasions between 11 May and 8 June 2016.

[Mrs A] first presented to [Mr B] on 11 May 2016. [Mrs A] advised that she took imaging with her from a previous provider, so that she could give [Mr B] more information about her complex health condition and intrathecal pump. [Mr B] declined to review the imaging. [Mrs A] presented to [Mr B] on four more occasions between May and June 2016, and felt the treatment she received was gentle.

On 8 June 2016 (fifth visit), the treatment was more vigorous. [Mr B's] clinical documentation appears to be quite brief. There have been concerns related to [Mr B's] treatment. [Mrs A] was lying supine and had her right hip rotated while [Mr B] pulled down on the side of her pelvis and stretched the right knee toward the left shoulder. Next, she was put in a left side lying position with her legs lowered over the side and [Mr B], with his arm under [Mrs A], gave repeated thrusts from behind.

Within 40 minutes of leaving the practice after [Mr B's] treatment, [Mrs A] had severe lower back and right leg pain. Her caregiver noted she was tender to touch around the pump area. After which time, [Mrs A] contacted [Mr B] at [the clinic] for advice on the pain and was told to ice the area of concern, and return to the practice for complimentary acupuncture treatments if she wished. [Mrs A] applied ice for two days before contacting her GP, who thought the area looked bruised.

[Mrs A] had developed Autonomic Dysreflexia (dysreflexia) and her blood pressure was elevated in response to the pain that she was experiencing⁵. She was admitted [to hospital] on 13 June 2016 where a CT scan was undertaken and she was discharged on 27 June 2016, with pain medication.

may have difficulty controlling bowel or bladder movements; requiring assistance with the activities of daily living, such as eating, bathing, dressing, getting in/out of bed. Use of a powered wheelchair or car is noted. Level of personal cares is noted, for example number of hours-a-day or otherwise.

⁴ Intrathecal baclofen is being used to treat the patient's upper extremity hypertonia of spinal origin. This means that the pump is helping to treat stiffness of the muscles (spasticity) or jerky involuntary movements. The osteopath would usually note the presence of hypertonic muscles and level of involuntary movements. Baclofen is a medication that acts in the spinal cord with side effects: drowsiness, dizziness, weakness, nausea, headaches. Potential red flags include: alteration in the amount of Baclofen being delivered by the pump as this will cause symptoms (seizures). The pump is a round metal disc (1 inch x 3 inches in diameter) abdominal implant, battery operated, programmable and inserted into the spine at various levels. Other red flags associated with the Baclofen pump are: device malfunction, although infrequent require monitoring so that treatment can be accorded in a timely manner.

⁵ Autonomic dysreflexia is potentially dangerous and in some cases, a lethal clinical syndrome which can develop after spinal cord injury, resulting in acute, uncontrolled hypertension. Red flags: high blood pressure, sweating and skin changes above the level of the injury and/or headache, slowing heart rate, seizures, cool clammy skin. Causes: irritation/stimuli occurring below the level of injury.

Referral instructions

I have reviewed the enclosed documentation. I will provide opinion on whether I consider the care provided to [Mrs A] by [Mr B] to be reasonable in the circumstances, and opinion on:

The adequacy and appropriateness of the care provided by [Mr B];

The adequacy and appropriateness of the post-treatment care and advice provided to [Mrs A] by [Mr B] and [the clinic];

The overall standard of [Mr B's] clinical documentation;

Whether it was reasonable for [Mr B] to decline to review the previous imaging [Mrs A] presented with, at her first appointment;

History taken prior to commencing treatment on each consultation;

The standard consent processes followed by a practitioner, prior to commencing treatment;

Any other issues that you feel warrant comment.

For each question, I will advise:

What is the standard of care/accepted practice?

If there has been a departure from the standard of care or accepted practice, how significant a departure I consider this to be?

How would it be viewed by my peers?

Recommendations for improvement that may help to prevent a similar occurrence in future.

If there are any different versions of events in the information provided, I will give my advice in the alternative. For example, whether the care was appropriate based on scenario (a), and whether it was appropriate based on scenario (b). I have not entered into any discussions about my advice. I understand that my advice may be requested and disclosed under the Privacy Act 1993, and the Official Information Act 1982.

Breadth of the review and descriptors

Definitions of descriptors used, relevant to the statement of facts outlined in the Commissioner's letter of instruction dated 20 March 2017, are consistent with standards pertaining to the Capabilities for Osteopathic Practice⁶. When a departure is identified, how significant a departure has been outlined using the following descriptors: mild > moderate > severe departure.

⁶ Capabilities of osteopathic practice can be found at this link: http://www.osteopathiccouncil.org.nz/images/stories/pdf/new/Capabilities_April52013.pdf



Response:

The adequacy and appropriateness of the care provided by [Mr B]

What is the standard of care/accepted practice?

[Mr B's] Assessment Notes Report documents treatment on 8 June 2016 as: 'diaphragm ql liver rib springing. Lumbar spine/Sacro iliac joint mobilisation'.

The standard of care/accepted practice would be to avoid mobilisation in this area, given that there is a catheter and Baclofen Pump inserted at L3. Mobilisation to the lumbar spine would indicate a red flag (contra-indicated to being applied to the same area). Furthermore, [Mrs A] has a C5/6 incomplete tetraplegia negating the use of mobilisation and risk of this acting as an irritant (dysreflexia).

If there has been a departure from the standard of care or accepted practice, how significant a departure I consider this to be?

I consider that the lack of adequacy and appropriateness of the care provided by [Mr B], represents a moderate > severe departure, i.e. serious departure from the expected standards of care. This is particularly the case, given the standard of care/accepted practice would be to identify and appropriately record risks and benefits for management [2.5]. [Mr B] does not evidence this. I believe that my peers would agree with this view.

Recommendations for improvement that may help to prevent a similar occurrence in future?

[Mr B's] Annual Practicing Certificate will have the 'Preceptorship' condition on the scope of practice and this means that he will need to successfully complete the 12-month Competent Authority Pathway Programme (CAPP) before this condition can be removed, with increased focus as follows:

Months 1–3 should focus on disclosing the findings of this report to the Preceptor to contextualise CAPP, completing all modules and particularly the Learning Needs Analysis (the focus being on red flags, yellow flags, contraindications to mobilisation, building an effective patient rapport, treatment agreement and therapeutic alliance).

Months 4–6 should focus on all modules and particularly the Self Learning report; Critical Incident Report 1; Case based discussion; Interprofessional collaboration (the focus being on red flags, yellow flags, contraindications to mobilisation, safety and patient oriented care).

Months 7–9 should focus on all modules and particularly the Self Learning report; Critical Incident Report 2; Case Analysis Reflections; Case notes from Case Analysis reflections and; Interprofessional collaboration (the focus being on red flags, yellow flags, contraindications to mobilisation, recognising if patient safety is undermined and acts accordingly).

Months 10–12 should focus on all modules and particularly the Self Learning report; Critical Incident Report 3; Case Based Discussion 2 and Records Audit; Interprofessional Collaboration; Checking all learning needs analysis topics have been addressed relative to red flags, yellow flags, contraindications to mobilisation and continuously reflecting on the respectful patient-centredness of the osteopathic management of the patient. In Month 12 schedule final phone/skype discussion with Preceptor and forward a copy of the completed report to the HDC.

The adequacy and appropriateness of the post-treatment care and advice provided to [Mrs A] by [Mr B] and [Mr B's] Osteopathy

[Mr B's] Letter of response to [Mrs A], describes the chain of events occurring on 8th June 2016, following his receipt of [Mrs A's] phone call, advising [Mr B] of [Mrs A's] adverse reaction to his treatment:

'When you [patient] rang [the clinic] to report that you were experiencing pain after the treatment, I took it to be a treatment reaction as this is not uncommon at all. The symptoms can be seen to be worse for a couple of days and then gradually settle. That is why I suggested ice applied to the area, alongside Acupuncture ...' ([Mr B]).

