HEALTH & DISABILITY COMMISSIONER
TE TOIHAU HAUORA, HAUĀTANGA

A Decision by the Deputy Health and Disability Commissioner

(Case 20HDC02288)

Introduction

1. This report is the opinion of Dr Vanessa Caldwell, Deputy Health and Disability Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

2. The report discusses the care provided to Ms A by registered nurse (RN) B and Dr C.

3. On 30 October 2020, Ms A attended a beauty clinic for a dermal filler (lip filler)[1] appointment with RN B. Ms A developed a vascular occlusion,[2] which was managed by RN B under the guidance of Dr C. This report discusses the adequacy of the care provided to Ms A by RN B prior to and following the filler procedure, and the appropriateness of the advice provided to RN B by Dr C about Ms A's management.

4. The following issues were identified for investigation:

- *Whether RN B provided Ms A with an appropriate standard of care between 30 October 2020 and 6 November 2020.*
- *Whether Dr C provided Ms A with an appropriate standard of care between 30 October 2020 and 6 November 2020.*

5. The parties directly involved in the investigation were:

Ms A	Consumer/complainant
RN B	Provider
Dr C	Provider

6. Independent clinical advice was received from Dr Teresa Cattin (Appendix A) and RN Emma Lindley (Appendix B).

7. Further information was received from the beauty clinic.

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[1] A soft-tissue filler injected into the skin at different depths to provide volume.
[2] A blood vessel blockage caused by a clot or pressure on arteries after a dermal filler procedure.

Information gathered

Background

RN B

8. At the time of these events, RN B was a cosmetic injector nurse working as a contractor out of the beauty clinic. She worked for the beauty clinic from November 2019 to August 2022 with a break between 23 March 2020 and 13 May 2020 due to COVID-19 restrictions. RN B told HDC that she became a cosmetic injector in 2019 (having previously worked in a hospital) and that she worked at another clinic between March and November 2019.

9. RN B said that in her previous role, she received training in facial anatomy, botulinum toxin A (Botox)[3] and dermal fillers, and the training involved both theory and practical education, including brief education on identifying vascular occlusion and administering hyaluronidase (Hyalase).[4]

10. RN B said that on joining the beauty clinic, she was asked to read information online, which included clinic policies. She stated that only one registered nurse was working at the clinic at any one time, which meant that '[t]here was little opportunity for clinical mentoring or support'.

11. In response to the provisional opinion, the beauty clinic told HDC that its injectors have regular in-person training sessions with registered nurse trainers. The beauty clinic provided HDC with RN B's training logs.

Dr C

12. The beauty clinic told HDC that at the time of these events, Dr C was one of the beauty clinic's medical directors. Dr C was based in the North Island (off-site) but she was in regular contact with registered nurses at the clinic via video-conference meetings, phone, and SMS messaging.

13. The beauty clinic said that in the case of a medical issue, 'the [registered nurse] contacts Dr C directly for assistance by phone. They will then most likely move to video call so Dr C can assess and assist in the treatment of the client.' The beauty clinic told HDC that if Dr C was unavailable (ie, on planned leave), the nurses were to contact the other medical director.

14. The beauty clinic told HDC that nurses work under 'Standing Orders' that allow them to administer treatments such as Dysport (Botox) and Hyalase. Standing orders are written documents that allow non-doctor health professionals (eg, nurses or pharmacists) to administer or supply medications without a prior doctor's consultation, provided certain standards are met. The Clinical Aesthetic Network of New Zealand (CANNZ) states:

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[3] Injections using a toxin to prevent a muscle from moving for a limited time. Usually, the injections are used to smooth wrinkles on the face.

[4] An enzyme (delivered by injection) that breaks down hyaluronic acid (the main ingredient in fillers).

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'In the field of Cosmetic Medicine, this allows nurses, medics, or pharmacists who have been assessed by the issuing doctor as suitably competent, to administer injectable treatments such as [Botox] or [Hyalase] without the presence of that doctor.'

30 October 2020

15. Ms A told HDC that she telephoned the beauty clinic at 9.30am on 30 October to book an appointment to have lip filler at 4.30pm that afternoon.

Pre-treatment discussions and informed consent

Treatment options

16. Ms A said that she was seen by RN B, and they discussed Ms A's reason for visiting the clinic — that she wanted a 'small' amount of lip filler and not a full 1mL. Ms A said that RN B advised that she would be better to purchase a 'package' which included 1mL of lip filler and Dysport[5] in her upper lip (a 'lip flip'). Ms A stated that RN B told her that she had a 'gummy smile', and the 'lip flip' would improve its appearance. Ms A said that initially she had wanted to spend only the cost of the filler. She stated: 'When I reiterated that I didn't want 1mL of filler in my lips, [RN B] stated "You have bigger lips to begin with so will need more filler. You're just going to have to trust me, ok?".'

17. RN B said that Ms A told her that she had had Botox previously but had not had filler, and she did not want the full 1mL but was happy to be guided by RN B. RN B told HDC that she assessed Ms A's lips both at resting and while smiling, which she does with all clients. She said that she proceeded to give multiple treatment options and explained that because Ms A did not have 'small lips' to begin with, she believed that best results would be achieved with 1mL of lip filler. RN B stated that she explained to Ms A that because there was a significant amount of surface area to cover (compared to someone with smaller lips), this would result in quite a subtle difference in volume. RN B told HDC: '[Ms A] agreed with my rationale and again reiterated that she has seen my work and knows that I aim to achieve subtle and natural results.'

18. RN B told HDC that during the consultation, she noted that Ms A might also benefit from Dysport in her LLSAN muscle (upper lip). RN B said that this muscle pulls the top lip up, which for some people can result in a 'gummy smile'. She said that she provided Ms A with the option of relaxing the muscle, as the clinic offered a package deal for a lip flip and lip filler, and Ms A seemed pleased with that plan and wanted to go ahead with the package deal.

