Osteopath, Mr C

Osteopathy Clinic

A Report by the

Deputy Health and Disability Commissioner

(Case 14HDC00614)

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Executive summary

1. Baby A was born in early 2014. Since birth, Baby A had suffered colic and was a very unsettled baby.

2. On 24 April 2014, when Baby A was a few weeks old, Ms A, Baby A's mother, took Baby A to see an osteopath, Mr C, at an osteopathy clinic (the Clinic). Baby A's father, and Baby A's grandmother, Mrs B, accompanied Ms A.

3. Mr C noted Baby A's history and carried out an assessment, diagnosing Baby A with "reduced dural sac function". Mr C then treated Baby A, which Ms A and Mrs B told HDC consisted of Mr C hovering his hands over Baby A. Ms A said that by the end of the treatment Baby A appeared to have settled, so she was able to feed him.

4. On 1 May 2014, Ms A and Mrs B took Baby A back to see Mr C for a second treatment. During his assessment, Mr C identified a new palpatory finding, which he told HDC indicated an intracranial bleed.

5. Mr C said that he then proceeded with his treatment, and became reassured by Baby A's response that he had not in fact suffered an intracranial bleed, and did not require any further specialist assessment.

6. Mr C stated that at the end of the treatment he told Ms A and Mrs B that during his assessment and treatment he had noted some findings that were consistent with a stroke, but that this was a differential diagnosis that could not be confirmed. Ms A told HDC that when she asked Mr C whether Baby A had had a stroke, Mr C said "yes", but that Baby A was "healing himself and that it was fine".

7. Ms A said that she was very upset by the time she left the consultation, and she went home immediately and looked on the internet and convinced herself that something was seriously wrong with Baby A.

8. The following day, Mrs B contacted Mr C to ask why he had told them that Baby A had had a stroke. Mr C apologised to Mrs B and told her that there was nothing to worry about. Mr C then called Ms A to apologise to her as well.

9. Ms A later took Baby A to his general practitioner, who advised that there was no evidence that Baby A had suffered a stroke.

Decision

10. Mr C failed to provide Ms A with sufficient information about his initial assessment and proposed treatment on 24 April and, accordingly, breached Right 6(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[1] As a consequence,

[1] Right 6(1)(a) states: "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including — (a) an explanation of his or her condition …"

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Mr C also breached Right 7(1) of the Code[2] for providing services to Baby A without informed consent.

11. For failing to provide Ms A with adequate information in relation to his assessment findings on 1 May, Mr C breached Right 6(1) of the Code.

12. By forming a differential diagnosis based on flawed clinical reasoning, Mr C failed to provide services to Baby A with reasonable care and skill and breached Right 4(1) of the Code.[3]

13. By failing to refer Baby A to a specialist, proceeding with his treatment during the consultation on 1 May, and for not documenting any discussions he had with Ms A and Mrs B, nor the assessments he carried out, Mr C failed to provide services that complied with the Osteopathic Council's *Capabilities for Osteopathic Practice*, a relevant professional standard, and breached Right 4(2) of the Code.[4]

14. The Company that owns the clinic is not vicariously liable for Mr C's breaches of the Code. However, concern was raised in relation to its lack of written policies and procedures.

Complaint and investigation

15. The Commissioner received a complaint from Mrs B about the services provided to her grandson, Baby A, by Mr C. The following issues were identified for investigation:

- *The appropriateness of the care provided to Baby A by Mr C in April and May 2014.*
- *The appropriateness of the care provided to Baby A by the Company in April and May 2014.*

16. An investigation was commenced on 15 January 2015. This report is the opinion of Rose Wall, Deputy Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

17. The parties directly involved in the investigation were:

Baby A	Consumer
Ms A	Mother/complainant

[2] Right 7(1) states: "Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise."

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

[4] Right 4(2) states: "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards."

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Mrs B	Grandmother/complainant
Mr C	Provider/osteopath
The Company	Provider

Also mentioned in this report:

Ms D	Osteopath/clinic director
Mr E	Mr C's lawyer
Ms F	Osteopath

18. Independent expert advice was obtained from osteopath Robert Moran (**Appendix A**).

Information gathered during investigation

Background

19. Baby A was born in early 2014. Baby A's mother, Ms A, advised that since birth Baby A had suffered from "reflux/colic" and was a very unsettled baby.

20. Ms A had become exhausted, and family friends told Ms A and Baby A's grandmother, Mrs B, that they had taken their child, who had also been an unsettled baby, to see a cranial osteopath, and that treatment had helped the baby. Ms A discussed this option with Baby A's Plunket nurse and midwife, and decided that she would try it. After looking for an osteopath in the area, Ms A and Mrs B found the Clinic.[5] Ms A contacted the clinic, and an appointment was subsequently made with osteopath Mr C, for 24 April 2014.

21. This report analyses the standard of care Mr C provided to Baby A, including the adequacy of the information Mr C provided Ms A (Baby A's legal guardian).[6]

Mr C

22. Mr C is a New Zealand registered osteopath. According to clinic information, Mr C first qualified as an osteopath in 2005, and he has an interest in cranial osteopathy.[7] He is a self-employed contractor at the clinic.

24 April 2014

23. On 24 April 2014, when Baby A was a few weeks old, Ms A, Ms A's partner, (Baby A's father), and Mrs B took Baby A to the clinic for his appointment with Mr C.

24. Mr C documented in the clinical records that Baby A's presenting complaint was "major" reflux. In addition, Mr C noted a plateau in weight gain over the last few

[5] According to the clinic's advertising, it can treat problems including baby related problems e.g. colic, reflux, sleep disturbance.

[6] The definition of "consumer" in Clause 4 of the Code includes, for the purposes of Rights 5, 6, 7(1), 7(7) to 7(10), and 10 of the Code, a person entitled to give consent on behalf of the consumer.

[7] Cranial osteopathy is a type of osteopathic treatment that uses light touch to the bones in the skull, with the theory that it encourages the release of stresses and tensions throughout the body.

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days, poor sleep during the day, variable sleep at night, that Baby A "seem[ed]" to be in pain, and that he had a possible cows' milk intolerance, noting that some blood had been seen in two recent nappies. Mr C also noted that Baby A had oral thrush, and had had green stools for two weeks.

25. Mr C documented Baby A's delivery history, noting that the second stage of labour had been 2–3 hours long, and that Baby A had been delivered by forceps.

26. Under "Neonatal", Mr C documented: "Marked across [right] eye. Bleeding on forehead? Fluid on lungs → airways cleared." Under "Osteopathic diagnosis", Mr C documented: "[F]orceps issues → affecting dural[8] sac. Birth compression from [very] long 2nd stage [and] induced." Mr C told HDC that this meant that his working diagnosis was "reduced dural sac function", which he explained to HDC was shorthand for the following diagnosis:

> "The long second stage of birth and forceps delivery irritated the dura.
>
> This led to neurogenic inflammation, which contributed to the central sensitisation of the Central nervous system (CNS) and increased allostatic load (A/L).[9]
>
> Sensitisation of the myo-dural bridge, connecting the spinal dura mater to the sub occipital musculature [muscles at the base of the skull], led to somatic dysfunction[10] of the suboccipital area [back of the head/neck], irritated the vagus nerve, contributing to the severe colic symptoms and irritation of the hypoglossal nerve affecting the sucking coordination."

Mr C's account

27. Mr C stated that prior to his assessment he explained to Ms A and Mrs B the palpation and treatment techniques he was planning to use on Baby A, "in order to obtain [Mrs B's and Ms A's] informed consent". Mr C said that Mrs B and Ms A provided verbal consent for the treatment. He also said that he invited them to ask any questions if they were unclear or uncomfortable about the process. The details of this discussion are not documented.

28. Mr C told HDC that during the "assessment and treatment phases" of the consultation he "made light contact with [Baby A], including [Baby A's] neck and head". Mr C said that this is a normal part of cranial osteopathy. Mr C did not document in the clinical records his palpation findings or any other assessment findings.

29. Mr C then proceeded with his treatment. In his translation of his notes, Mr C stated that his treatment involved the following:[11]

[8] The membrane that surrounds the brain and spinal cord.

[9] Allostatic load or "wear and tear" is a long-term effect of stress.