In response to [Mr B's] letter of response, [Mrs A] recollects a phone call on the afternoon of the treatment on 8th June 2016. At that time, [Mr B] did not seem to have a clear recollection of the Intrathecal Baclofen Pump (pump) being in situ, as stated in his response letter. Upon examination of [Mr B's] clinical notes, it is not possible to find mention of the location of the pump.

In addition, [Mr B's] notes do not detail the telephone conversation. Although, the standard of care/accepted practice is to clearly document the details of communications, including telephone discussions. According to the Osteopathy Assessment notes, however, these appear not to have been documented by [Mr B].

What is the standard of care/accepted practice?

The standard of care/accepted practice would be to not respond to the patient's concerns as being a, 'treatment reaction as this is not uncommon at all'. This highlights, [Mr B's] continued lack of awareness of the serious nature of dysreflexia. [Mr B] did not:

recognise when further information was lacking and needed investigation;

respond accordingly to cues emerging from case review;

recognise when to withdraw or modify the plan of care and therefore was unable to act appropriately on the information received.

1. Further information

This section seeks to provide clarification of the first point made above. Specifically the overall picture of the standard of care/accepted practice. Such as those pertaining to the case history notes, applicable to [Mrs A's] presentation.

The capabilities of osteopathy practice provide a framework for competency (Boud, Hager, & Stone, 2009). Implicit is a concept of duty of care and associated

responsibilities⁷. When turning to the standard of care/accepted practice of osteopathic practice, 'Capabilities 1' is an obvious place to start, because it concerns clinical analysis.

Capabilities 1 requires the osteopath to show evidence in the case history notes of having oriented activities towards the patient. So it is usual to be able to locate some kind of evidence in the notes of integrating the examination, diagnosis, prognosis, plan and treatment using a variety of information retrieval mechanisms [1.1.1] (Boud et al., 2009). Implicit is demonstrating areas of complexity and levels of uncertainty within the notes, which [Mrs A's] presentation dictates.

Inherent within the standard of care/accepted practice, a level of uncertainty on the osteopath's part is usually seen, coming through in the case history notes. For example, evidence of having sought out extra information to bridge levels of uncertainty, as in undertaking extended note taking, about [Mrs A's] case. Some of the details which could be included are aspects which require ongoing review (see Footnotes 2–5 for some examples of what this might look like).

Showing evidence of critical reflection and uncertainty in the case history notes, evidences the osteopath recognising and remaining open to clinical challenges [1.6.1]. This would be represented in the case notes, i.e. documenting additional notes, as a means to bridging the complex nature of the presentation, as well as ongoing review. Not only does this show the osteopath is critically aware of potential clinical challenges and uncertainties but it also evidences adjusting a commitment, oriented towards patient safety.

The usual standard of osteopathic treatment is to obtain the necessary information and/or advice from osteopathic or other sources as appropriate [3.5.1]. Obtaining the relevant information supports safety and ensures the osteopath is able to act accordingly. These efforts are usually evidenced in the notes as a shared decision process, documenting outcomes in the notes, including decisions related to declining treatment partially or completely.

Other contributory factors which build into the overall picture of care, concern the patient's phone call and symptoms (dysreflexia). Had the practitioner recognised when further information was required, this would have been flagged for referral. Imperative is referring the patient on to their General Practitioner and/or referring the patient on for medical assistance as a matter of urgency.

In sum, the standard of care/accepted practice would be to document levels of uncertainty, such as presenting pathology of dysreflexia and associated monitoring of potential red and/or yellow flags. However, [Mr B's] notes do not evidence any recognition of uncertainty or that further information was lacking and needed.

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⁷ This includes the need to accurately demonstrate recording information regarding the patient, and interventions used in facilitating care, treatment and support of the patient (Osteopathy Council of New Zealand, 2017).

2. Responding to cues

In addition to recognising when further information is required, the second point noted above concerns the need to demonstrate acting appropriately on all information received. In the case of [Mrs A's] presentation, this means continuously gathering evidence to monitor for changes in the patient's circumstance. For example, showing evidence of monitoring functional levels, daily activities of living (recording levels of bowel management, blood pressure levels) and monitoring these over the treatments [3.5.2].

3. Withdrawing/modifying care

Points (1) and (2) above culminate into the final aspect, of clinical analysis, outlined here as (3) withdrawing/modifying care. Pertinent to [Mrs A's] case is the need to recognise when to withdraw or modify the plan of care. This implicates ability to act appropriately on the information received.

In terms of what withdrawing/modifying care means for [Mrs A's] presentation, it would be usual to find certain indicators in the case notes. Such that the osteopath practitioner either obtains the necessary information which enables safe, effective treatment. If the osteopath is unable to source the relevant information, to support safe and effective treatment, then osteopathic care should be modified or withdrawn at this point.

The lack of information in [Mr B's] notes regarding these matters, builds into an overall picture. The overall picture is that the capabilities required for osteopathic practice have not been integrated by [Mr B]. The overall conclusion is that [Mr B] did not recognise when further information was lacking and needed investigation pertaining to osteopathic capabilities⁸ (see Capabilities of Osteopathic Practice) (Boud et al., 2009).

Aftercare and Acupuncture referral

Within the capabilities of osteopathic practice are primary healthcare responsibilities. This capability requires the osteopath to be knowledgeable about health, disease, disease management and prevention and health promotion. (Boud et al., 2009, p. 9). I believe that an osteopath with a duty of care would research the potential effects of ice on a patient at risk of dysreflexia.

Based on the information provided, [Mr B] did not identify when information was lacking, when to withdraw or modify the plan of advice delivered, and this ultimately led to the dissemination of inappropriate after-care advice. [Mr B's] advice encouraging the application of ice applied to the skin could potentially act as an irritant and further complicate the patient's presentation (dysreflexia) (Showkathali & Tarek, 2007).

Turning to the issue of acupuncture referral, as a registered TCM Acupuncturist, I am of the opinion that referring a patient with possible dysreflexia for treatment to an Acupuncturist is inadvisable. Inserting an acupuncture needle below the patient's spinal

⁸ The capabilities refer to 1. Clinical analysis. Specifically 1.1; 1.2; 1.3; 1.4; 1.5; 1.6 — but particularly 1.5: Recognises when further information is required (Boud et al., 2009, p. 2).



lesion level in people who are at risk for developing dysreflexia, has been suggested to lead to an increased pattern of imminent dysreflexia (Averill, Cotter, Nayak, Matheis, & Shiflett, 2000). The patient was already exhibiting signs of dysreflexia and therefore referring her to an acupuncturist placed her at greater risk.

Even though I am an osteopath, trained in acupuncture, I believe that an osteopath with a duty of care would research the effects of acupuncture. The decision to refer [Mrs A] in terms of appropriateness, timing and to whom the referral is made in this case is questionable. Clinical analysis requires an osteopath practitioner synthesises and recognises when further information is required.

In [Mrs A's] case, further information was required. Making appropriate arrangements to receive additional information, from the patient's GP or otherwise was necessary. This would have enabled [Mr B] to, (a) recognise the symptoms of possible dysreflexia and, (b) be aware that acupuncture was inappropriate for a person presenting with symptoms of dysreflexia. To reiterate, I believe that an osteopath practitioner, adept at obtaining the necessary information, would have recognised a high threshold for referral of [Mrs A] to a 'safe-haven', i.e., the patient's GP/hospital, and would not have referred her to an acupuncturist.