19. RN B said that she offered Ms A the option of reassessing at a two-week review and proceeding with Dysport at that time, but Ms A was happy to go ahead with both treatments at the same time. RN B stated: 'I do not believe that Ms A was pressured in any way to have more product than what was required to achieve her desired results.'

20. The above discussion (paragraphs 16–19) is not documented in the clinical records.

[5] Botox.

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Discussion of risks and benefits

21. RN B told HDC that Ms A had done research herself prior to undergoing treatment, and she was already aware of the risk of vascular occlusion. In any event, RN B said that she explained the risks of vascular occlusion to Ms A, along with the signs and symptoms to look out for in the following 72 hours, such as dark or light patches, lace-like patterns, pustules, areas of pain, or sluggish capillary refill (more than three seconds). RN B said that she also advised Ms A that swelling and bruising is common post-procedure, and that she would review Ms A in two weeks' time. However, this discussion is not documented in the clinical notes.

22. Ms A told HDC that it is difficult for her to recall the conversations that took place prior to the filler being administered. She said that she believes that RN B explained that an occlusion was possible but 'reversable'. Ms A said that she was not told whether a doctor would be available on site, and she was not advised about what was involved in treating an occlusion. Ms A told HDC that she was not aware of the risk of vascular occlusion prior to presenting for her filler appointment.

Consent form

23. The consent form (completed by RN B and Ms A) noted that Ms A had received Dysport in her forehead previously but had not received any hyaluronic acid filler in the last six months (Ms A had never received filler). The form explains what hyaluronic acid is, how long the filler will last, and the risks of filler. The form states:

> 'Common injection-related reactions include redness, swelling, pain, itching, bruising, and tenderness at the injection site. These reactions are generally mild to moderate and usually last less than 7 days after treatment.'

24. The form also includes a list of other 'rare' risks, including ischaemia[6]/necrosis.[7] Vascular occlusion is not mentioned specifically. The form also lists pre-treatment and post-treatment instructions, and states:

> 'I have been informed regarding the Treatment, risks, possible results and potential side effects. I am aware and acknowledge that undergoing the Treatment may carry risk of causing harm or damage to my health and safety … I have been given the opportunity to ask questions relating to the Treatment and have received satisfactory answers to my questions ... I understand that certain reactions are common as a result of the injections.'

25. The form was signed by Ms A, along with a 'Patient Photo Release Consent' form and an 'Informed Consent — Cosmetic Treatment with Hyaluronic Based Dermal Fillers' form. However, no consent form was signed for the Dysport treatment.

[6] Reduced blood flow to part of the body.
[7] Death of body tissue.

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Treatment

26. The clinical notes state that RN B injected 10 units of Dysport (five on each side) to the LLSAN muscle and then injected '1mL [lip filler] to top and bottom lip body and top vermillion border[,] combination of vertical struts and linear retrograde threads'.

27. RN B told HDC that during the injection of the lower right lip, she noticed blanching and bleeding from the injection site. She said that she massaged the area for around five minutes and tested the capillary refill[8] multiple times, and it was sluggish but occurred within three seconds. RN B said that delayed capillary refill can be caused by the formation of a haematoma, and, in most cases, it improves in the hours following treatment.

28. RN B said that she told Ms A that she had noticed blanching and that a small bruise was forming on her lower lip, but that her capillary refill was satisfactory. RN B stated that she asked Ms A to return to the clinic first thing the next morning for review. RN B said that although usually she would review clients two weeks post treatment, she wanted to make sure that the capillary refill was improving and that there was no vascular occlusion. Ms A told HDC that she was sent home from the clinic despite RN B 'feeling unsure if the lip was occluded'.

29. None of the information from paragraphs 27–28 is documented in the contemporaneous clinical notes. Following these events (on 7 November), RN B made a retrospective note that included reference to Ms A experiencing pain and mild blanching at the site and that following a five-minute massage there was no further pain and the capillary refill test showed 'quick return' of less than two seconds. The retrospective note also states that RN B arranged for Ms A to come for review the following morning.

Post-treatment

30. RN B told HDC that about 30 minutes following treatment, Ms A telephoned the clinic to advise that she had a small amount of spontaneous bleeding at an injection site and that the area was 'filling up with blood like a blood blister'. Ms A sent RN B pictures of her lips and, given that Ms A had no pain, the bruising had not worsened, and her capillary refill time was still within three seconds, RN B advised Ms A to let her know if she had any further concerns that evening.

31. Ms A sent further photos to RN B at around 9pm that evening and told her that she had some 'strange lace like bruising beneath [her] lip'. RN B responded to Ms A that it could be normal and asked her to check the capillary refill time and send a further video. Ms A sent a further video of her testing the capillary refill time, and RN B responded that it looked 'ok' and that there was 'good' capillary refill. RN B asked Ms A if she could still see her the following morning and advised that she should apply cream and a warm compress to the lips. RN B provided her cell phone number to Ms A and told her to call her during the night if she had any concerns.

[8] Amount of blood flow through the peripheral tissues tested by applying pressure to the skin for five seconds and then releasing to assess the time taken for the skin to regain the original colour.

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32. RN B said that because of the time of night, she was unsure about contacting Dr C for advice (as per the usual process at the beauty clinic — see Appendix C). Instead, she messaged another nurse at a different beauty clinic branch for advice and provided her with a video sent by Ms A. The other nurse responded that she would 'hyalase for sure' but that it could wait until the following morning.

33. None of the above information is documented in the contemporaneous clinical notes. However, in the retrospective note of 7 November, RN B documented that Ms A had advised that a bruise had come up and the lip had bled at the site of the massage. RN B also documented that she spoke to Ms A that night via video call and that she advised Ms A to use a warm compress and to sleep elevated.