[10] The impaired or altered function of related components of the somatic (bodywork) system.

[11] Because Mr C's documented clinical records use a lot of shorthand, he provided HDC with a translation of his records.

HDC

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"Synchronise initiating and supporting a journey to neutral. Reaching a point of stillness. Gaining a sense of whole. Achieving fluid body function, with perfect form.
Transparency to health. Spontaneous ignition in Zone A."

30. Mr C provided HDC with two articles relating to osteopathy techniques in the treatment of colic and pain. One discusses the cause of colic; the numerous hypotheses on the cause, including from compression of the cranium during protracted labour or from the incorrect use of forceps; and the use of chiropractic and osteopathic techniques in the treatment of colic.[12] The other article discusses the physiological response to joint movement and manipulation to support the use of osteopathic manipulation for joint pain management.[13]

31. At the end of the treatment, Ms A fed Baby A. Mr C noted that Baby A had an improved suckle and managed to feed well after treatment. Mr C documented that he "felt [he had] done enough".

Family's account

32. Both Mrs B and Ms A told HDC that at the beginning of the appointment Mr C told them that he talks out loud during the appointments. Mrs B and Ms A stated that Mr C did not discuss with them his initial assessment or proposed treatment prior to starting.

33. Mrs B said that Mr C placed Baby A on a pillow in front of him and spoke to Baby A, saying things like, "[L]et it go [Baby A], that's it, let it go." Mrs B said that Mr C never actually touched Baby A with his hands, but hovered them over the top of Baby A's body. She stated that at one stage during the appointment Baby A started crying, and that Mr C picked Baby A up, laid him over his arm, and put his finger in his mouth. Mrs B said that this settled Baby A, and that at the end of the treatment Ms A was able to feed him.

34. Ms A told HDC that at the end of the appointment they did not feel that Mr C had done much, but considered that since Baby A had settled down after the appointment they would keep an open mind. Subsequently they booked a second appointment for Baby A to see Mr C on 1 May 2014.

1 May 2014

35. Ms A said that overnight on 30 April Baby A had a terrible night, and so on 1 May she tried to cancel the appointment for that day. However, when Ms A contacted the clinic she was advised that she would be required to pay the cost of the treatment anyway, owing to the lateness of the cancellation. Ms A decided to keep the appointment.

[12] Lim, K, "Infantile colic: A critical appraisal of the literature from an osteopathic perspective", *International Journal of Osteopathic Medicine* (2006) 9, 94–102.

[13] Howell, JN and Wilard, F, "Nociception: New Understandings and Their Possible Relation to Somatic Dysfunction and Its Treatment", *Ohio Research and Clinical Review* (2005), A joint publication of the Ohio University College of Osteopathic Medicine and the Ohio Osteopathic Foundation.

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36. Mrs B again accompanied Ms A to the appointment.

Mr C's account

37. Mr C told HDC that at the start of the appointment Ms A reported that Baby A had had a mixed week and the previous night had been particularly bad.

38. Mr C said that he undertook an initial assessment and treatment of Baby A, but it is unclear exactly what this consisted of. In his statements to HDC, Mr C refers to undertaking a palpatory assessment, which involved "light contact" of Baby A's head and neck. It appears that the palpation was both Mr C's assessment and treatment. However, the documentation in relation to the assessment and treatment is very limited. Mr C's translation of his notes from this consultation state:

> "Synchronised, Journey to Neutral, established ignition.
> Stillness leading to a sense of whole. Suspect treating intracranial bleed, relatively minor but a part of the birth process trauma. Decided this causing increase in allostatic load and stress response in gut, as all started to treat well.
>
> Suggested to return in one week …"

39. Mr C told HDC that, based on his palpatory findings (which are not documented), coupled with research, his assessment was that Baby A might have suffered an intracranial bleed. Mr C's lawyer, Mr E, stated on behalf of Mr C:

> "He [Mr C] found the overriding palpatory finding was an extreme sense of shock at the cranium, particularly in the right [posterio-]lateral[14] aspect of the head, which he associated with findings that he's seen in adult stroke patients. There was also a sense of increased tone to the gut which he felt was related to the altered cranial function."

40. In his statement to HDC, Mr C referred to research that has shown that intracranial bleeds in newborns are common, and that MRI scanning of asymptomatic newborns has shown that a number have suffered minor intracranial bleeds, but that they are mostly undetected and asymptomatic and resolve by themselves.[15]

41. Mr C said that he was "very concerned" by his assessment findings that Baby A had suffered an intracranial bleed, but emphasised to HDC that this was only a differential diagnosis made "on the basis of palpatory findings during the second treatment of [Baby A]". Mr C said that his differential diagnosis that Baby A may have suffered an intracranial bleed was never confirmed, "as during treatment[16] other clinical signs indicated that Baby A had not suffered a stroke". In particular, Mr C stated that Baby A demonstrated "a relaxing to his gut, a general increase in his relaxation, observed

[14] The back of the head on the right-hand side.

[15] Looney, CB, Smith, JK, Merck, LH, Chescheir, NC, Hamer, RM, and Gilmore, JH, "Intracranial haemorrhage in asymptomatic neonates: prevalence on MR images and relationship to obstetric and neonatal risk factors", *Radiology*, Feb (2007), 242(2): 535–41. Mr C also provided a copy of a summary of research published in MedPage Today in January 2007, written by Michael Smith.

[16] It is unclear exactly what Mr C's treatment of Baby A was but, as above, it appears that it consisted of palpation or "light contact" with Baby A's head and neck.

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by more expansive breathing and a better pallor". Mr C also said that Baby A demonstrated "other clinical signs" that indicated that he did not have an intracranial bleed, including demonstrating an "[a]ppropriate level of engagement with the world, including eye contact and response to stimuli from [Mr C] and [Baby A's] carers", "[a]ppropriate skin tone, temperature, colour and pallor", "[n]ormal breathing rate and rhythm and excursion of the abdomen during breathing indicating normal thoracic [diaphragm] function", "[a]bsence of muscle asymmetry", and "[n]o sign of seizure, extreme sleepiness or use of one side of [Baby A's] body only". Furthermore, Mr C advised that he "engaged in muscle co-ordination of movement testing and continual monitoring of breathing", which did not indicate that Baby A had suffered an intracranial bleed. This assessment is not documented. The only documentation of this consultation is the summary of Mr C's treatment referred to in paragraph 38.

42. Mr C said that at the completion of the treatment he explained his findings to Ms A and Mrs B and, as is his usual practice, asked if they had any questions. Mr C stated that at that stage Mrs B said that she "wanted to know everything [he] had felt during the treatment". Mr C said that Mrs B was "forceful and persistent in her request for him to provide detailed information as to [his] findings following palpation and treatment of [Baby A]".

43. Mr C stated that he then "explained the treatment and findings in more detail", and that at this point he advised Mrs B and Ms A that, during palpation at the commencement of the second consultation, "he had sensed a brief palpatory finding consistent with a stroke", but that this was only a differential diagnosis, and could not be confirmed. Mr C said that he told Mrs B and Ms A that he had found no other clinical indicator consistent with a stroke, such that he did not consider referral to a medical practitioner necessary. There is no record of this discussion.

Family's account

44. In contrast, Ms A told HDC that the treatment started just like the previous one, with Mr C lying Baby A in front of him on some pillows. Mrs B said that the session again consisted of Mr C hovering his hands above Baby A. She said that it is difficult to describe, but explained that Mr C kept hitting himself on the back of his own head and pushing his chin to the side. Mrs B said that he never gave them any explanation about his assessment or proposed treatment.

45. Both Mrs B and Ms A told HDC that towards the end of the session Mr C made the comment that he had "never seen anything like this before", and said, "I have only seen this in elderly patients." Mrs B said that up to this point neither she nor Ms A had said anything. Mrs B then questioned Mr C as to what he meant by these comments, and said that Mr C told them that he felt that Baby A had been hit on the back of the head. Ms A responded by clearly stating that Baby A had not been hit on the head, to which Mr C said that he had only "felt this feeling" in adult stroke victims, and that he felt that Baby A had possibly had a stroke during labour.