If there has been a departure from the standard of care or accepted practice, how significant a departure I consider this to be?

I consider that the lack of adequacy and appropriateness of the post-treatment care provided to [Mrs A] by [Mr B] and [Mr B's] Osteopathy, represents a moderate > severe departure, i.e. serious departure from the expected standards of care. This is particularly the case given standard practice, which would be to avoid putting [Mrs A] at further risk by making an inappropriate referral [5.3]. [Mr B] does not evidence this. The referral was not underpinned by an appropriate knowledge base and shows serious departure from the standard of care expected of an osteopath practitioner. I believe that my peers would agree with this view.

Recommendations for improvement that may help to prevent a similar occurrence in future?

See 1. above that [Mr B's] APC will have the 'Preceptorship' condition on the scope of practice and this means that he will need to successfully complete the 12-month Competent Authority Pathway Programme (CAPP) before this condition can be removed. He will complete Months 1–12 with focus being placed on Interprofessional collaboration/education learning and absolute contraindications for acupuncture treatments.

The overall standard of [Mr B's] clinical documentation?

Review of clinical documentation (Assessment Notes Record)

Client, DOB, Age, Claim No. DOI, Occupation (unemployed), Mechanism (pulled on a hosepipe).

Assessment notes: 11.5.16. Diagnosis (12th rib/diaphragm. Differential Diagnosis (S5y3. Sprain Rib Cage right Side. Subjective: strained R ribcage pulling a hose.

Objective: no neuro. Treatment: diaphragm ql liver rib springing. Exercise details: ql R. Analysis: Slightly better.

Assessment notes: 18.5.16 (as above) and: Subjective slight improvement for 2/7 then relapsed feels as though she can't extend her spine. Treatment: diaphragm ql liver rib springing visceral. Analysis good.

Assessment notes: 25.5.16 (as above) and: Subjective less tension.

Assessment notes: 1.6.16 (as above) and: subjective not much change.

Assessment notes: 8.6.16 (as above) and: Subjective not much change was sore for 2/7 after last treatment. Treatment: diaphragm ql liver rib springing, lsp/sij mobilisation.

First, the documented clinical notes are brief.

The accepted practice is to keep accurate patient records that clearly document the presence and absence of relevant signs, symptoms, clinical information and medications prescribed, as well as options discussed, decisions made and the reasons for them, information given to the patient, and the proposed management plan.

If there has been a departure from the standard of care or accepted practice, how significant a departure I consider this to be?

Areas of concern have been noted, in relation to [Mr B's] documentation. As evidenced by the notes, there are gaps in gathering, organising and recording a focused personal health record. The gaps refer to a lack of documentation in the notes indicating the complex nature of the presentation, ongoing review, challenges and uncertainties, oriented towards patient safety.

Taking into account all these aspects (history taking, level of detail in the notes, etc) the overall view is that the overall standard of [Mr B's] clinical documentation, represents a moderate > severe departure, i.e. serious departure from the expected standards of care. This is particularly the case, given the standard of care/accepted practice would be to keep accurate patient records [1.1-1.6]. [Mr B] does not evidence this. I believe that my peers would agree with this view.

Recommendations for improvement that may help to prevent a similar occurrence in future.

[Mr B] construct a structured case history form based on the Osteopathy Council of New Zealand's Guidelines for Clinical Record Keeping, to be used as an appropriate prompt with all patients in future. All of the Clinical records components should be incorporated into the case history form⁹. [Mr B] should provide evidence to the HDC within a one month time frame (from the date of this report).

Whether it was reasonable for [Mr B] to decline to review the previous imaging [Mrs A] presented with at her first appointment?

⁹ See Guidelines for Clinical Record Keeping — Appendix 1, p.7 at: http://www.osteopathiccouncil.org.nz/images/stories/pdf/new/Gdlnes%20Clncal%20Recrd%20Kpping.pdf



[Mrs A] first presented to [Mr B] on 11 May 2016. [Mrs A] advised that she took radiographic imaging (imaging) with her from a previous provider, so she could give [Mr B] more information about her complex health condition and Intrathecal Baclofen Pump. [Mr B] declined to review the imaging.

Although [Mrs A] attended five treatments from 11 May 2016 through 8th June 2016, there is no mention in the Assessment Notes Report of [Mr B] making appropriate arrangements to receive additional information as required, or corresponding with healthcare practitioners for test results and other relevant details.

Osteopaths are required to achieve competence in history taking, physical examination, being aware of varied differential diagnosis and formulating diagnosis. Implicit is advanced communication, clinical reasoning and decision making. Also important is awareness of boundaries to the osteopath practitioner's knowledge and competence, and evidence of viewing imaging is part of appropriate investigation.

Implicit within osteopathic examination, is understanding findings of imaging and reports, and having the ability to act on these. This includes being fully familiar with the standards of osteopathic practice which requires analysing imaging, or corresponding with healthcare practitioners for test results and other relevant details [1.2.3]. Reading the imaging supports a duty of care and specific to this case, would have enabled [Mr B] to check and document the location of the intrathecal pump and is also a means of checking that the original x-ray report has been correctly reported.

Sometimes the viewing conditions may not be amenable to the osteopath on the day (i.e. unable to access images from a CD), in which case a written report will need to be obtained. The standard of osteopathic practice requires making appropriate arrangements to receive additional information as required. Such as corresponding with healthcare practitioners for test results and other relevant details [1.2.3].

In the case of [Mrs A's] presentation, [Mr B] declined to review the imaging. The serious nature of past injuries sustained by [Mrs A] required identification and documentation of the potential risks of treatment. For example, the presence of a fracture-dislocation requires ascertaining the location and severity via imaging, to prevent risk of increasing or precipitating nerve root irritation or compression in possible unstable segments of the spine.

For [Mrs A], it would be imperative that imaging examination occur prior to proceeding with osteopathic treatment. Even so, with experience and sensitive application, most osteopathic techniques can be applied to a wide variety of patients. Caution, however, would be employed in [Mrs A's] presentation, since the history of [the accident] resulted in severe spinal changes, the presence of other serious pathological condition must be borne in mind¹⁰.

With [Mrs A's] medical history, strong rotatory techniques could result in compromising her seriously, particularly if irritation/stimuli occurred below the level of

¹⁰ For example, the presence of a Baclofen pump, a history of burst fracture at C5 or potential degenerative changes in the spine, would preclude the use of strong rotatory techniques.

the cervical spine injury. For example, strong rotation could result in irritation/stimuli. This is potentially dangerous for [Mrs A], given her history of dysreflexia.

Even when the presentation of a patient is apparently a benign musculo-skeletal situation, supporting evidence is appropriately noted in the patient's records. The osteopath practitioners' notes would be able to demonstrate having ruled out potential red flags, through a process of differential diagnosis. This requires including medical differential diagnosis, documenting having viewed radiographic imaging, reasoning and determining a plan of care in an integrated manner.

Given all these elements and criteria, the decision to refrain from viewing the imaging poses serious questions about [Mr B's] duty of care. The lack of overall standard of [Mr B's] notes presents serious risk for potentially aggravating [Mrs A's] presenting symptoms. In sum, I would have expected [Mr B] to document in his records, sufficient evidence of screening of imaging, diagnosis, prognosis, condition and management from a patient-oriented context.

If there has been a departure from the standard of care or accepted practice, how significant a departure I consider this to be?

I consider that the lack of the overall standard of [Mr B's] clinical documentation, represents a moderate > severe departure, i.e. serious departure from the expected standards of care [1.2.3]. The fact that [Mr B] did not consider it necessary to review the imaging is a serious departure. I believe that my peers would agree with this view.