31 October

Morning consultation

34. RN B contacted Dr C for the first time the following morning at around 7.30am. RN B advised Dr C that a client had a suspected vascular occlusion and provided Dr C with a video from Ms A. RN B told Dr C that Ms A was not experiencing pain in the area. Dr C responded that the capillary refill did look sluggish, and both agreed that RN B would consult with Dr C again when she saw Ms A later that morning.

35. Ms A attended the clinic to see RN B at around 8.30–8.45am. RN B said that she checked Ms A's capillary refill multiple times and took further videos, which she sent to Dr C for advice. RN B told Dr C that the capillary refill was within three seconds, and Dr C responded that she would be happy to monitor Ms A. Dr C responded:

> '[Capillary] refill looks good, no mottling of skin or pallor … I suspect with the massage she's unoccluded … She looks comfortable too … usually with occlussions … there is gnarly pain! … I'd be happy for you to continue to watch and see but I suspect it'll improve over the coming days.'

36. RN B told HDC that she also discussed Ms A's care over the telephone with Dr C, and Dr C spoke to Ms A on speaker phone. RN B said that Dr C confirmed that the lace-like bruising was not a concern, and that while Ms A had pain in various areas, it was consistent with bruise-like pain but did not appear significantly more uncomfortable. RN B said that there was also no mottling of the skin or pallor at that time. The details of this consultation are not documented contemporaneously, but the retrospective note of 7 November states that RN B saw Ms A in the morning and there was a 'darkened area of bruising on [the] lip and some bruising below [the] lip but good capillary refil[l] and no pain in [the] area'. RN B also documented retrospectively that she sent multiple videos to Dr C for assessment, and Dr C advised that 'she was also happy to watch and see if [there were] any further signs of complication'.

Afternoon consultation

37. RN B assessed Ms A again at 2.45pm. RN B said that the capillary refill was still slightly sluggish but was within three seconds and had not worsened. She stated that Ms A was still describing the pain as bruise-like pain, and that the darkened area on the outside of her lip

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was extending into her mucosa slightly. RN B said that she explained to Ms A that they might need to dissolve the filler in the coming days.

38. RN B again sent videos to Dr C at 2.57pm. At 3.25pm Dr C responded that there did appear to be some central sluggishness compared to the rest of the area, and that the bruising had extended to the internal mucosa. Dr C advised that she would be 'tempted to err on the side of caution now and [administer Hyalase]'.

39. It appears that by the time of Dr C's response, Ms A had left the clinic. RN B responded to Dr C's message and said that she had organised for Ms A to return on Tuesday morning, but questioned whether she should get Ms A back in immediately. Dr C responded: 'You could give her another 24 hours but it looks like she might still be partially occluded.' After further text exchange, Dr C said that she would be tempted to reverse it 'now' but that ultimately it was RN B's decision.

40. RN B sought an update and videos from Ms A at 4.45pm and said that if her symptoms were worse, she would get her in again that afternoon before she left the clinic. Ms A sent a further video to RN B that showed further bruising/mottling extending down and beyond the lower lip. RN B said that she then spoke with Ms A on the phone, and Ms A reported that she was experiencing tingling and numbing sensations in the area. RN B asked Ms A to return to the clinic immediately.

41. The retrospective note made by RN B on 7 November states that when Ms A returned to the clinic at 2.45pm, she was experiencing the same pain, and the capillary refill was sluggish but still under three seconds. RN B also documented that the darkened area had extended slightly further into the mucosa, and that she sent further videos to Dr C, who advised that Hyalase should be administered.

Administration of Hyalase

42. Ms A returned to the clinic and RN B administered two vials of 1500u Hyalase (total 3000u) to Ms A's bottom lip followed by a ten-minute massage. RN B told HDC that following the massage, capillary refill improved.

43. At the request of RN B, Ms A sent her a video of her lip at 9.29pm and said that the lip was sore but that she thought it was better. RN B asked Ms A to press the corner of the outside of her lip and said that she was 'much happier with that'. Ms A responded that it was 'all very tender' but was feeling better. RN B asked Ms A to send her another video the next morning.

44. The details of the administration of Hyalase are not recorded in the contemporaneous clinical notes, but the retrospective note made by RN B on 7 November states:

> 'The client came back and 3000u hyalase was administered to bottom lip at various depths. Lignocaine injected subcutaneously prior to minimise pain. Hyalase massaged in well and capil[l]ary refill much improved after this. Client teary but very understanding, stating she was aware this was a consented risk.'

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Subsequent events

45. Ms A developed further pain on 1 November, along with pustules (small white dots) just below the lip. Ms A informed RN B about the pain and pustules and sent several further videos and photos. RN B reassured Ms A that the area looked better but organised for Ms A to visit the clinic again at 12.30pm to see a colleague, as she was working elsewhere that day. Ms A asked whether she should visit a doctor, to which RN B recommended that Ms A see the nurse at the clinic first, as generally doctors are not familiar with injectables and do not know the protocols for Hyalase.

46. RN B sent the further videos to Dr C for advice, including on the new pustules, and Dr C responded confirming that the pustules 'may be' tissue breakdown but that the area was looking a lot better. Dr C told RN B that she should administer more Hyalase if she was even remotely unsure.

47. Dr C told HDC that on being made aware of the pustules, she communicated with RN B to continue with further Hyalase, as the pustules 'reflected potential ongoing ischaemia'.

48. Subsequently, Ms A decided to present to the hospital instead of returning to the beauty clinic as arranged. The nurse who had arranged to review Ms A told HDC that once it became clear that Ms A was going to hospital, she recommended that RN B organise for Hyalase to be dropped off at the hospital, and, if possible, for her to be present when Ms A was reviewed so that there was someone there who was familiar with the treatment of vascular occlusion. RN B spoke with the hospital registrar and provided clinical information, and a decision was made to administer further Hyalase (from the beauty clinic). Ms A required further presentations to the hospital and further treatment with Hyalase to resolve the damage sustained to her lip as a result of the vascular occlusion.