46. Ms A remembers asking Mr C whether he was saying that Baby A had had a stroke, and that Mr C said "yes". Mrs B said that she asked Mr C "exactly what he was seeing", and that Mr C replied: "[I]t is a mixture of what I see and feel and what [Baby A] is telling me." Mrs B said that Mr C then went on to tell them that research

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in Britain has shown that out of 100 babies born by normal vaginal birth 80% had "brain bleeds on MRI scan".

47. Mrs B said that Mr C told them that Baby A did not require any medical intervention, and that he would not refer Baby A to a specialist. Mrs B said that Mr C told them that Baby A was "healing himself and that it was fine".

48. Mrs B told HDC that at that stage she was very concerned that what Mr C was saying was very upsetting for Ms A. Mrs B said that she asked Mr C how many treatment sessions Baby A needed, and that Mr C said that he was not sure, but that after the fourth session they would get a discount and he would then discuss a reduced rate if needed.

49. Ms A said that after they left the appointment she was very upset. Both Mrs B and Ms A deny that Mr C ever told them that his opinion that Baby A had had a stroke was not a diagnosis. Ms A said that when they left, her understanding of what Mr C had told them was that Baby A had had a stroke but that he would be fine.

50. Ms A said that she went home and searched the internet, and convinced herself that Baby A had had a stroke.

Other comment from Mr C

51. Mr C told HDC that his comment that Baby A was "healing himself" was "a straight forward way to convey to [Mrs B and Ms A] the osteopathic principal [sic] that health is the natural state of the body". Mr C said that Mrs B then requested more information about his findings, and "[i]n an effort to communicate his palpatory information in relation to the possible intracranial bleed [he] used the word 'stroke'". Mr C said that he "was at pains to expressly state" that this was not a clinical finding or a confirmed diagnosis, and that he could not confirm that Baby A had had a stroke. Mr C stated that he explained that his palpatory finding was similar to Baby A having been hit on the back of the head, but said that he never actually said that Baby A had been hit on the back of the head. Mr C also said that he denies that he hit himself on the back of the head but that, as part of his explanation to Mrs B and Ms A, he "indicated on his head a similar area to the area being discussed on [Baby A's] head with reference to the palpatory finding". Mr C said that he did this for the "sake of full communication to [Ms A] and [Mrs B]". Mr C stated that he was not aware of any concerns at that stage, and that Ms A booked a third appointment with the receptionist.

2 May — conversations with Mr C

52. Mrs B told HDC that she contacted the clinic the following day and asked to speak to Mr C, requesting that he call her back.

53. When Mr C returned her call, Mrs B asked why he had told them that Baby A had had a stroke, and told him that this was "dangerous information" to give to a concerned mother. Mrs B said that Mr C apologised to her and told her that there was nothing to worry about.

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54. Mr C's account of this conversation is similar to Mrs B's. Mr C also said that he called Ms A and reassured her of Baby A's well-being.

55. Ms A told HDC that Mr C called her and apologised for using the word "stroke". Ms A said that he told her he should have said "brain bleed" instead. Ms A stated that she was confused, as she understood this to be the same. She recalls Mr C saying again that while he felt that Baby A had had a brain bleed, Baby A was fine because he was healing himself, and she did not need to worry. Ms A said that she did feel "a bit more reassured" after this telephone call.

56. Mr C did not document his telephone conversations with Mrs B or Ms A.

2 May — conversation with Ms D

57. Mrs B said that later that day she was telephoned by Ms D, who is one of the Company directors and principal osteopath. Ms D agreed to refund the cost of one of the consultations, which Mrs B accepted. Mrs B said that Ms D also offered to treat Baby A herself for free, but that she (Mrs B) declined the offer.

Clinical note — 6 May 2014

58. On 6 May, Mr C added the following retrospective note to Baby A's clinical record, commenting on the consultation on 1 May:

> "Very clear palpatory finding suggesting stroke, as opposed to vascular or meningeal tear or bleed. Felt perception of (carers) feeling something awry which is why they kept pushing for honesty and transparency."

Ongoing care of Baby A

59. Ms A said that she took Baby A to his general practitioner, who reassured her that there was no evidence of stroke, and no justification for referring Baby A for an MRI or further testing.

60. Mrs B said that Baby A is developing normally and is a healthy child.

Further comment from Mrs B and Ms A

61. Mrs B told HDC that she is very concerned that Mr C told them that Baby A had had a stroke without any proof, and she questioned why Mr C thought it was appropriate to give them this kind of information without recommending further assessment. Mrs B stated: "I find words 'Stroke or Brain Bleed' terrifying words for a new Mum and would definitely need very careful explanation which did not occur in this instance … Words are very damaging without tests to check these allegations."

62. Ms A stated that she went to see Mr C with an open mind, not really knowing much about what osteopaths do. She said that she found the information Mr C provided them during the final appointment very upsetting and, after doing some research on the internet, convinced herself that there was something seriously wrong with Baby A.

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Further comment from Mr C

63. Mr C obtained his own advice on the care he provided to Baby A, from osteopath Ms F.

64. Ms F considered that Mr C's "assessment, management and overall care of this child [Baby A] were appropriate and of a relevant standard of osteopathic care as would be expected of his peers".

65. Ms F advised that she reached this conclusion based on the fact that Mr C submitted that any reference to intracranial bleed or stroke was made only in response to questioning by Mrs B, at the end of the 1 May consultation. Ms F noted Mr C's submission that he considered an intracranial bleed but "undertook other neurological screenings and observations which made it clear that this was not the case". Ms F discussed the use of palpation in osteopathic diagnosis, commenting that it is "a necessary part of an osteopathic clinical assessment tool kit". Ms F noted that it is common practice for serious pathology to be considered and then dismissed through further assessment. Ms F said that "according to [Mr C's advice]" he undertook a "number of clinical screening observations and engagement with tissues" that allowed him to assess adequately that Baby A had no serious pathology and that it was safe for him to proceed with treatment. Furthermore, Ms F stated: "The events described by [Mr C] in his portrayal of his assessment of [Baby A] subsequent to his initial palpatory findings do in my opinion construe a relevant and appropriate clinical neurological screening of a new born." Ms F does not refer to what the "neurological screenings and observations" that Mr C undertook were, or where they are recorded in the clinical records, but states that she finds "[Mr C's] statement that he reviewed his clinical palpatory findings in the light of on-going tissue responsiveness and neurological screening entirely believable and clinically appropriate".

66. Furthermore, Ms F considers that, having accepted Mr C's version of events, the information he provided Ms A and Mrs B was appropriate in the context of an osteopath "making strenuous efforts to talk through as many issues around all elements of the case and analysis as possible in order to satisfy the patient's or family's need for clarification".

Further comment from the Company

67. In a statement to HDC, Ms D said that Ms A should not have been advised that she would be charged for Baby A's appointment on 1 May if she did not attend. Ms D stated:

> "The complaint brought to our attention a possible misunderstanding, about our cancellation practises in relation to illness. Following the complaint being made … we spoke with our reception staff about our booking and cancellation processes. This was to endeavour that parents with children weren't made to feel they needed to bring their children in — when unwell or otherwise to avoid a cancellation fee …"

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Response to Provisional Opinion

Mr C

68. Mr C accepted the findings of my provisional opinion, including the recommendations made in the report.

The Company

69. Ms D confirmed on behalf of the Company that it did not wish to comment on my provisional opinion.

Mrs B

70. Mrs B told HDC that upon reading the facts gathered section of my provisional report she was confused by Mr C's use of terminology and felt that he contradicted himself in a number of places. Overall, Mrs B reiterated that she felt that Mr C did not provide them with an appropriate standard of care, nor did he provide them with adequate information to enable them to make an informed decision.

71. Mrs B stated:

> "My Daughter-in-law is only just starting to recover from [over 12 months] months of Post Natal Depression symptoms. I strongly feel [Mr C] certainly did not help or assist with his comments or findings on this day [1 May 2014].
>
> …
>
> "I certainly do not wish to see any other young Mother ever having to go through this experience".

Opinion: Mr C — Breach

Introduction

72. Mrs B was concerned about the care osteopath Mr C provided to her grandson, Baby A. In particular, she was concerned about the diagnosis Mr C reached during his second consultation with Baby A, and the way he then communicated this information to Baby A's mother, Ms A.