Recommendations for improvement that may help to prevent a similar occurrence in future?

See 1. above [Mr B's] APC will have the 'Preceptorship' condition on the scope of practice and this means that he will need to successfully complete the 12-month Competent Authority Pathway Programme (CAPP) before this condition can be removed. He will complete Months 1–12 with focus being placed on Interprofessional collaboration and Learning needs analysis to include protocols and procedures to receive additional information (including imaging) as required, such as: (a) clinic policy and procedures for reviewing medical imaging provided by patients; (b) corresponding with healthcare practitioners for test results and other relevant details.

History taken prior to commencing treatment on each consultation

[Mr B's] Osteopathy Assessment Notes do not provide a baseline measure of routine daily care activities.

Establishing and recording a prognosis relevant to appropriate outcome measures, reviewing patient progress and modifying the plan of care is accepted practice. The standard of care/accepted practice would be to clearly document how the patient with tetraplegia is coping with for example, personal cares (washing, dressing etc.), walking, standing, employment/homemaking, lifting, sitting, travelling, social life.

[Mr B's] Assessment Notes Report documents [Mrs A's] name, date of birth, ACC claim number, occupation (unemployed).

The standard of care/accepted practice is to gather, organise and record a focused personal health record which should, in addition to (a) above, include the patient's GP name, ethnicity, cultural factors, present/past occupation, children, sports/hobbies/activities.

[Mr B's] Assessment Notes Report documents the mechanism of injury (pulled on a hosepipe).

The standard of care/accepted practice is to describe the cause of stress, positioning (standing, seated) and direction of force.

[Mr B's] Assessment Notes Report does not document:

The presenting complaint (site, radiation, character, intensity, duration, frequency, aggravating/relieving/non-affecting factors.

Baseline assessment of 3–5 important activities which the patient is unable to do day-to-day.

General health, energy levels, height, weight and whether this is constant.

A functional scale of the area affected.

Family, social (incl. smoking, alcohol, psycho-social).

The patient's expectation of treatment.

Obtaining consent prior to physical examination or treatment.

The standard of care/accepted practice is to accurately record examination (noting 'negative' or 'normal' results following clinical testing).

[Mr B's] Assessment Notes Report does not document the medication history past or present.

The standard of care/accepted practice is to accurately record the presence of a catheter, Baclofen Pump inserted at L3 indicating a red flag (absolute contra-indication to mobilisation application to the same area).

[Mr B's] Assessment Notes Report does not document: Medical history past and present (operations, illnesses, accidents, respiratory, cardiovascular, gastrointestinal, genitourinary, gynaecological, neurological, haematopoietic, immune.

The standard of care/accepted practice is to document the history of [Mrs A]. For example: [Mrs A] has a C5/6 incomplete tetraplegia and a Baclofen pump in situ, following [an] accident in 2006, [Mrs A] was left with a C4–5 fracture-dislocation, burst fracture C5, C5 ASIA C spinal cord injury, C5 corpectomy and anterior C4–6 fusion, resulting in incomplete tetraplegia. She also has a Baclofen pump inserted at L3 and a spinal cord stimulator in situ. At this point negative findings (nad) would be noted relative to negating the presence of dysreflexia:

Bladder: nad (infection, retention, blockage, catheterisation issues);

Bowel: nad (over distention, constipation, impaction, infection, irritation);

Skin: nad (direct irritant, pressure by object, pressure sores, ingrown toenails, burns (sunburns or hot water), tight clothing);

Gynae: nad (menstrual cramps, other pain in the pelvic region);

Other: nad (bone or muscle trauma).

[Mr B's] Assessment Notes Report details:

Differential diagnosis: 'S5y3. Sprain Rib Cage Right Side'

Diagnosis: '12th rib / diaphragm'

The standard of care/accepted practice is for there to be two or three current working hypotheses which need exploring within the examination, than diagnosis of the problem occurring, prior to examining the patient (Stone, 1999). The examination plan proceeds in order to confirm or deny potential hypotheses leading to, (a) provisional diagnosis, further testing and referral, or (b) diagnosis, treatment plan, prognosis. Additionally, accepted practice is to keep accurate patient records that clearly document prognoses, as appropriate care is determined on that basis.

[Mr B's] Assessment Notes Report does not document: Medical examination, Special tests, Osteopathic examination.

The standard of care/accepted practice is to conduct and document: Medical examination, Special tests (the following tests can assist to rule out complications involving an Intrathecal Baclofen pump, or dysreflexia in a patient living with tetraplegia) (Carda, Cazzaniga, Pozzi, & Taiana, 2008)¹¹:

Cardiac examination (blood pressure and pulse rate as this related to the patient's history and presenting condition);

Abdomen and immune (lymph nodes);

Skin temperature, condition (erosion from pump or catheter rubbing);

Checking the calf muscles for possible deep vein thrombosis (risk of Baclofen Pump) and presence of hypotonia (flaccid muscle).

After confirming that there are no pathological possibilities, osteopathic examination can be performed and the standard of care/accepted practice is to document the findings.

¹¹ In order to ensure the safe treatment of the patient living with tetraplegia. Autonomic Dysreflexia is a frequent, serious acute syndrome occurring in patients with spinal cord lesions at level T6 and above. It can be a dangerous and fatal disease, resulting directly from sustained, severe peripheral hypertension (retinal/cerebral haemorrhage, myocardial infarction, seizures, and mortality can result).

On measure of the information provided, the practitioner diagnosed 'S5y3. Sprain Rib Cage Right Side'. In order to arrive at this diagnosis, the standard of care/accepted practice in osteopathic practice, requires conducting a physical examination. It is not possible to locate in the Osteopathy Assessment Notes Report, any range of possible findings indicative of a rib sprain, for example:

Observation of standing and sitting view from all planes (sagittal, posterior, frontal) spinal curvatures, scapula positioning and biomechanics are noted comparing right to left sides;

Thoracic spine active range of motion (flexion, extension, side-bending, rotation);

Thoracic spine seated passive range of motion;

Rib cage and rib motion (standing, seated, supine), noting the findings for example, T12 rib torsion (superior or inferior), restricted in exhalation;

Diaphragm assessment and findings;

Special tests: quadrant test (facet joint compression); valsalva for disc problem; slump test for impingement of the dural lining, spinal cord or nerve roots; spring test; tuning fork over the ribs. All of the above would need to be adapted (minimal technique in a patient with tetraplegia).

[Mr B's] Assessment Notes Report does not document prognosis (likely course of the rib sprain presentation).

The standard of care/accepted practice includes noting the likely course of the rib sprain presentation. For example, 'pain free in several days', or; 'pain free in 2–3 weeks', or; 'injured tissue', 'restoration majority of strength within six weeks in ideal healing conditions', etc. The purpose of documenting a prognosis is the ability to monitor the patient's progress as a negotiated outcome and this can also act as a valid outcome instrument.

If there has been a departure from the standard of care or accepted practice, how significant a departure I consider this to be?

I consider that the lack of the overall standard of [Mr B's] history taking undertaken prior to commencing treatment on each consultation, represents a moderate > severe departure, i.e. serious departure from the expected standards of care. The fact that [Mr B] did not consider it necessary to document the presenting complaint, baseline assessments, general health, functional scale, family social history, patient's expectation of treatment or consent (see (a) above) is a serious departure [3.4].

In addition, [Mr B] did not consider it necessary to document the medication or medical history and matters pertaining to the Baclofen pump or several working hypothesis requiring examination and diagnosis, or accurate records of these elements is a serious departure [1.2]. [Mr B] does not evidence this. I believe that my peers would agree with this view.