Further information

Dr C

49. Dr C accepted that soon after the filler was injected, there was possible evidence of vascular compromise. However, she noted that Ms A had a capillary refill of less than two seconds.

50. Dr C acknowledged that ideally, Hyalase should have been commenced as soon as the signs of an occlusion were first noted on 30 October 2020. She noted that the beauty clinic's protocol provides for the injecting nurse to commence therapy as soon as there is evidence of an occlusion. Dr C agreed that as soon as Ms A contacted RN B post-treatment to report that the area was looking 'dusky' and bruised with associated pain, Ms A required immediate Hyalase treatment. However, Dr C noted that she was not contacted by RN B until the following morning (31 October).

RN B

51. RN B accepted that she failed to act decisively when responding to Ms A's symptoms of vascular occlusion, and that the failure fell below the acceptable standard of care. RN B acknowledged that she should have contacted Dr C immediately following Ms A's appointment on the afternoon of 30 October but said that she did not do so as the blanching was only mild and it subsided straight away after massaging, and the capillary refill was

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within three seconds. RN B also noted that as she was the only one working in the clinic at the time of Ms A's appointment, she had no one else with whom to discuss the situation.

52. RN B accepted that she did not document the mild blanching seen immediately post treatment, or her plan to review Ms A again the following morning, at the time of the appointment. RN B said that this was because appointment times were short (30 minutes with no gap in between appointments) and she had spent longer than usual with Ms A as she had to massage her lips and talk through the signs and symptoms of vascular occlusion in detail. She also stated that she was working at the beauty clinic part time and entered the retrospective note when she was next in the beauty clinic on 7 November 2020.

53. In response to the provisional opinion, the beauty clinic told HDC that appointment times for filler treatment are 45 minutes and not 30 minutes.

Responses to provisional report

Ms A

54. Ms A was given the opportunity to respond to the 'information gathered' section of my provisional report. Where relevant, her comments have been incorporated into this report. Ms A also told HDC that she believes that the beauty clinic relying on 'virtual medical assessment' poses a real risk of negligence. She told HDC:

> 'I would also query whether the beauty clinic, Dr C or RN B have amended practice whereby they communicate clearly with clients not only about the risk of vascular occlusion but also the emergency protocol, name and location of clinic doctor. This ensures transparency for all parties involved. My repetitive comments about documentation are based on general medicinal clinical practice standards whereby any medical practitioner is required to document when a patient procedure has taken place. I am unclear as to why those in private practice are not held to the same requirements.'

Dr C

55. Dr C accepted the findings in the provisional opinion.

RN B

56. RN B was given the opportunity to respond to relevant sections of my provisional report. Where relevant, her comments have been incorporated into this report. RN B accepted the findings, and most of the recommendations, in the provisional report. In addition, RN B's response stated:

> 'In our submission RN B's documentation does not warrant adverse comment given that she identified that her clinical notes had been insufficient and took steps to rectify this by writing a further clinical note a week later. RN B acknowledges though that despite this, documentation of her discussions with Ms A prior to treatment remained incomplete. RN B addresses this in her reflection accompanying this response.'

The beauty clinic

57. The beauty clinic was given the opportunity to respond to my provisional report. Where relevant, the beauty clinic's comments have been incorporated into this report. The beauty

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clinic told HDC that injectors can contact not only the medical directors, but also the clinical franchisee or Head of Office at 'anytime'. The Director of the beauty clinic also stated that if she had been contacted by RN B then she could have made calls to the head office and medical directors to 'help quicken the response time'. The beauty clinic also stated: 'Our nurses are not left in the clinic on their own, they do not have keys to open and close the clinic. An Owner, Manager or Senior Therapist is on every single shift.'

58. Regarding appointment times, the beauty clinic told HDC that the appointment time for filler is 45 minutes, and a consultation is another 15 minutes, but all nurses at the beauty clinic know that occlusions or suspected occlusions take priority over any other appointments for the rest of the day. The beauty clinic stated:

> 'It is expected that all client notes are complete on the day of treatment, and if it runs over clinic opening hours, the most senior staff member on would stay behind with the nurse until they finish.'

59. Regarding RN Lindley's comments about treatment with Dysport and filler on the same day, the beauty clinic advised that it disagrees with this advice.

Opinion: RN B — breach

60. RN B became a cosmetic injector in 2019 and was working as a contractor out of the beauty clinic between March and November 2019. RN B said that due to the COVID-19 lockdown, she did not work as a cosmetic injector between 23 March and 13 May 2020.

61. While RN B was a relatively inexperienced cosmetic injector at the time of these events, she had a responsibility to provide care of an appropriate standard to Ms A. As part of my assessment of the care provided to Ms A by RN B, I obtained independent clinical advice from cosmetic injector RN Emma Lindley.

62. RN Lindley advised that the fact that Ms A suffered a vascular occlusion as a result of the lip filler does not (in itself) indicate a departure from accepted standards. RN Lindley said that vascular occlusion is a 'rare unfortunate [and] consented potential side effect' of the treatment. She also advised that once RN B had contacted Dr C for guidance at 7.21am on 31 October, Dr C assumed overall responsibility for Ms A's care. I accept this advice. However, RN Lindley identified several other concerns with RN B's care of Ms A, which I discuss below.

Management and escalation of vascular occlusion — breach

63. On 30 October following the administration of the filler, Ms A experienced mild blanching, bleeding, and slightly delayed capillary refill. Ms A was told to return to the clinic the following morning.

64. RN Lindley advised that while blanching at the time of injection can indicate the superficial placement of filler, it can also indicate vascular occlusion. However, as no photos were taken at the time of treatment, she was unable to comment on whether Hyalase should have been administered at that time.