73. This report analyses Mr C's assessment and treatment of Baby A, and the appropriateness and adequacy of the information Mr C provided Ms A. In particular, the report considers whether Mr C's assessment that Baby A might have suffered an intracranial bleed, and his communication with Ms A in relation to this, were reasonable in the circumstances.

Information and consent

24 April 2014

74. On 24 April 2014, Ms A, Baby A's father, and Mrs B took Baby A to see Mr C, for treatment of the reflux/colic that Baby A had suffered since birth.

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75. Mr C advised that initially he assessed Baby A as having "reduced dural sac function" and treated him for this. Mr C said that, at the beginning of his treatment, he explained his assessment and proposed treatment techniques to Ms A and Mrs B, and that they provided verbal informed consent for treatment. In contrast, neither Ms A nor Mrs B recall Mr C discussing with them his initial assessment or proposed treatment before starting. Mr C did not document anything to suggest that the proposed treatment was discussed, or that Ms A gave her informed consent to the treatment provided. In the absence of any supporting documentation, I am not satisfied that Mr C provided Ms A with adequate information about his initial assessment findings and his proposed treatment.

1 May 2014

76. During the next treatment, on 1 May 2014, Mr C considered an intracranial bleed as a differential diagnosis. Mr C said that he never diagnosed Baby A as having suffered an intracranial bleed or stroke, but that this was a differential diagnosis based on his palpation findings during the treatment. Mr C stated that he continued to monitor Baby A during the treatment and, in light of his further assessment findings, he did not consider that Baby A had suffered a stroke or intracranial bleed. Mr C said that he told Ms A and Mrs B that "he had sensed a brief palpatory finding consistent with stroke" only because of pressure from Mrs B for details. Mr C also told HDC that he told Mrs B and Ms A that this was not a clinical finding, and he could not confirm whether Baby A had had a stroke, and that there were no clinical indicators that made him think that referral to a medical practitioner was necessary. Mr C did not document this discussion.

77. In contrast, both Ms A and Mrs B told HDC that, at the end of the session, unprompted by them, Mr C told them he felt that Baby A had been hit on the back of the head, and that he had had this "feeling" only in adult stroke patients, and he considered that Baby A may have suffered a stroke during labour.

78. Regardless of Mr C's reason for advising Mrs B and Ms A that he felt that Baby A had suffered a stroke or intracranial bleed, it is evident from the accounts of Ms A, Mrs B, and Mr C that he did not provide them with an adequate explanation about his findings. It is also clear that, as a result of not being provided with this information, Ms A experienced ongoing concern. I note Mrs B's comments: "I find words 'Stroke or Brain Bleed' terrifying words for a new Mum and would definitely need very careful explanation which did not occur in this instance … Words are very damaging without tests to check these allegations." I agree with these comments.

Conclusion

79. Mr C had a duty to provide Ms A with all the information that a reasonable consumer would expect to receive. This included providing Ms A with all the relevant information about his assessment findings and proposed treatment.

80. Overall, I am of the view that Mr C did not provide Ms A with sufficient information on 24 April 2014 and 1 May 2014. In particular, Mr C did not provide Ms A with adequate information about his initial assessment findings and proposed treatment on 24 April and, accordingly, Mr C breached Right 6(1) of the Code. As a consequence,

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Ms A was unable to give her informed consent for this aspect of Baby A's treatment, and I find that Mr C also breached Right 7(1).

81. I am also concerned about the information Mr C provided to Ms A about his assessment findings during the consultation on 1 May 2014, which resulted in Ms A feeling confused and upset. I conclude that on 1 May 2014 Mr C failed to provide Ms A with adequate information about his assessment findings and the options available to her, and breached Right 6(1) of the Code.

Standard of care

Initial assessment, diagnosis and treatment approach

82. Ms A took Baby A to Mr C for treatment of his "reflux/colic". At the beginning of treatment Mr C obtained a history from Ms A and noted that Baby A had been born by forceps delivery following a 2–3 hour second stage of labour. Mr C noted that Baby A was "Marked across [right] eye. Bleeding on forehead? Fluid on lungs airways cleared." Mr C assessed Baby A as having "reduced dural sac function" as a result of his delivery. According to Mr C, he then assessed Baby A using palpation, but did not document his assessment or findings.

83. Ms A and Mrs B told HDC that Mr C never touched Baby A, and that the assessment and treatment consisted of Mr C hovering his hands above Baby A.

84. My independent expert advisor, osteopath Robert Moran, advised that based on Mr C's clinical notes, his treatment approach appears to have been "cranial osteopathy". Mr Moran advised that while there is limited research regarding the effectiveness of cranial osteopathy for the treatment of colic/reflux, "or any other condition", this approach is practised by a number of osteopaths throughout New Zealand. Mr Moran advised that cranial osteopathy techniques are considered to "lie within the scope of practice defined by the Osteopathic Council of [New Zealand]". While I accept that Mr C's palpation technique looked as though he was not touching Baby A, I am satisfied that Mr C was using light touch as part of his cranial osteopathy approach.

85. Mr Moran advised that Mr C's initial working diagnosis of "reduced dural sac function" was "consistent with the other clinical information gathered by [Mr C] through observation and interaction with [Baby A] and his carers", and is "likely to be within the standard accepted by osteopaths employing a cranial approach in infants".

86. I accept Mr Moran's advice and conclude that Mr C's initial assessment, diagnosis and treatment of Baby A during the consultation on 24 April 2014 was consistent with what would be expected of an osteopath employing "cranial osteopathy" techniques.

Assessment and diagnosis, 1 May

87. On 1 May, Ms A and Mrs B brought Baby A to see Mr C for a second consultation. Mr C said that during this consultation he carried out further palpation and, according to the statement provided by Mr C's lawyer, "[Mr C] found the overriding palpatory finding was an extreme sense of shock at the cranium … which he associated with findings that he's seen in adult stroke patients". He also found a "sense of increased tone to the gut which he felt was related to the altered cranial function". However, again Mr C did not document his assessment findings.

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88. Mr C said that his assessment findings were similar to what he would expect to see if Baby A had been hit on the back of the head, and considered that his findings were suggestive of Baby A having suffered an intracranial bleed. Mr C stated that his impression was based on his palpatory findings and research that has shown that intracranial bleeds in newborns are common and normally asymptomatic, and resolve on their own. Mr C provided HDC with two summary articles hypothesising that normal vaginal birth can cause intracranial bleeds in infants. I note Mr C's submission that he continued to monitor Baby A during his treatment, and that Baby A's response to treatment, coupled with "other clinical signs", and "[the fact that Baby A was] engaged in muscle co-ordination movement testing and continual monitoring of breathing" reassured him that Baby A had not suffered an intracranial bleed. However, the only documentation Mr C completed refers to his view that Baby A had had an intracranial bleed, which Mr C considered was relatively minor. Mr C did not detail what, if any, further assessment he undertook. In particular, Mr C did not document any neurological examination, nor did he document his palpation or any other physical examination findings.

89. The Osteopathic Council *Capabilities for Osteopathic Practice,* Section 1, Clinical Analysis states that the osteopath:

> "…
>
> 1.2 Synthesizes information into a suitable working diagnosis and an understanding of general health status …
>
> 1.5 Recognises when further information is required and acts appropriately on all information received …"

90. Mr Moran advised that the "diagnosis of 'stroke' or 'brain bleed' is not an appropriate diagnosis for an osteopath to reach based on a history and palpatory findings". However, Mr Moran said that with appropriate history taking and physical examination, which would include neurological examination, it is "well within the competencies expected of an osteopath" to be able to identify signs and symptoms indicative of an intracranial bleed. Mr Moran advised that as part of the normal process of diagnostic clinical reasoning, practitioners need to consider a wide range of disorders. However, Mr Moran advised that he can find no record of any objective history or clinical examination findings that support the diagnosis of an intracranial bleed.

91. Mr Moran stated: "It appears from the information provided, that [Mr C] has arrived at a suspicion of intracranial bleed based on connecting his background knowledge of a research paper … combined with a subjective palpatory exam and other impressions, but in the absence of any documented confirmatory signs or symptoms in the clinical records that would support the clinical reasoning necessary to arrive at this assessment." Mr Moran advised that he has been unable to find any peer-reviewed literature or other expert opinion that supports the "validity of identifying an intracranial bleed on the basis of palpation", and that Mr C "arrives at the diagnosis [of intracranial bleed] without any of the confirmatory signs or symptoms necessary".