Recommendations for improvement that may help to prevent a similar occurrence in future.

See 1. above that [Mr B's] APC will have the, 'Preceptorship' condition on the scope of practice and this means that he will need to successfully complete the 12-month Competent Authority Pathway Programme (CAPP) before this condition can be removed, with increased focus as follows: Cased based discussion, submit the anonymised case records using a structured case history form¹².

The standard consent processes followed by a practitioner, prior to commencing treatment

What is the standard of care/accepted practice?

[Mr B's] letter describes that,

'during all consults, and before I carried out any technique, I always asked your permission before proceeding — and only after gaining your verbal consent. I courteously recall asking you before anything I did during the treatments whether what I was going to do would affect your pump in any way. I believe that I always acted in good faith'.

According to [Mr B's] response regarding the use of consent, he discusses that during all consults, and before carrying out any technique that, 'permission' was asked before proceeding with treatment. Asking, 'permission' implies [Mr B] carried out technique based on the existence of the surrounding circumstances (for example, patient lying on the table receiving treatment inferring consent from signs and actions, inaction or silence). On this basis, it is likely that [Mr B] used implied consent, which is really only used for the most basic of procedures. [Mr B's] Assessment Notes Report does not document process of informed consent.

The standard of care/accepted practice follows Osteopathy Council of New Zealand guidelines, that appropriate informed consent is obtained in light of risks and benefits being explained to the patient and understood by the patient and/or their carer. Informed consent must be granted before making physical contact with the patient. These guidelines outline a particular process for informing the patient. Firstly, the Assessment Notes Report must evidence that the patient has been given sufficient information to assist their understanding of a diagnosis, prognosis, explanation of the proposed treatment, risks, side effects, possible complications, other options for treatment, option to defer treatment, right to withdraw consent to treatment at any time.

Working from the Assessment Notes Record, it would appear that on 8th June, 2016 [Mr B] treated a 40-yr old female patient. On the fifth treatment [Mr B's] Assessment Notes Report details a change in the treatment as including the use of lumbar spine/sacro iliac joint mobilisation. [Mr B] explains that before he carried out any technique he always asked the patient's permission before proceeding — and only after gaining verbal consent. He recalled asking the patient before anything he did during the treatments whether what he was going to do would affect the Baclofen pump in any

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¹² The structured case history form (which will have already been sent to the HDC) should be utilised throughout CAPP.

way. That this is not documented in the Assessment Notes Record is a serious departure.

[Mrs A] has a C5/6 incomplete tetraplegia. She receives seven hours care per day but was able to drive herself to appointments and work prior to her consultation with [Mr B] on 8th June, 2016. On her fifth appointment, [Mrs A] experienced treatment which she describes as vigorous manipulation and extended range of motion. [Mrs A] refutes [Mr B's] reference to consent as she trusted [Mr B]. [Mrs A] also disagrees that [Mr B] asked about the pump before every technique was carried out. It was discussed at times during consultations but not before the mobilisation of the facet joints on 8th June 2016.

If there has been a departure from the standard of care or accepted practice, how significant a departure I consider this to be?

I consider that the lack of the overall standard of [Mr B's] standard consent processes followed by a practitioner, prior to commencing treatment represents a moderate > severe departure, i.e. serious departure from the expected standards of care. This is particularly the case, given the standard of care/accepted practice would be to obtain consent having discussed risks and benefits [2.5]. [Mr B] does not evidence this. I believe that my peers would agree with this view.

Recommendations for improvement that may help to prevent a similar occurrence in future?

The Osteopathic Council's Informed consent guidelines will be used to construct the case history form. [Mr B] should provide evidence to the HDC within a one month time frame (from the date of this report) (See 3. above: [Mr B] will construct a structured case history form).

Any other issues that you feel warrant comment?

Some cases of tetraplegia will be readily apparent to others, and others will be less so (Biering-Sorensen et al., 2011). There are wider implications of not keeping accurate patient records that clearly document the history and journey of [Mrs A's] spinal cord injury since 2006. An individual with partial tetraplegia is at risk of being the target of prejudice and discrimination (Health and Disability Commissioner, 2017). Refusing to document the patient's history denied her an opportunity to have her disability 'seen' and confirmed. Individuals with disabilities which are less obvious, whether physical, cognitive or psychiatric, are often the target of more prejudice and discrimination than those with visible disabilities.

The standard of care/accepted practice follows Osteopathy Council of New Zealand guidelines which incorporates an osteopath's ability to adapt the consultation process to the individual. This involves being sensitive to their needs and goals, recognising their central place in ongoing decision making, whilst displaying cultural awareness. This encompasses the osteopath orienting their communication, to best aid the individual in decision making. It also includes education about the diagnosis, prognosis, proposed management plan, self-management and other options of care that may become appropriate over time.

If there has been a departure from the standard of care or accepted practice, how significant a departure I consider this to be?

I consider that the wider implications of [Mr B] not keeping accurate patient records, represents a moderate > severe departure, i.e. serious departure from the expected standards of care. This is particularly the case, given the standard of care/accepted practice would be to synthesise information in a suitable working diagnosis and an understanding of socio-cultural factors in communication and management strategies [1.2]. [Mr B] does not evidence this. I believe that my peers would agree with this view.

Recommendations for improvement that may help to prevent a similar occurrence in future?

See 1. above that [Mr B] will complete the Health and Disability Commission module which is part of the CAPP, with a focus on incorporating the findings from the document, 'Making communication easy' (Health and Disability Commissioner, 2017). Use the document to underpin Learning Needs Analysis, Self Learning report 1, 2 and 3."

The following further advice was obtained from Dr Awatere:

"I have been asked to provide an opinion to the Commissioner on this case. I have read, and agree to follow the Commissioner's Guidelines for Independent Advisors.

Qualifications of Advisor

I am a registered practitioner, with a current Annual Practicing Certificate and hold a Bachelor of Science degree in Osteopathy, and a Master of Health Science (Public Health), and a PhD (Candidature in Public Health). I am also registered in Traditional Chinese Medicine (TCM) Acupuncturist with the New Zealand Register of Acupuncturists and hold a current Annual Practicing Certificate. I have worked on the Osteopathic Council of New Zealand's (OCNZ) Competence Review Committee for three years. I am a preceptor/mentor as part of the OCNZ's Overseas Assessment Competent Authority Pathway: The Registration Competency Programme.

Sources of Information Reviewed

In preparing this report, I have reviewed the following sources of information provided by the Commissioner:

Response to notification by [lawyer] acting on behalf of [Mr B] and [the clinic] dated 31 October 2017;

Additional notes for [Mrs A] entitled, 'Assessment Notes Report' (five pages);

Example notes from [Mr B] (two pages).

In addition to the above sources, the Capabilities for Osteopathic Practice (published by the Osteopathy Council of New Zealand), have been reviewed.

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¹³ hdc.org.nz/media/158412/making%20communication%20easy.pdf

Background

In my report of 28 August 2017, I considered concerns about the care provided by [Mr B], which required formal investigation. In particular, to address the issue of [Mrs A] having expressed concerns, about the appropriateness of treatment that she had received from [Mr B] on four occasions between 11 May and 8 June 2016. [Mrs A] first presented to [Mr B] on 11 May 2016.

In accordance with my previous report, the findings considered there to be a lack of adequacy and appropriateness of care provided by [Mr B]. Further, that [Mr B's] response represented a moderate > severe departure, i.e. serious departure from the expected standards of care. This was particularly the case, given the standard of care/accepted practice would be to avoid risk of mobilisation acting as an irritant (dysreflexia) [1.2]. [Mr B] did not evidence this and I believed at that time, that my peers would agree with that view.