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65. At around 9pm on 31 October, Ms A sent further photos and videos to RN B and reported that she had strange 'lace-like' bruising beneath her lip. RN B responded that the lace-like bruising could be normal, and that the capillary refill at that time looked 'ok'. She reiterated to Ms A that she would see her in the morning, and that Ms A could contact her if she was concerned.

66. RN B told HDC that when she was contacted by Ms A at 9pm, she became concerned about a potential vascular occlusion and so she contacted another beauty clinic nurse. She then planned to administer Hyalase the following morning (to which the other nurse had agreed). However, RN B did not contact Dr C until 7.21am the following morning (31 October) in line with the beauty clinic's occlusion protocol.

67. The protocol stated that if there was a suspected vascular occlusion, the treating nurse should contact the medical director and administer Hyalase under the guidance of the medical director.

68. RN Lindley advised that on review of the photos and videos sent at 9pm, there was a delayed capillary refill, and Ms A's symptoms at that stage were a 'text-book' presentation of vascular occlusion. RN Lindley stated:

> 'There was obviously delayed capillary return, violaceous purpura (or purple net like pattern) and a pale appearance of [the] surrounding area. It was also concerning that when describing this video in her first statement RN B wrote "From the video, her capillary refill appeared improved from what I had seen in the clinic". This implies she had more severe symptoms that had not been acted on at an earlier stage.'

69. Conversely, RN B said that by the time Ms A's symptoms had worsened and she became concerned about vascular occlusion, it was 9pm and too late to get Ms A to return to the clinic for treatment. RN B said that she was also reassured that the other nurse from whom she had sought advice that evening had agreed that treatment could wait until the following morning.

70. In response, RN Lindley advised:

> 'This is not an acceptable reason to deny the patient the urgent treatment they require. Patients are provided with after-hours contact details so they can immediately notify the practitioner of any side effects and receive appropriate management promptly, even after-hours … [T]imely recognition, and intervention for the emergency event of vascular occlusion is crucial for proper management.'

71. Although I am unable to make a finding on whether or not Hyalase should have been administered immediately following treatment, I accept RN Lindley's advice that by 9pm on 30 October, Ms A was showing clear symptoms of a vascular occlusion, and RN B should have asked her to return to the clinic for the administration of Hyalase at that stage.

72. I acknowledge RN B's comments that she was in a difficult situation, working alone in the clinic at the time that Ms A was reporting possible symptoms of a vascular occlusion.

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However, there was a clear protocol in place at the beauty clinic for the management of a suspected vascular occlusion, and RN B failed to follow this policy in that she did not contact Dr C immediately and administer Hyalase with Dr C's guidance. I also note RN Lindley's comment that initially it was the responsibility of RN B to act on Ms A's clinical symptoms and then escalate to Dr C, who would then have shared responsibility for establishing a management plan. RN Lindley advised:

> 'The fundamental issue is that RN B failed to recognise and act on a "text book" presentation of [vascular occlusion] in the evening of the 30/10/2020 and possibly even before this … Additionally, RN B didn't follow [the beauty clinic's] occlusion protocol and failed to inform her prescribing doctor … until the morning of 31/10/2020.'

73. I accept RN Lindley's advice and concur that RN B's failure to administer Hyalase immediately on the night of 30 October represents a moderate departure from accepted standards.

74. Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code) states that every consumer has the right to have services provided with reasonable care and skill. While I acknowledge that RN B was a relatively inexperienced cosmetic nurse at the time of these events and was working under remote supervision on the day in question, the beauty clinic policy is clear that if signs or symptoms of a vascular occlusion appear, nurses should immediately contact the beauty clinic medical director for approval of Hyalase treatment. In my view, by failing to recognise the signs of vascular occlusion and by failing to follow the beauty clinic policy in that she did not contact Dr C immediately when she noticed concerning symptoms, RN B failed to provide services of an appropriate standard to Ms A and breached Right 4(1) of the Code.

Documentation — other comment

75. There are several instances of poor contemporaneous documentation by RN B.

76. Immediately following the lip filler treatment on 30 October, RN B noticed possible symptoms of vascular occlusion but failed to document her observations in the clinical notes following treatment. RN B accepted that she did not document the observed symptoms adequately, or her plan to review Ms A the following morning. RN B said that this was because her appointment times were short (30 minutes with no gap in between appointments) and she had spent longer than usual with Ms A as she had to massage her lips and talk through the signs and symptoms of vascular occlusion in detail.

77. With respect to the lack of documentation of the consultation, RN Lindley considered that along with the inadequate informed consent (discussed above), the incomplete documentation of the details of the consultation (including the blanching seen immediately post treatment) represented a mild departure from accepted standards. RN Lindley also noted that there was no documentation of the Botox treatment, and I note that there was no contemporaneous documentation of the administration of Hyalase (which required a standing order).

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78. While I accept that appointment times at the beauty clinic may have presented a challenge in such circumstances, I do not consider this an adequate reason for RN B not to have documented the details of her consultation with Ms A at that time. I also note that there is a lack of contemporaneous documentation of subsequent appointments with Ms A, and that RN B also failed to document her out-of-hours contacts with Ms A. I acknowledge the mitigating factor that RN B made a detailed retrospective entry in the clinical notes on 7 November following these events (detailed in the 'information gathered' section of this report). However, in this case it was particularly important for RN B to document the treatment and all other details regarding Ms A's symptoms contemporaneously, as Ms A was showing signs of a serious and rare side effect of treatment. Retrospective notes provide an opportunity to enter information with the benefit of hindsight, but the purpose of notes and the emphasis on taking them at the time of the consultation or follow-up treatment is to provide an accurate account of what has occurred at that time.

79. I encourage RN B to reflect on my comments and those of RN Lindley and ensure that she maintains adequate documentation.

Informed consent — other comment

80. RN B told HDC that Ms A had done her own research prior to getting lip filler and that she was already aware of the risk of vascular occlusion. Conversely, Ms A said that she was not aware of the risk of vascular occlusion prior to presenting to her filler appointment.