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92. In Mr Moran's view, Mr C's clinical reasoning is flawed and a departure from osteopathic standards, which would be viewed with "substantial" disapproval by Mr C's peers. I accept Mr Moran's advice.

93. Furthermore, Mr Moran advised that, in a situation where a serious pathology such as intracranial bleed or stroke is suspected, the appropriate course of action is to refer the patient to an appropriate specialist for further investigation and care. The Osteopathic Council *Capabilities for Osteopathic Practice* Section 4: Primary Healthcare Responsibilities state:

> "4.2 Recognises and responds to professional capabilities and limitations, as a primary healthcare provider
>
> "4.2.1 Identifies situations where other healthcare professionals may be required to perform these roles, in whole or part and acts accordingly".

94. In Mr Moran's view, having arrived at an impression of an intracranial bleed, Mr C's failure to refer Baby A to an appropriate specialist in this case is a departure from osteopathic standards and "is of considerable concern", and would be viewed with "substantial" disapproval from Mr C's peers.

95. Mr C told HDC that, while it was his initial assessment that Baby A had suffered an intracranial bleed, this was never his diagnosis, as he found no other clinical signs consistent with this diagnosis. He therefore did not consider that referral to a medical practitioner was necessary. However, as noted above, Mr C did not document any findings to indicate that he carried out any further assessment. To the contrary, as noted by Mr Moran: "[I]n this case the likelihood of intracranial bleed was not recorded as being unlikely in light of further examination, rather it was recorded in the 1 May notes as being the entity that was being treated." Furthermore, Mr C again referred to his assessment of an intracranial bleed/stroke in his subsequent commentary documented on 6 May 2014, which stated: "[V]ery clear palpatory finding suggesting stroke as opposed to vascular or meningeal tear or bleed." As noted by Mr Moran, this "further highlights the strength of [Mr C's] clinical suspicion about the presence of pathology", and should have resulted in a referral.

Treatment

96. Despite Mr C's view that Baby A had suffered an intracranial bleed, which was part of his differential diagnosis formed at the beginning of the consultation, Mr C proceeded to treat Baby A. According to Mr C's clinical records, this involved: "Synchronised. Journey to Neutral, established ignition." Mr Moran advised that "[s]uspicion of intracranial bleed is considered to be a contraindication to osteopathic treatment of the cranium". Accordingly, in light of Mr C's assessment that Baby A might have suffered an intracranial bleed, treating Baby A on 1 May was inappropriate. I note Mr Moran's advice that treating Baby A in these circumstances "would be considered below the accepted standard of care expected of an osteopath".

Conclusion

97. I have significant concerns about Mr C's assessment and diagnosis of Baby A on 1 May 2014.

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98. First, Mr C has documented no clinical findings that are suggestive in any way that Baby A had suffered an intracranial bleed or stroke. I accept Mr Moran's advice that Mr C's clinical reasoning behind how he reached his suspicion that Baby A might have suffered an intracranial bleed or stroke was flawed.

99. Next, if Mr C was of the view that Baby A had suffered an intracranial bleed, the appropriate course of action would have been to refer Baby A to a specialist for further assessment. I do not accept Mr C's explanation that while the differential diagnosis of an intracranial bleed was considered based on the initial findings, further assessment allowed him to reject this as a differential diagnosis (therefore justifying why he did not refer Baby A to a specialist). Indeed, as noted above, the clinical records indicate that a stroke continued to be his primary diagnosis, even after the completion of the consultation and the receipt of Mrs B's verbal complaint. I further note Ms A's recollection that, on 2 May when Mr C telephoned her to provide her with reassurance, he commented that he should have used the words "brain bleed" rather than "stroke".

100. Finally, in light of Mr C's considerations during the treatment that Baby A had suffered an intracranial bleed, his decision to proceed with treatment was inappropriate.

101. Overall, I find that Mr C's clinical reasoning in relation to how he formed the view that Baby A might have suffered an intracranial bleed was flawed, and conclude that Mr C failed to provide services to Baby A with reasonable care and skill and breached Right 4(1) of the Code. By failing to refer Baby A to a specialist, and proceeding with treatment during the consultation on 1 May, Mr C failed to provide services that complied with Section 4 of the Osteopathic Council *Capabilities for Osteopathic Practice*, a relevant professional standard, and therefore breached Right 4(2) of the Code.

Documentation

102. As noted by Mr Moran, "[Mr C's] documentation of the two consultations with [Baby A] and his carers is excessively brief." There is no documentation relating to any discussions Mr C had with Ms A and Mrs B, nor is there any detail about the assessments he carried out. Mr Moran advised that overall Mr C's documentation fell below the standard expected of an osteopath.

103. It is a fundamental requirement of good clinical practice that a health provider keep clear and accurate records of care provided, and a requirement of osteopathic practice. The Osteopathic Council *Capabilities for Osteopathic Practice*, element 1.1: Clinical Analysis states: "1.1.5 Ensure full recording of osteopathic physical examination and palpation findings as part of a personal health record." Mr C failed to comply with this professional responsibility and, accordingly, breached Right 4(2) of the Code.

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Opinion: The Company — No breach

104. The Company advised HDC that Mr C operates out of "The clinic" as a "sub-tenant", which means that while he uses the facilities, he practises as an independent practitioner. In considering this arrangement, for the purposes of the Health and Disability Commissioner Act 1994 (the HDC Act), Mr C is considered to be an agent of the Company, and the Company is an employing authority.

105. Under section 72(3) of the HDC Act, employing authorities are vicariously liable for any breach of the Code by an agent. Under section 72(5) of the HDC Act, it is a defence for an employing authority to prove that it took such steps as were reasonably practical to prevent the act or omission that breached the Code.[17]

106. The directors of the Company told HDC that "[t]he principal osteopath and one of the directors ([Ms D]), has on occasion in a non-directional capacity, talked to and guided the practitioners, on guidelines, policies and best practice", but that individual practitioners must practise in accordance with the requirements of their professional bodies. In my opinion, there is also a responsibility on any employing authority to ensure that its staff provide appropriate services.

107. It is not enough for an employing authority to rely on the individual practitioner to provide care of an appropriate standard; it also needs to provide guidance and support to its staff. While Mr C had an individual professional responsibility, the Company also had a responsibility to ensure that its staff were adequately supported and guided.

108. Policies and procedures can be valuable in setting out the minimum requirements to assist a practice to ensure the safe and effective provision of care, and to ensure that consumers receive sufficient information about their condition and treatment options.

109. However, in my view, Mr C's errors in this case were the result of individual clinical decision-making, and cannot be attributed to the lack of policies and procedures in place at the time. Accordingly, I do not find the Company vicariously liable for Mr C's breaches of the Code. However, I am concerned about the Company's lack of written policies and procedures.

110. I note that the Company has since drafted a Code of Conduct for its staff and taken steps to discuss the case with Mr C, and has carried out an informal assessment of his practice.

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[17] While the defence set out in section 72(5) refers to "employees", it is generally considered to be available in respect of agents (see *Totalisator Agency Board v Gruschow* [1998] NZAR 528).

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Recommendations

111. In accordance with the recommendations of my provisional opinion Mr C has agreed to:

a) Provide a written apology to Ms A, apologising for his breaches of the Code. This should be sent to this Office within three weeks of the date of this report, for forwarding to Ms A.

b) Review his practice in light of the findings of this report, and report back to me on his learnings within one month of the date of this report.

c) Undertake further training on communication with clients. Mr C should provide evidence of his attendance/enrolment in an appropriate workshop/seminar within three months of the date of this report.

112. I recommend that the Company develop guidance documents for the providers who work out of its premises, particularly in relation to informed consent for treatment. A copy of a draft document should be provided to this Office within three months of the date of the final report.

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 of New Zealand, and it will be advised of Mr C'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 district health board, and it will be advised of Mr C's name.

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

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Appendix A — Independent osteopathic advice to the Commissioner

The following expert advice was obtained from osteopath Robert Moran:

"I have been asked to provide further advice to the HDC on this case (Letter of instruction received 6 March 2015). Item 1 in the advice requested is: whether, having reviewed the new information, I wish to amend my original advice. I have updated the original advice in this document. This re-issued report should be read in conjunction with my responses to Items 2 to 8 of the advice requested.