In light of the response of 31 October 2017, I have changed my advice from 'moderate > severe departure, i.e. serious departure from the expected standards of care' to: **severe departure**. I will provide a number of facets explaining my reasoning, summarised here as an, inability to safely:

- 1. respond to the wider social context of health and disease, including the patient's disability and psychosocial needs;
- 2. review x-rays provided by the patient:
- 3. adapt the treatment adequately (safely);
- 4. follow-up directly:
- 5. address safe onward referral;
- 6. provide adequate clinical documentation at any consultation;
- 7. synthesise information into a suitable working diagnosis and understanding of general health status, including social and personal factors;
- 8. follow standard consent processes (lacking an evidence base, 1–7 above);
- 9. construct written policies concerning informed documentation, and specialist referrals to date.

The response has focussed on superficial features, raising serious safety and competence concerns. That there is no evidence of written policies or procedures having occurred over the interim, is a warning sign that urgent correction is needed to protect the public from harmful treatment. For these reasons I am certain that the osteopathy preceptee programme would be an <u>unsuitable</u> option.

The adequacy and appropriateness of the care provided by [Mr B]

Wider social context of health and disease, including the patient's disability and psychosocial needs

There is a major disconnect between my previous opinion (report) and the response, leading me to conclude that learning from the complaint has been limited. In the response I am only able to locate [Mrs A] being instructed to 'do things':

'[Mr B] asked [Mrs A] to lie on her right-hand side ... [Mr B] asked [Mrs A] to straighten her right leg'.

I am unable to find evidence of recognising [Mrs A's] central place in an ongoing process of shared decision-making. Elements of which require identifying and integrating patient concerns into [the clinic]al analysis (2.4) (Capabilities for Osteopathic practice, 2009). The response indicates there being further barriers to effective communication in the details concerning, obtaining a patient history:

[Mr B] can recall that [Mrs A] spoke at length about how her disability severely impacted on her life. She told him what medications she was taking and their side-effects. One of her major problems was constipation. She told [Mr B] that one of the medications she was taking caused muscle weakness and that once she had been able to stand/weight bear with the aid of a walking frame but was now unable to ([Mr B], 2017).

Over the course of obtaining a patient history, recognition concerning the risk of treatment and clinical consequences is lacking. The response suggests basic communication difficulties, and lack of understanding the patient's presenting complaint within the social context of health and disease, including the patient's disability and psychosocial needs. Basic communication difficulties, are known to impact on increased risk for accidental injury through treatment (Himmelstein, Lawthers, Peterson, & Pransky, 2003), amounting to serious clinical outcomes. In light of the response, my advice has changed to this being a **severe departure.**

X-ray review

Additional information that has caused me to change my advice and reasoning concerns the x-ray review. The response discusses reasoning supporting [Mr B's] decision to not examine [Mrs A's] x-rays:

[Mr B] did not review the x-rays [Mrs A] brought to the appointment as he did not intend treating anywhere near the pump location [where it was inserted L3], which was clearly visible ... This [treatment] involved gentle mobilisation of the right lumbar spine and the right sacro-iliac joint as the right lumbar region was so compressed ([Mr B], 2017).

There are contradictions of having not reviewed the x-rays, 'as he did not intend treating anywhere near the pump location', alongside discussing providing treatment 'near' the Baclofen pump. I remain unable to distinguish demonstrative reasoning and justification for choosing not to review the x-rays. Particularly as it appears that [Mr B] clearly went about mobilising the lumbar spine at various spinal levels, is a matter of concern.

Consequently I can find no evidence of 'a duty to care' for [Mrs A] through the synthesis of information into a suitable working diagnosis, or understanding of general health status (1.2). Implicit within osteopathic examination, is understanding findings of imaging and reports, and having the ability to act on these. The response has not acknowledged the importance of patient safety, for instance locating the presence of the historical fracture-dislocation location and severity.

The response has focussed on the importance of building, 'rapport', relative to viewing the x-ray ([Mr B], 2017). Even so, I am unable to find evidence of safe clinical reasoning and decision-making, that lead to the construction of an adequate differential diagnosis, supportive of providing safe treatment, or understanding of the nature of tetraplegia, or risk of mobilisation acting as an irritant (dysreflexia). The omission of a safety focus has led me to change my advice to: **severe departure.**

Adapting the treatment

In the previous report I noted [Mrs A] had developed Autonomic Dysreflexia (dysreflexia) and her blood pressure was elevated in response to the pain that she was experiencing 14. She was admitted to [a public hospital]. After searching [Mr B's] response I am unable to find acceptance of responsibility concerning the provision of treatment that proceeded, or an adequate understanding of information supportive of a suitable working diagnosis:

[Mr B] does not accept that the treatment he provided could have caused a soft tissue injury. He accepts that there can be muscular pain after a treatment, especially if the muscles have not been flaccid or fibrotic, but to injure a soft tissue takes a lot of force. [Mr B] does not accept that the treatment he provided could have caused a soft tissue injury. He accepts that there can be muscular pain after a treatment, especially if the muscles have not been flaccid or fibrotic, but to injure a soft tissue takes a lot of force ([Mr B], 2017).

Throughout the response, I am unable to evidence reference to [Mrs A's] unique presentation, specifically the physiological effects of her condition. Patients with a history of spinal injury tend to have a, 'loss of sensation, and suffer with poor tissue health, that slows their ability to heal' (Findlay, 2010, p. 151). There appears to be an inability to acknowledge conditions or situations that are not amenable to osteopathic intervention and appropriate action (3.3.2) in the response.

[Mrs A's] history complicates the physiological effects of her condition pertaining to her history. For example the response discusses that, 'to injure a soft tissue takes a lot of force' ([Mr B], 2017), which may or may not be applicable to [Mrs A's] history. Specifically a history implicating fracture-dislocation, burst fractures, spinal cord injury, corpectomy and fusion, resulting in incomplete tetraplegia and Baclofen pump inserted at L3 and a spinal cord stimulator in situ.

As in the case of [Mrs A's] history, there is likely to be a loss of sensory perception and altered perception of sensation. The patient may not be able to feel pain or a light touch. Within the response I am unable to locate evidence of critical selection and adaption of appropriate techniques based on an evaluation of the patient's unique presentation relevant to her condition and tissue responses, including disabilities, social and personal factors.

¹⁴ Autonomic dysreflexia is potentially dangerous and in some cases, a lethal clinical syndrome which can develop after spinal cord injury, resulting in acute, uncontrolled hypertension. Red flags: high blood pressure, sweating and skin changes above the level of the injury and/or headache, slowing heart rate, seizures, cool clammy skin. Causes: irritation/stimuli occurring below the level of injury.

Osteopathic philosophy places strong emphasis on relating palpatory findings and tissue states to an analysis of underlying physiological processes, pathological states, responses to injury and adaptations that the body makes (Capabilities for Osteopathic practice, 2009). The response does not make reference to any of these processes. Due to the paucity of findings and conversations concerning these matters, I am unable to evidence that these were taken into consideration.

Rather than there being indication of a tailored response, there is suggestion of a 'one-size-fits all' approach. Adopting such a strategy does not allow for common-sense to prevail, and is not applicable to safe, patient-oriented care (Bartels, Mueser, Pratt, Santos, & Wolfe, 2017). The response outlined therefore is unlikely to have benefitted [Mrs A's] physical and neurological disabilities. These omissions have led me to change my advice to: **severe departure.**

Follow-up directly

Working with uncertainty creates a need to tailor responses to circumstances, than 'off-the shelf solutions'. Although, a key theme throughout the response has concerned a knowledge base and asset of values that are difficult to locate, within the complexities of [Mrs A's] case. The knowledge base serves as a resource that assists appropriate solutions to fit the requirements of the specific practice situation.