81. RN B said that she explained the risks of vascular occlusion to Ms A, including the signs and symptoms that she should look out for in the following 72 hours, such as dark or light patches, lace-like patterns, pustules, areas of pain, or capillary refill of longer than three seconds. RN B said that she also advised Ms A that side effects such as bruising and swelling are common. However, this discussion was not documented in the clinical notes or on the consent form. It is unclear whether the risks of Dysport were discussed with Ms A, as this is not documented and no consent form for Dysport was provided.

82. Ms A signed the beauty clinic's consent form in relation to the lip filler. RN B said that this was the standard consent form provided for use by the beauty clinic, and she was unable to alter it. Ms A indicated on the consent form that she had not had filler previously. The consent form explains what hyaluronic acid is, how long the filler will last, and the risks of dermal fillers, including redness, swelling, pain, itching, bruising, and tenderness at the injection site. The form also mentions 'rare' risks such as ischaemia/necrosis. The risks of vascular occlusion specifically and/or its signs and symptoms are not stated on the form.

83. RN Lindley advised that while the consent form listed potential risks including ischaemia/ necrosis, it lacked detailed descriptions of those risks.

84. RN B told HDC that she had a detailed discussion with Ms A about the risks and benefits of the procedure, and that as the consent form itself contains details of what is discussed as part of the consent process, it is her usual practice to confirm in the clinical notes that consent was obtained to avoid duplication.

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85. RN Lindley advised that while she agrees that RN B could not have used a different consent form than the one provided by the beauty clinic, she could have handwritten or typed a more detailed description of ischaemia/necrosis on the form or documented her discussion about risks in the clinical notes. RN Lindley considered that the failure to do so represents a mild departure from accepted practice. She advised:

> 'During an initial consultation, even if no treatment happens, it's important to clearly document that verbal consent was discussed with the patient. This meets the requirement for verbal informed consent, and the written consent form confirms that the patient understands and agrees with what is in the consent form.'

86. I agree. While I acknowledge the limitations of the consent form provided by the beauty clinic (discussed in relation to the beauty clinic below), there were several other options available to RN B to ensure that she documented adequate informed consent for treatment. However, despite the poor documentation of the consent, I am satisfied that RN B provided Ms A with adequate information to understand the procedure and risk of vascular occlusion before commencing treatment.

Treatment options — other comment

87. Ms A said that when she attended her appointment with RN B, she wanted only a 'small' amount of filler and not a full 1mL. However, Ms A said that RN B advised her that she would be better to purchase a 'package' that included 1mL of filler and Dysport in her upper lip (a 'lip flip'). Ms A said that RN B informed her that as she had bigger lips to begin with, she would need more filler. Ultimately, Ms A decided to proceed with the package.

88. RN B said that Ms A told her that she was happy to be guided by her, and she explained to Ms A that as she did not have small lips to begin with, she believed that best results would be achieved with 1mL of lip filler. RN B said that she explained to Ms A that as there was a bigger surface area to cover, 1mL would result in quite a subtle difference in volume. RN B said that she also considered that Ms A might benefit from Dysport in her LLSAN muscle (upper lip), which is why she offered Ms A the package. RN B stated that Ms A seemed happy to proceed with this option.

89. While I accept that both treatments may have been appropriate for Ms A (for the reasons outlined by RN B), it is clear that Ms A attended the clinic wanting only a small amount of filler in her lips, and, ultimately, she left with 1mL of filler and Dysport in her upper lip. I also note Ms A's comment that she was left with a smile that wasn't hers and which she 'hates'. Accordingly, I remind RN B of the risks of amending the treatment plan at the same time as the planned treatment, and to ensure that if a client comes in with a treatment in mind, the client is provided with the risks and benefits of all treatment options and given time to consider the options, so that they do not feel they need to proceed with further treatment if they are uncomfortable doing so.

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Opinion: Dr C — breach

90. At the time of these events, Dr C was the beauty clinic medical director. Dr C had the responsibility to provide clinical advice to the beauty clinic nurses remotely in the case of medical issues. Dr C issued RN B's standing order, which allowed her to administer Dysport treatment.

91. As part of my assessment of this complaint, I sought independent clinical advice from Dr Teresa Cattin. Dr Cattin advised that doctors who issue standing orders are 'completely liable for all aspects of the use of the standing order'.

92. On 30 October 2020, following Ms A's initial filler treatment, RN B noticed blanching and sluggish capillary refill. Subsequently, Ms A was sent home from the clinic without treatment of the suspected vascular occlusion. Dr C was not contacted by RN B until the following day, 31 October 2020.

93. At 7.21am on 31 October, RN B sent a message to Dr C saying that a client had a suspected occlusion and attached a video of Ms A's lips from the previous evening. RN B sent a further video to Dr C (from that morning) of Ms A's lips. Dr C responded that the lip looked better and that it could have 'unoccluded itself'. RN B consulted with Ms A in person that morning and sent videos of her lips to Dr C for advice. RN B told Dr C that the capillary refill was within three seconds, and she had massaged the area. Dr C responded to RN B that she would be happy to monitor Ms A at that stage. Dr C also advised RN B that Ms A looked comfortable and that usually there is 'gnarly pain' associated with a vascular occlusion.

94. Dr Cattin advised that if a vascular occlusion is suspected, accepted practice is for Hyalase to be administered and repeated hourly (pulsed dosing) thereafter 'with the patient kept at [the] clinic for observation'. However, in this case, Hyalase was not administered for almost 24 hours post treatment. Dr Cattin reviewed the images sent to Dr C and advised that these should have been recognised as showing signs of vascular compromise requiring immediate attention and treatment. I accept this advice.

95. On 1 November 2020, following the administration of Hyalase the previous afternoon, Ms A sent a photo and video to RN B showing small white pustules near the treatment site. Dr C reviewed the images at the request of RN B, who asked whether she should be concerned about tissue breakdown. Dr C responded that it 'may be' tissue breakdown, but that she considered that the area was looking a lot better. Dr C did advise RN B that she should administer more Hyalase if she was even remotely unsure about whether the area was improving.