Qualifications of Advisor

I am a registered osteopath with a current Annual Practising Certificate and hold a Bachelor of Science (Human Physiology); a Bachelor of Science (Clinical Science), and a Master of Health Science (Osteopathy). I am a Senior Lecturer within the Department of Community & Health Services (Osteopathy) at Unitec, and have 13 years experience in teaching Osteopathic Principles & Practice, Clinical Diagnosis and Management, Clinical Reasoning and Therapeutics, Pain Science and Research Methods to students on the Bachelor of Applied Science (Human Biology) and Master of Osteopathy programmes. I am also a clinical examiner for the clinical training component of the Master of Osteopathy degree.

Sources of Information Reviewed

In preparing this report I have reviewed the following sources of information provided by the Complaints Assessor:

(a) Letter of instruction including Summary of complaint dated 15 September 2014
(b) Copy of [Mrs B's complaint]
(c) Copy of [Mr C's] response in the form of a letter by [Mr C's] representative [Mr E].
(d) Copy of an abstract for a journal article Looney et al. (2007); and copy of a news article published in MedPage Today on Jan 30, 2007 that discusses the Looney et al (2007) research.
(e) Copy of [Mr C's] clinical notes for consultations on 24 April 2014, 1 May 2014, and notes documenting a phone call dated 2 May 2014.

Additionally, I have reviewed the Capabilities for Osteopathic Practice published by the Osteopathic Council of New Zealand (OCNZ), available online here and attached as Appendix 1: http://osteopathiccouncil.org.nz/images/stories/pdf/new/Capabilities_April52013.pdf

Background

A summary of complaint outlining the sequence of events is provided in the Commissioner's letter of instruction dated 15 September 2014.

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Referral Instructions

I have been asked to review the information provided and provide an opinion on three issues, itemised below (1–3); and for each issue, to include in the advice an explanation of (a) what is the relevant standard of care or accepted practice? (b) has there been a departure from the relevant standard of care or accepted practice; and if so, how significant is that departure? (c) how would the departure be viewed by your peers?

1. Did [Mr C] provide [Baby A] with a standard of care that accords with accepted practice, with particular reference to assessment, treatment and communication? (If not, to what degree did [Mr C's] care depart from accepted practice?)
2. Did [Mr C] provide [Baby A's] family with clinically sound information and the consultations in question, with particular reference to the diagnosis of a 'stroke' or 'brain bleed'? In your view, are these appropriate diagnoses for an osteopath to reach?
3. Should [Mr C] have referred [Baby A] to a specialist following his assessment that [Baby A] had suffered a 'stroke' or 'brain bleed'?

Descriptors used for consideration of departures from relevant standards

In generation of this report, aspects that are consistent with the relevant standards of care or accepted practice have not been highlighted as the brief is to review when there have been departures. If a departure from relevant standards of care is identified, the brief requests that an indication is included of 'how significant is that departure?'. For this purpose, I have employed an ordinal scale of descriptors for both the magnitude of departures, and for the significance with which that departure would be viewed by peers:

None > Trivial > Mild > Moderate > Substantial > Severe.

Advice:

1. **Did [Mr C] provide [Baby A] with a standard of care that accords with accepted practice, with particular reference to assessment, treatment and communication? (If not, to what degree did [Mr C's] care depart from accepted practice?)**

With reference to *assessment*: Commentary in relation to assessment is included in the response to Question 2 (below).

With reference to *treatment*: Based on reading [Mr C's] clinical notes, it is clear that the treatment approach was 'cranial osteopathy' and treatment is recorded in the notes for both consultations. As a treatment approach to manage colic/reflux, 'cranial osteopathy' is commonly employed, and although there is very limited clinical research available regarding effectiveness of cranial osteopathy for colic/reflux, or any other condition, the approach is practised by a number of osteopaths in NZ in the treatment of infants, children, and adults. As a form of

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osteopathy, 'cranial osteopathy' techniques are considered to lie within the scope of practice defined by the Osteopathic Council of NZ.

It is relevant to record here that since 2010, the OCNZ has been working on the development of 'Paediatric Capabilities' and Council have indicated that there will be a defined scope of practice related to paediatrics, although this is not yet in place. Therefore the general scope of practice applies here.

The specific treatment techniques used by [Mr C] in both consultations are handwritten in note form using abbreviations and technical jargon and this would be typical of a large number of osteopaths. [Mr C] has provided further information to clarify the notes recorded under the heading 'Osteopathic Diagnosis'. In light of this information I accept that a working diagnosis was made that, when considered alongside [Mr C's] full explanation, is likely to be within the standard accepted by osteopaths employing a cranial approach in infants.

In the clinical notes for both consultations there is no record of informed consent having been discussed. It could be that informed consent was not addressed, or that elements of informed consent were addressed, but are not recorded.

With reference to *communication*: On reading [Mrs B's] complaint and [Mr C's] response, my impression is that [Mr C] has been communicative and responsive to [Mrs B's] enquiries both within the consultation and in response to [Mrs B's] telephone calls. [Mrs B's] and [Mr C's] submissions include reference to [Mr C] apologising for the distress caused by him, and [Mr C] did, after talking to [Mrs B], speak directly with [Ms A] in an effort to alleviate her concerns. [Mr C's] responsiveness is well within the standards of care expected. The limitations of communication in this case are not those of too little communication, as it seems [Mr C] was attempting to be open and direct in his explanations as evidenced by a clinical note added 6 May 2014 that he perceived [Baby A's] carers were '… pushing for honesty and transparency'. [Mr C] does not appear to have understood the likely emotive nature of his diagnostic explanations (regardless of their validity) and the impact this information would have on [Baby A's] carers.

(1a) what is the relevant standard of care or accepted practice?

The relevant standards of care that accord with accepted practice, and that are most relevant to this case (specifically communication, and treatment; excluding assessment which is described in 2. below) are described in the Capabilities for Osteopathic Practice, Section 2: Person Oriented Care and Communication; and Section 3: Osteopathic Care and Scope of Practice.

(1b) has there been a departure from the relevant standard of care or accepted practice; and if so, how significant is that departure?

Elements relevant to this case, in which the relevant standards appear not to have been satisfied and there has been a departure from these standards include:

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Section 2: Person Oriented Care and Communication

> *2.1 Considers socio-cultural factors in communication and management strategies [and 2.1.3]*
>
> *2.3 Ensures patient and/or care giver comprehension [and 2.3.1, 2.3.4, 2.3.5]*
>
> *2.4 Ensures patient's and parent's or care giver's goals and concerns are identified and integrated into the clinical analysis [and 2.4.2, 2.4.3]*
>
> *2.5 Obtains consent having discussed the risks and benefits [including 2.5.1, 2.5.2]*

Collectively, the departures from accepted standards under Section 2 are 'mild to moderate'.

Section 3: Osteopathic Care and Scope of Practice.

> *3.1 Implements an appropriate management plan that reflects the application of osteopathic philosophy [and 3.1.2, 3.1.3]*
>
> *3.3 Recognises and acts within the scope of osteopathic practice [and 3.3.1]*
>
> *3.7.1 Conditions or situations where the knowledge and management skills of the practitioner are insufficient are identified and appropriate alternative action is organised and taken*
>
> *3.8.2 Critically evaluates evidence by applying a knowledge of research methodologies and statistical analysis*

Collectively, the departures from accepted standards under Section 3 are 'mild to moderate'.

(1c) how would the departure be viewed by your peers?
In my opinion, the departures from appropriate standards of care as described in (1b) would meet with *moderate* disapproval by the provider's peers.