In addition to being unable to locate a knowledge base on standards of safety, is the decision to delay writing a Policies/Procedures Manual (manual) for [the clinic]. The delay in constructing the manual, suggests that this is not a time-limited priority, although in the response, [Mr B] accepted that it was a failure on his part not to follow-up with [Mrs A] directly. Aside from expressing regret, I am unable to locate acknowledgment of the serious nature of failing to follow-up [Mrs A's] efforts to make contact:

[Mr B] deeply regrets not contacting [Mrs A] when she first contacted him after the 8 June 2016 treatment and then failing to follow-up with her both during her hospital admission and afterward. [Mr B] is aware that his actions could be perceived as uncaring and he believes that he let himself and [Mrs A] down by not doing so. He is saddened that his treatment of [Mrs A] has caused her pain and discomfort and for that he is truly sorry. [Mr B] has taken steps to improve both his personal professional standards and that of [the clinic] as a result of this matter and while saddened that the events have occurred, is optimistic that they will not occur again ([Mr B], 2017).

The response seems to 'miss the point', that developing clear and definitive manual and procedures for handling [Mrs A's] telephone calls as she sought assistance, relates to 'showing respect to patients as people'. I am unable to locate in the response notes about these encounters with the patient, only 'regret' ([Mr B], 2017) expressed, and this leads me to change my advice to: **severe departure**. I am unable to ascertain a level of professionalism, care or safety for the patient or of there being a system set in place currently, that is tracking patient complaints and ensuring patients' concerns are being resolved in an appropriate and timely manner.

Onward referral

Additional information that has caused me to change my advice and reasoning concerns the response regarding referral processes:

This is generally left to the osteopath's discretion, however, there is an agreed protocol that if a patient has not improved after three treatments then they are either referred on, or the case is discussed amongst staff to explore other options, including referral to another osteopath or to another modality (i.e. acupuncture or a musculoskeletal specialist). Patients are referred on to another osteopath, if they can offer a different skillset (i.e. cranial or visceral osteopathy). Patients are referred for x-rays or ultrasounds, where there are suspected fractures, osteoarthritis, pathology or soft tissue injuries. There are referral pads which are filled in and provided to patients so that they can immediately make an appointment. [The clinic] can access the results online and if requested by the patient can advise the patient of the results by telephone or by e-mail ([Mr B], 2017).

The response incorporates that a 3-treatment protocol is being used for referral to another osteopath or modality. Although this might be a useful guideline, there is an expectation that working in a bureaucratic way would not only compromise professional principles but also trivialise a reflective approach, required to adequately address [Mrs A's] presentation. In the response, I am unable to locate the critical reflections relating to onward referral concerning [Mrs A] explicitly to an acupuncturist, which leads me to change my advice to: **severe departure**.

In my previous report, I noted that even though I am an osteopath, trained in acupuncture, I believe that an osteopath with a duty of care and common-sense for pragmatism would research the effects of acupuncture. The decision to refer [Mrs A] in terms of appropriateness, timing and to whom the referral was made in this case was not safe and has not been addressed appropriately in the response. The goal of referral is to care for patients, appropriate to their needs.

Successful referral processes are based on: identifying risk and assessment of problems that would benefit from consultation and referral. Further, recognition that care is continuous with evaluation and analysis of performance. There would normally be a procedure in place that records in the patient's records, and/or a copy of a referral letter is placed on file. The patient record would reflect discussions held with the patient regarding the referral, supported by critical reflections.

Adequate clinical documentation

Having written records that document the reflective processes behind decision-making are invaluable. For instance, presenting a complete record, when we are called to account for some reason. Accordingly the response outlined:

We enclose a complete copy of the patient records and notes for [Mrs A]. We understand that the previous set of clinical notes provided by [Mr B] were incomplete and did not include a print out of the 'Medical History' screen. A copy of any internal review or investigation in relation to this complaint. No formal internal review or investigation has been undertaken ... [Mr B] accepts that his clinical notes were

minimal. He understands now that this has left them open to interpretation. This issue was also identified to him recently in an ACC clinical notes review ... [Mr B] has changed his note taking practices and has a greater appreciation of the importance of comprehensive note taking as a result of the ACC review process and responding to this complaint. [Mr B] accepts that his focus on being a 'clinician' has impacted on the time he has dedicated to note taking. He now spends more time documenting findings, and writes 'nil' in all fields/boxes that are not relevant. He has also increased his consultation time from 30 minutes to 40 minutes to ensure that neither treatment, nor note taking time is compromised. An example of a recent set of anonymised patient notes is enclosed ([Mr B], 2017).

The print out of the medical history screen does not provide any information that changes my initial opinion. Even more, the response notes the length of time taken to make amendments (after an ACC review), which has led me to scale my opinion up to my advice considering the documentation to have been a **severe departure**. I find it surprising that [Mr B] is relying on an ACC review and the outcomes of [Mrs A's] complaint, to provoke ongoing professional development in note taking.

I do, however, commend [Mr B] for discussing his attempts to make amends to his note taking. Although I do believe that there remains cause for concern, as the response appears to be more about 'ticking boxes' and following procedure, than giving full attention to developing a positive approach to the problems that have been encountered in [Mr B's] professional practice, specific to [Mrs A]. Case notes and reflective accounts provide evidence, and for registration requirements is a requirement, as is making an ongoing case for being considered fit to practice.

Synthesis of information

In my previous report, I discussed that the standard of care/accepted practice is to synthesise information in a suitable working diagnosis. Specific to adopting a working hypothesis, the response outlined:

[Mr B] observed that on inspiration [Mrs A's] diaphragm was restricted as the lower ribs bilaterally were not moving laterally. When palpating the right 12th rib it was restricted moving anteriorly and the intercostal muscles between the 11th and 12th rib was restricted moving anteriorly and the intercostal muscles between the 11th and 12th ribs felt tight. On these findings, his differential diagnosis was restricted 12th rib right side due to a tight diaphragm. [Mr B] considered that he should treat [Mrs A] by attempting to free the 12th rib and release the diaphragm to ease her discomfort when sitting in her wheelchair ([Mr B], 2017).

In my previous report, I discussed at length, elements that would need to be excluded through the notes before proceeding to the diagnosis of a sprained, 'S5y3. Sprain Rib Cage Right Side'. The response is narrow and there is little indication of there being a process that is comparing and contrasting a working hypothesis (1.2.1), use of medical differentials (1.2.2), appropriate arrangements to incorporate additional information (1.2.3) or adapting care appropriately, rendering the explanation of mobilisation to influence the diaphragm inappropriate to [Mrs A's] presentation (1.2.4). It is for these reasons that I have changed my advice to **severe departure**.

Consent processes

In my previous report, I considered that the lack of the overall standard of [Mr B's] consent processes, prior to commencing treatment. Specifically that this represented a serious departure from the expected standards of care. This was particularly the case, given the standard of care/accepted practice would be to obtain consent having discussed risks and benefits [2.5], which [Mr B] was unable to evidence at that time, and outlines in the response:

Informed/valid consent

Staff obtain verbal consent from clients before undertaking any objective assessment or treatment. This involves discussing observations, subjective assessment and proposed treatment. The clinic uses [a] Practice Management System. This software includes an option to tick a 'tick box' at the bottom of the daily notes page to confirm that verbal consent to treatment was obtained. In addition to ticking [the] 'tick box', [Mr B] also notes in his patient notes that verbal consent was gained. He has adopted this practice since June 2017 as a result of the ACC notes review and requires all staff to do the same. [Mr B] and his staff are familiar with the Informed consent guidelines for osteopaths ... After taking the case history, [Mrs A's] carer helped her onto the treatment table. She was lying supine ([Mr B], 2017).