96. Regarding Dr C's management following the administration of Hyalase on the afternoon of 31 October, Dr Cattin advised:

> 'Once [Hyalase] was eventually commenced, the continued clinical deterioration of the vascular compromise does not appear to have been recognised by Dr C … Dr C did not seem to recognise that the appearance of pustules indicated impending necrosis and needed immediate attention … There [was] a failure to recognise the signs of vascular

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compromise which started at that time of injecting [and was] progressive. This would be regarded as below the accepted standard by my peers. This failure resulted in delayed treatment with [Hyalase], allowing the effects of the vascular [occlusion] to become more serious and prolonged than may otherwise have occurred.'

97. Dr Cattin advised that overall, she considered that the care provided to Ms A by Dr C represented a moderate departure from the accepted standard of care. I agree.

98. While I acknowledge that Dr C was not treating Ms A in person and was relying on the information provided to her by RN B, Dr C was the beauty clinic's clinical director and ultimately was responsible for providing clinical guidance to RN B to assist her in managing a suspected vascular occlusion. In my view, RN B was in reasonable contact with Dr C from the morning of 31 October, and, as advised by Dr Cattin, Dr C had been provided with media that showed clear signs of a progressing vascular occlusion. It is also of note that RN Lindley advised that once Dr C was contacted by RN B, Ms A's care became Dr C's responsibility. In my view, by failing to advise RN B to administer Hyalase promptly when she was contacted at 7.21am, and for failing to identify the pustules as tissue breakdown and again clearly advise RN B to administer further Hyalase, Dr C failed to provide Ms A with an appropriate standard of care and breached Right 4(1) of the Code.

Opinion: Beauty clinic — no breach

99. As a provider of healthcare services, the beauty clinic had a responsibility to provide services of an appropriate standard to Ms A. This included the requirement to ensure that practitioners working in its clinics had an adequate environment in which to work and that it had appropriate tools in place to support its staff and fulfil its obligations under the Code.

Appointment times — educational comment

100. RN Lindley advised that accepted practice by New Zealand Society of Cosmetic Medicine (NZSCM) doctors and the nurses for whom they prescribe would be not to treat a patient with dermal filler on the same day as the initial consultation, especially if the patient has not had filler treatment previously. However, RN Lindley advised that there are variations to this if there is a justified reason for it, and numerous clinics do not adhere to this standard of care.

101. RN B said that the standard advised by RN Lindley above was not the standard of treatment at the beauty clinic, and, more often than not, filler treatment was provided during the initial consultation. However, RN B said that her standard practice is to remind patients that they do have the option of treatment on another day if they wish.

102. RN Lindley advised that while it may be frequent practice in such clinics, it does not mean it is accepted by healthcare professionals. She said that NZSCM is the only body recognised by the Medical Council of New Zealand (MCNZ) to regulate cosmetic medicine doctors, and NZSCM recommends against routinely treating with dermal filler at the initial consultation except for reasons such as the patient having a deadline or travelling. RN Lindley advised

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that even then, the practitioner must be confident that the patient has a good understanding of the proposed treatment.

103. It is clear from the information available to me that the beauty clinic routinely offered treatment during an initial consultation, and did not require that patients return another day for treatment after all pertinent information had been provided to them.

104. RN Lindley advised that there are two issues with treating patients during an initial consultation — the first being that the patient has not had a 'cooling off' period to consider the risks and benefits explained to them at the initial consultation. Secondly, the consultation may not provide enough time to perform both a consultation and treatment to an acceptable standard for a new patient. At the time of the events, the beauty clinic offered only 30-minute consultations, which RN B said were often back-to-back. RN Lindley advised:

> 'Many … clinics only allocate 30–45 minutes for an initial consultation, as this fits their business model. I believe there are few practitioners who would consider this sufficient time for an accepted standard of consultation and filler treatment on a new patient.'

105. I agree. While RN Lindley did not identify a departure in relation to treating patients on the same day as an initial consultation, I encourage the beauty clinic to reflect on my comments and those of RN Lindley.

Concurrent treatment — other comment

106. RN Lindley commented on the use of filler and Dysport (Botox) to treat the same area, on the same day. She said that while administering Botox and filler in the same treatment area is not ideal, it is not contraindicated. However, she said that usually it is better to wait, review, and then treat, as concurrent treatment can make it harder to interpret the relative success of each treatment. RN B and the beauty clinic disagreed with RN Lindley's advice in this regard.

107. RN Lindley said that while it is not a criticism, she considered her comments to be advice to avoid a similar event occurring in the future, particularly in light of Ms A's comment that she was left with a smile that isn't hers and that she 'quite frankly hates'.

108. I accept RN Lindley's advice, and while I am not critical of the beauty clinic in this regard, I encourage it to reflect on RN Lindley's comments.

Consent form — other comment

109. RN Lindley advised that the consent form offered by the beauty clinic did not include sufficient detail about the risks of dermal filler. She also noted that there was no Dysport (Botox) treatment consent form provided by the beauty clinic. RN B told HDC that she was unable to alter the consent form provided by the beauty clinic.

110. I agree with RN Lindley's comments that the dermal filler consent form provided by the beauty clinic did not include sufficient detail about the risks of dermal filler, particularly the risk of vascular occlusion, and/or what symptoms to be aware of following treatment. While RN Lindley did not identify a departure relating to the lack of detail on the consent form, I

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remind the beauty clinic of the importance of ensuring that all risks and benefits of treatment are clearly explained and documented, and I consider that a more detailed consent form would assist the beauty clinic practitioners in doing so.