2. **Did [Mr C] provide [Baby A's] family with clinically sound information and the consultations in question, with particular reference to the diagnosis of a 'stroke' or 'brain bleed'? In your view, are these appropriate diagnoses for an osteopath to reach?**

In general terms, the diagnosis of a 'stroke' or 'brain bleed' is not an appropriate diagnosis for an osteopath to reach based on a history and palpatory findings. However, it is appropriate and well within the competencies expected of osteopaths, that an osteopath would, with appropriate history taking and office based physical examination (eg neurological screening examination), be able to identify signs and symptoms *suggestive* of an intracranial bleed should these be present. If an osteopath identified the presence of such a clinical picture this would require urgent medical referral for further investigation, definitive

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diagnosis and appropriate care. In this case, there is no record in the clinical notes of any objective history or clinical physical examination findings (other than subjective palpatory findings) that support a diagnosis of intracranial bleed. I note that [Mr C] has advised the HDC that [Baby A] demonstrated clinical signs that indicated that [Baby A] did not have an intracranial bleed (these signs are listed in [Mr E's] letter of 18 February 2015). [Mr C] reports that his suspicion of intracranial bleed was made on impressions gained from palpatory findings alongside the absence of confirmatory clinical signs. Having undertaken a search of the research literature, I can find no peer-reviewed literature, nor any other expert opinion, that supports the validity of identifying an intracranial bleed on the basis of palpation. It appears from the information provided, that [Mr C] has arrived at a suspicion of intracranial bleed based on connecting his background knowledge of a research paper (Looney et al., 2007) combined with a subjective palpatory exam and other impressions, but in the absence of any documented confirmatory signs or symptoms in the clinical record that would support the clinical reasoning necessary to arrive at this assessment.

As part of the normal process of diagnostic clinical reasoning, practitioners need to consider a wide range of disorders, including 'ruling out' serious pathologies based on the presence of certain 'red flags', as well as identifying disorders that may be 'ruled in' based on the absence of red flags and coupled with a clinical picture suggestive of a given diagnosis. Clinically, an intracranial bleed might be considered during the process of reasoning, however, in the absence of certain signs and symptoms ('red flags') would be considered unlikely and therefore 'ruled out'. To 'rule in' or confirm a diagnosis requires a slightly different reasoning process, and is based on the presence of confirmatory signs and symptoms from the history, physical examination, and further investigations/specialist referral (eg imaging). In this case, [Mr C] arrives at the diagnosis without any of the confirmatory signs or symptoms necessary. The flawed nature of the diagnostic clinical reasoning demonstrated here is concerning, particularly in a paediatric context in which the limitations of communication with the patient are higher than with adults. The harms of incorrect diagnoses, especially 'false negative' errors (missing a condition when it is present) can be particularly serious in vulnerable populations such as infants. However, in this case, the flawed diagnostic reasoning resulted in a 'false positive' diagnosis (incorrectly concluding that a condition is present), and although atypically for this type of error, there were no unnecessary or invasive procedures undertaken, the resulting harms were psychological and emotional (distress, upset, worry, doubt etc).

(2a) what is the relevant standard of care or accepted practice?
The relevant standards of care are best considered in light of the Capabilities for Osteopathic Practice, Section 1: Clinical Analysis.

(2b) has there been a departure from the relevant standard of care or accepted practice; and if so, how significant is that departure?
Specific elements relevant to this case, in which the relevant standards appear not to have been satisfied include:

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Section 1: Clinical Analysis

1.1 Gathers, organises and records a focused personal health record [and 1.1.5]

1.2 Synthesizes information into a suitable working diagnosis and an understanding of general health status [and 1.2.1, 1.2.2, 1.2.3]

1.3 Devises and instigates a plan of care addressing the person's presenting disorder and their general health, in consultation with that person (or their representative or carer) [and 1.3.1, 1.3.5]

1.5 Recognises when further information is required and acts appropriately on all information received [and 1.5.1]

Collectively, the departures from accepted standards under Section 3 are '*moderate to substantial*'.

(2c) how would the departure be viewed by your peers?
In my opinion, the departures from appropriate standards of care as described in (2b) would meet with *substantial* disapproval by the provider's peers.

3. Should [Mr C] have referred [Baby A] to a specialist following his assessment that [Baby A] had suffered a 'stroke' or 'brain bleed'?

In *general* terms, arriving at a 'false positive' diagnosis (incorrectly diagnosing a condition that is not truly present) can lead to unnecessary investigations and therapeutic intervention, and also introduces a burden of worry and distress in the patient and their whanau. In this case, the distress and worry introduced as a consequence of an incorrect diagnosis is aggravated by the potentially serious nature of the explanation in the context of an already challenging time in caring for [Baby A], who presented [at a few weeks old] with 'severe reflux/colic'. In addition to the flaws in diagnostic clinical reasoning apparent in this case, it is of considerable concern that after arriving at an impression of intracranial bleed — a serious diagnostic hypothesis that demands investigation, [Mr C] did not undertake to arrange referral for further investigation. Given [Mr C] was confident enough in his reasoning to explain this to [Baby A's] carers, it follows that a referral would be the only expected action. In summary, if [Mr C] believed [Baby A] had suffered an intracranial bleed, then his duty of care would include arranging an appropriate referral, which he did not.

(3a) what is the relevant standard of care or accepted practice?
The relevant standard of care is best considered in light of Section 4: Primary Healthcare Responsibilities.

(3b) has there been a departure from the relevant standard of care or accepted practice; and if so, how significant is that departure?
Elements relevant to this case, in which the relevant standards appear not to have been satisfied include:

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Section 4: Primary Healthcare Responsibilities

4.1.2 The 'gate-keeper' and 'health-screening' roles of an osteopath as a primary healthcare practitioner are performed appropriately

4.2 Recognises and responds to professional capabilities and limitations, as a primary healthcare provider

4.2.1 Identifies situations where other healthcare professionals may be required to perform these roles, in whole or part and acts accordingly

Collectively, the departures from accepted standards under Section 4 are '*moderate to substantial'*.

(3c) how would the departure be viewed by your peers?
In my opinion, the departures from appropriate standards of care as described in (3b) would meet with *substantial* disapproval by the provider's peers.

Other comments

The description of [Mr C] 'slapping the back of his own head' outlined in the Summary of Complaint and also described in [Mrs B's] complaint, strikes me as being quite unusual and is clearly an inappropriate action for any health practitioner. However, [Mr C] offers an explanation that he was touching his hand to his own head to indicate the comparable area on [Baby A's] head when explaining his findings. As [Ms F] points out, this type of self-demonstration is quite common amongst osteopaths while explaining findings. The language used by [Mrs B] ('slapping the back of his own head') is not consistent with a practitioner simply indicating an area of the body on themselves, but self-demonstration does seem to be the most obvious explanation.

Please contact me should you require clarification of the contents of this report.

Sincerely,

Robert Moran

Reference

Looney CB, Smith JK, Merck LH, Wolfe HM, Chescheir NC, Hamer RM, et al. Intracranial hemorrhage in asymptomatic neonates: prevalence on MR images and relationship to obstetric and neonatal risk factors. *Radiology* 2007;**242**:535–41.

Appendix

Stone C, Hager P, Boud D. Capabilities for Osteopathic Practice. Osteopathic Council of New Zealand, Wellington: NZ. Available:
http://osteopathiccouncil.org.nz/images/stories/pdf/new/Capabilities_April52013.pdf"

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Further advice

"I have been asked to provide further advice to the HDC on this case (Letter of instruction received 6 March 2015).

I have updated and re-issued the initial report in response to new information being provided (Item 1 of Advice Requested). This document addresses Items 2 to 8 of the Advice Requested and should be read in conjunction with the re-issued report.

Further Sources of Information Reviewed
In preparing this report I have reviewed the original sources of information provided by the Complaints Assessor as listed in the re-issued report dated 20 April 2015, together with the following new sources of information:

(a) Copy of additional statement from [Mr C] dated 18 February 2015, include a copy of advice [Mr C] obtained from Ms F.

(b) Copy of patient notes together with [Mr C's] transcript/translation of his notes.

(c) Record of telephone conversation with [Mrs B] dated 24 February 2015.

(d) Record of telephone conversation with [Ms A] dated 27 February 2015.

(e) Copy of statement from [the Cinic], dated 10 February 2015.

Advice requested:
(1) Please advise whether, having reviewed the new information, you wish to amend your original advice. If so, please re-issue your advice report.

Please see re-issued report dated 20 April 2015.

First consultation — 24 April 2014
(2) Was the diagnosis of 'reduced dural sac function' reasonable in the circumstances?