There have been a number of facets where I have explained my reasoning to support a view that there has been a **severe departure** (see 1–7 above). At its most basic level, valid consent includes discussing details of diagnosis, prognosis, uncertainties about diagnosis, options for treatment, purpose of the procedure (risks and benefits), possible side effects, the option of not treating the patient and the consequences. Further, ensuring the patient and/or caregiver understands, and then communicates clearly with respect to diagnosis prognosis, and a range of other options to care (2.5–2.10) (Capabilities for Osteopathic practice, 2009).

Surprisingly, the response noted that, [Mr B] had only commenced implementing informed/valid consent processes since June 2017 (after an ACC notes review). These actions convey that acknowledging or accepting shared responsibility for [Mrs A's] health (4.1) (Capabilities for Osteopathic practice, 2009) has not been prioritised. As the response progresses to discussing taking case history to [Mrs A's] carer, 'helped her onto the treatment table', I am unable to locate a clear pathway incorporating obtaining informed consent.

This disconnect concerning informed consent, leads me to doubt whether this is being implemented at all. By omitting informed/valid consent from the conversation, I am left to assume [Mrs A] has been denied autonomy to make personal choices concerning her treatment. Van Daalen-Smith (2006) continues this discussion, concerning the imperative for informed consent with particular reference to people with disabilities, as they are often deemed:

different, deficient or of lesser value are socially marginalised, disempowered, devalued and face innumerable barriers to health and quality of life. Through oppression, discrimination, and constant degradation, marginalised groups are denied the basic human right of dignity ... (p. 266)

Detached interpersonal interactions with a healthcare provider that is insensitive and fails to seek informed consent, can place a negative skew on the life quality of a person with disabilities. The result of these interactions can lead to feeling objectified. The culminations of such interactions can leave the patient with disabilities feeling as if they are viewed as less than human (dehumanising) (Van Daalen-Smith, 2006).

The response does not enter into any conversations pertaining to the right of [Mrs A] to be treated with respect. Neither is there discussions concerning the right for [Mrs A] to be provided with services that take into account her needs. Given the nature of [Mrs A's] condition and potential risk administering mobilisation technique, I also expected to find evidence of informed consent in writing, concerning having discussed the potential for significant risk of adverse effects on the patient. For all these reasons, my advice has shifted to recognising there being **severe departure**.

Written policies

The response concerning written policies outlines that there has been no formal internal review undertaken in relation to the complaint. Further that there is no information (including relevant documentation) regarding employment relationships:

[Mr B] intends to write a Policies/Procedures Manual for [the clinic] to include patient referral and follow-up policies. He has sought input from colleagues into the process and content of a Policies/Procedures Manual ... [Mr B] has also instigated the following changes to [the clinic]al practice at [the clinic]. To formulate a comprehensive policies/procedures manual that will incorporate verbal consent, referral policies, follow-up telephone call protocols, logging of all telephone conversations between patients and practitioners, including the nature of the outcome and advice given. The manual will also state that if any practitioner is presented with any unusual or complicated presentation, then no treatment is to be given until all the facts/history are gained to prevent any unnecessary risks. To undertake a regular review of all [the clinic] staff medical notes on a monthly basis to ensure that they meet the minimum ACC standards. To conduct weekly meetings with all practitioners at [the clinic] to discuss various patients, approaches to the treatment plans, referrals and any problems staff have encountered and how they dealt with them. The meetings are to provide practitioners with a chance to receive second opinions and the opportunity for reflection and ongoing education ([Mr B], 2017).

Similar to the response concerning 'follow-up' (4. above), the decision to delay writing a Policies/Procedures Manual for [the clinic], suggests that this is not a time-limited priority. Policies are simple statements of how [the clinic]al practitioners are conducting their services, actions and business, providing principles to help with decision-making. In contrast, procedures describe how these should be put in place (who does what, steps to be taken, forms of documents to use).

The response has left me with the impression that policies of action, in the day-to-day operations of [the clinic], have not been determined. Further that decisions and actions and all activities taking place within the practice have yet to be determined. Within the context of [Mrs A's] complaint, I do not believe that the response adequately clarifies what safety aspects [the clinic] wants to do or knows how to do. Subsequently, my advice has shifted to recognising there being **severe departure**.

Summary

The wider social context of health and disease, including the patient's disability and psychosocial needs revealed a major disconnect. I was unable to find evidence of ongoing shared decision-making. The response suggested basic communication difficulties, lack of understanding concerning the patient's presenting complaint within the social context of health and disease, which for [Mrs A] led to serious clinical outcomes.

In the second place, the response concerning, 'x-ray review' presented contradictions of not reviewing imaging, due to the intention of not treating near the Baclofen pump. On the other hand the response outlines spinal mobilisation occurring in the vicinity of the same spinal segments. I was unable to find evidence of a duty to care, safe clinical reasoning, or attempt to understand the safety perspectives pertaining to a patient presenting with a history of incomplete tetraplegia.

Third, 'adapting the treatment' noted that the response did not provide a suitable working diagnosis, referencing [Mrs A's] unique presentation. Specifically, relative to a history implicating fracture-dislocation, burst fractures, spinal cord injury, corpectomy and fusion, resulting in incomplete tetraplegia and Baclofen pump inserted at L3, and a spinal cord stimulator in situ. It appears that a 'one-size-fits all' approach is being adopted, which I argued is not applicable to safe, patient-oriented care.

Concerning the fourth point regarding 'follow-up', a key theme was noted concerning a knowledge base incorporating asset values (base) being difficult to locate within the response. This base would usually serve as a resource, that assists fitting the requirements of specific practice situations. I was unable to locate clear, definitive procedures for handling [Mrs A's] telephone calls seeking assistance, which I equated to being about showing respect to patients as people.

In so far as 'Onward referral' (5.) is concerned, the use of a 3-treatment protocol being used to refer to another practitioner. I discussed that this could trivialise a reflective approach and that I was unable to locate critical reflections, or a duty of care.

Further 'Adequate clinical documentation' (6.), confirmed a lack of note-taking specific to [Mrs A]. I was surprised that [Mr B] relied on an ACC review to provoke ongoing professional development in note taking. He was open about his circumstances concerning the review, however, although it was noted that case notes provide evidence and for registration requirements consideration of a fitness to practice.

Regarding 'Synthesis of information' (7.), the response reiterated the narrow approach that was being taking of diagnosis, and did not take into account comparing and contrasting a working hypothesis. Nor is there utilisation of medical differentials, and a range of other competencies that I have detailed.

Concerning 'Consent processes' (8.), the response noted that this only started being implemented in June 2017, following an ACC notes review. I noted that there remained a disconnect, after informed consent was not incorporated into the response that outlined taking a case history, and then moving directly into treatment. I explained the

repercussions on people with disabilities (see detached interpersonal interactions with a healthcare provider).

Finally, 'Written policies' (9.) noted that the response indicated a delayed approach to construction of a Policies/Procedures Manual (manual), suggesting that this was not a time-limited priority. I outlined the purpose of the manual. My concern was that decisions and actions and all activities taking place have yet to be determined and did not adequately clarify safety intentions. Subsequently, my advice on the above points has in the process of receiving the response, shifted to recognising there being **severe departure**.

Overall, the response has focussed on superficial features, without understanding the serious nature of the complaint. That there is no evidence of written policies or procedures having occurred over the interim, is a warning sign that urgent correction is needed to protect the public from harm. For these reasons I am certain that the osteopathy preceptee programme would be an <u>unsuitable</u> option, and that my peers would agree the same.

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