In my initial report I noted the absence of a recorded working diagnosis for the initial consultation (24 April) and that the information recorded under the heading 'Osteopathic Diagnosis': 'forceps issues — affecting dural sac. Birth compression from [very] long 2nd stage [and] induced' was 'birth narrative' on the basis that except for the phrase 'affecting dural sac' the information recounts birth history as the aetiology, but doesn't connect the aetiology with the generation of symptoms or signs. I note that [Mr C] has subsequently explained to the HDC that this represents the working diagnosis of 'reduced dural sac function' which is [Mr C's] short-hand for a diagnosis that has been more fully explained as:

> 'The long second stage of birth and forceps delivery irritated the dura. This led to a neurogenic inflammation, which contributed to the central sensitisation of the central nervous system (CNS) and increased allostatic load (A/L). Sensitisation of the myo-dural bridge, connecting the spinal dura to the sub occipital musculature, led to somatic dysfunction of the suboccipital area, irritated the vagus nerve, contributing to the severe colic symptoms and irritation of the hypoglossal nerve affecting the sucking coordination.'

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[Ms F] provides a useful outline of the normal course of determining an osteopathic clinical assessment and decision to proceed to treatment ([Ms F's Report]). In this description it is highlighted that [paraphrasing] a 'final diagnosis' may take several consultations to be formulated, but that so long as a relevant working hypothesis is made then care can continue. I concur with this view, and accepting that the information recorded under the heading 'Osteopathic Diagnosis' at the first consultation is in fact a working diagnosis, and not a final diagnosis, and that this working diagnosis is consistent with the other clinical information gathered by [Mr C] through observation and interaction with [Baby A] and his carers; and accepting that the term 'affecting dural sac' is [Mr C's] clinical short-hand for the fuller explanation provided above, then the explanation is, in my opinion, likely to be within the standard accepted by osteopaths employing a cranial approach in infants.

(3) In light of the above diagnosis ['reduced dural sac function'] was [Mr C's] treatment of [Baby A] on 24 April appropriate given the circumstances?

Accepting that [Mr C] noted a working diagnosis that was reasonable under the circumstances, and in the absence of any other clinical information at the initial consultation of 24 April that would contraindicate treatment, the therapy (recorded in the notes under heading 'First Treatment') delivered to [Baby A] at this consultation would, in my view, be considered by those osteopaths working with a cranial approach to be appropriate and quite typical of the type of treatment applied by osteopaths employing this approach to treat infants.

Second consultation — 1 May 2014

(4) The appropriateness of [Mr C's] assessment that [Baby A] had suffered an intracranial bleed.

For the consultation of 1 May, [Mr C] recorded under the heading 'Osteopathic examination and treatment' that:

'Suspect treating intracranial bleed, relatively minor but a part of the birth process trauma'.

On arriving at a hypothesis of serious pathology with sufficient confidence that it is not dismissed during the reasoning process, but is instead considered a hypothesis to be actively considered and is therefore documented in the notes, the appropriate course of action expected of an osteopath would be to undertake further clinical examination that could be used to support or refute the hypothesis and inform decision making about the appropriateness of referral for further investigation.[18]

There are no entries in the 1 May notes of the findings of any clinical examination (eg neurological examination) that would be expected given a suspicion of intracranial bleed. [Mr E's] letter of 18 February includes a list of clinical signs that [Mr C]

[18] It is worth noting that clinical examination is not a pre-requisite for medical referral, and in some cases it would be appropriate for osteopaths to make medical referrals on the basis of clinical history alone. However, it would be more common for further clinical examination to form part of the rationale for referral.

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indicates were incorporated (pl). Further, [Ms F's] report includes a statement that ([Ms F's Report]):

> 'The osteopath contends that he briefly thought that brain bleed might be a relevant possible differential diagnosis, but that he undertook other neurological screenings and observations which made it clear this was not the case, and so he did not make a diagnosis of brain bleed or stroke, …'

There is no entry in the 1 May clinical notes that could be interpreted as representing the findings of 'neurological screening and observations'.

Notwithstanding the absence of any documented notes on 1 May that would represent the findings of neurological screenings and observations, there is an obvious conflict between the conclusion that the findings from screening and observations made it clear that this [brain bleed] was not the case, and the clinical notes of 1 May that clearly state [Mr C's] suspicion that he was 'suspect treating intracranial bleed'.

Based on the clinical notes of 1 May it appears that [Mr C] arrived at his suspicion of intracranial bleed based on his palpatory impressions gained during contact with [Baby A] coupled with background knowledge from a research article (Looney et al, 2007) reporting that intracranial bleeds had been identified using MRJ imaging in 1 in 4 (~26%) asymptomatic neonates in a sample of 88 neonates. The clinical signs considered by [Mr C] (as listed in [Mr E's] letter of 18 February 2015, and noted in #21 in the HDC summary of facts) collectively indicate that an intracranial bleed or stroke was not likely. However, despite these normal signs, the clinical notes of 1 May records [Mr C's] clinical suspicion that he was treating an intracranial bleed.

[Mr C] appears to have reasoned from three sources of information: i) knowledge of the background prevalence of intracranial bleeds in asymptomatic neonates being ~26%; ii) abnormal palpatory findings ('extreme sense of shock at the cranium'); and iii) normal clinical signs on screening and observations. In order to arrive at a strong clinical suspicion it would be expected that both palpatory findings and clinical signs on screening and observations would be congruent. In this case, [Mr C] arrives at a strong clinical suspicion based largely on abnormal palpatory findings but in the absence of any other corroborating signs of pathology. It is normal practice for an osteopath to make a working diagnosis and proceed to treatment, but also maintain a differential diagnosis that is reviewed on an ongoing basis in light of emerging clinical evidence. For instance, a working diagnosis of 'reduced dural-sac function' associated with a high probability, could be made alongside a differential diagnosis of intracranial bleed — associated with a low probability, but the differential diagnosis is maintained because it is potentially serious and not to be missed. If further clinical signs of pathology were not apparent on examination (ie normal neurological screening), and the response to initial treatment was favourable, then the likelihood of the differential diagnosis might be further reduced. However, in this case the likelihood of intracranial bleed was not recorded as being unlikely in light of further examination, rather it was recorded in the 1 May notes as being the entity that was being treated.

The clinical note added on 6 May 2014 records very clear palpatory finding suggesting stroke as opposed to vascular or meningeal tear or bleed further highlights the strength of [Mr C's] clinical suspicion about the presence of pathology.

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(5) The adequacy of [Mr C's] documented assessment of [Baby A].

As described in response to (4) above, there is an absence of documentation of any neurological screening or other assessment (eg observations and any other clinical reasoning) that would be expected to follow a clinical suspicion of an intracranial bleed. I note that in [Mr E's] letter of 18 February 2015, [Mr C] advises a number of signs were apparent to indicate that [Baby A] had not suffered a stroke. I note that [Ms F] holds the view that this assessment constitutes 'a relevant and appropriate neurological screening of a new born' ([Ms F's Report]). I concur with [Ms F's] view that the content of this list of signs represents appropriate assessment, however, a documented record of this assessment would be expected at the time of consultation. The absence of this documentation is below the standard of care expected of an osteopath.

(6) The appropriateness of [Mr C's] treatment of [Baby A].

Suspicion of intracranial bleed is considered to be a contraindication to osteopathic treatment of the cranium (Nicholas & Nicholas. 2008). Given the clinical suspicion for the potential presence of an intracranial bleed (as recorded in the notes of 1 May and 6 May) treating [Baby A] was not appropriate, and in my view would be considered below the accepted standard of care expected of an osteopath.

Documentation

(7) The adequacy of [Mr C's] documentation of his consultations.

[Mr C's] documentation of the two consultations with [Baby A] and his carers is excessively brief and generally below the accepted standard of documentation expected of an osteopath. I acknowledge that the time constraints of practice often preclude extensive reporting of negative examination findings, however, at least some kind of clinical short-hand or summary statement referring to the type of examination conducted (eg neuro screening) and the finding (eg NAD or no abnormality detected) would be the minimum standard expected. I note that [Mr C] has acknowledged his clinical note writing could be improved and he has advised of changes to his practice in this regard.

Other comment

(8) Any other comment you wish to make.

I have no other comment to make at this time. Please contact me should you require clarification of the contents of this report.

Sincerely

Robert Moran

Reference

Nicholas AS, Nicholas EA. Atlas of osteopathic techniques. Lippincott Williams & Wilkins. 2008. p479."

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