Changes made since events

The beauty clinic

111. Dr C told HDC that the beauty clinic has implemented the following changes:

- Instituted a policy that all potential vascular occlusion events must be notified to the overseeing doctor immediately.
- Adopted the NZSCM guidelines for management of vascular occlusion and implemented this policy. The beauty clinic nurses receive annual education sessions to support their knowledge and understanding of vascular compromise.
- Instituted a new role, which involves training and supervision for the beauty clinic nurses to provide additional support remotely to the nurses in case direct contact with a doctor cannot be made immediately.

112. In response to the recommendations made in the provisional report, the beauty clinic provided HDC with copies of its current consent forms for all cosmetic injectable treatments, which have been updated to include further detail of serious risks of dermal filler and what signs and symptoms to look out for.

113. The beauty clinic also advised that in November 2023 it changed to a new booking system, which allows the clinic owner to change appointment times for each individual nurse. The beauty clinic said that this means that the nurse can have more time if required for a specific treatment or for documentation. The beauty clinic also advised that its appointment times are 45 minutes, and a consultation is a further 15 minutes.

Dr C

114. Dr C told HDC that she has 'reflected extensively on this case over the last three years, undertaken further learning, and made amendments to [her] practice and that of the beauty clinics', including:

- In line with MCNZ requirements, she receives professional supervision from a colleague who is a Fellow of the New Zealand Society of Cosmetic Medicine (NZSCM), and they meet regularly to discuss cases, including complications from the use of dermal fillers, and its treatment. Dr C said that her professional supervisor also works for the beauty clinic and therefore is knowledgeable about the policies and practices. Dr C stated that she meets monthly to discuss cases in a formal manner and to receive professional support.
- She has undertaken further education in the assessment of vascular occlusion through her collegial support person. Dr C said that following this case, occlusions have been identified early and managed well, and in any ambiguous cases of vascular occlusion, she is able to communicate with her supervisor for advice if needed.

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- She has adopted a 'when in doubt, hyalase out' policy, which still balances the risks associated with Hyalase versus the risk of delayed treatment of vascular occlusion.
- She has improved her communication skills so that she communicates more clearly and concisely with the beauty clinic nurses as to what needs to be done and when.

RN B

115. RN B told HDC that she has made the following changes since the events:

- Completed an online course at the beauty clinic (along with all other nurses at the clinic), which addressed vascular occlusion.
- Completed her own independent research into vascular occlusions.
- Undertaken in-person education and skill development with doctors at her current place of work, to ensure that she is prepared for any future adverse events.
- She receives oversight and annual competency assessments that include refreshers for potential emergency situations, including vascular occlusions.
- She has personally reflected on the events and has learnt to be more decisive in her practice. She is now able to act more decisively and seek a second opinion if required.
- Each month 15–20% of her clinical notes and consent forms are audited (equating to 20–40 sets of notes each month). She has received positive feedback from her oversight doctor.
- She has completed an independent review of the New Zealand Nurses Organisation (NZNO) documentation guidelines (2021) and reflected on her learnings in her written reflection to HDC.

Recommendations

RN B

116. In my provisional report I recommended that RN B provide a written apology to Ms A, complete the HDC online learning module on informed consent, and provide a reflection of her learnings to HDC. In response to my provisional report, RN B confirmed that she had completed all three recommendations and provided evidence.

117. I have taken into account that RN B has undergone further training on the identification and management of vascular occlusion and that her oversight doctor conducts an audit of her clinical notes and consent forms each month, and I have no further recommendations in this respect.

Dr C

118. I recommend that Dr C provide a written apology to Ms A for the failings identified in this report. Dr C is to provide the apology to HDC, for forwarding, within three weeks of the date of this report.

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119. I have taken into account that Dr C has undergone further training on the identification and management of vascular occlusion and have no further recommendations in this respect.

The beauty clinic

120. In the provisional report, I recommended that the beauty clinic consider the comments made about appointment times and concurrent treatment and update its consent form to include further detail of serious risks of dermal filler and what signs and symptoms to look out for. In response to the provisional report, the beauty clinic advised and provided evidence that it had completed both these recommendations.

121. Accordingly, I recommend that the beauty clinic use an anonymised version of this report to provide training to nurses at the beauty clinic around the identification and management of vascular occlusion, with reference to its Occlusion Policy. Evidence of the training is to be provided to HDC within six months of the date of this report.

Follow-up actions

122. A copy of the sections of this report that relate to Dr C will be sent to the Medical Council of New Zealand.

123. A copy of the sections of this report that relate to RN B will be sent to the Nursing Council of New Zealand.

124. A copy of this report with details identifying the parties removed, except the advisors on this case, will be sent to the New Zealand Society of Cosmetic Medicine and the Medical Council of New Zealand.

125. A copy of this report with details identifying the parties removed, except the advisors 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 clinical advice to Commissioner

The following independent advice was obtained from Dr Teresa Cattin:

'1. I am Dr Teresa Cattin of Auckland (MSc, MBBCh, FRNZCGP). I have over 24 years' experience in cosmetic medicine and have held the positions of Censor and President of NZCAM (now NZSCM). I am a senior Faculty Member of the Allergan Medical Institute and hold positions on a number of advisory boards for both dermal fillers and botulinum toxins. I am a trainer in dermal fillers and botulinum toxin for the New Zealand Society of Cosmetic Medicine (NZSCM) Diploma in Cosmetic Medicine.

I have been asked to provide an opinion to the Commissioner on case number C20HDC02288.

I have read and agree to follow the Commissioner's Guidelines for Independent Advisors. I am not aware of any conflicts of interest.

2. I have reviewed all the documents supplied by HDC including the 27 photos/videos sent by the patient. I have considered the clinical management of this case with regards to the following:

(i). NZSCM Protocols:

Standing Orders

Annual Nurse Competency Checklist for Standing Orders 2021

(ii). NZSCM Standards and Clinical Procedures:

Temporary Dermal Fillers:

(5.1) Symptoms of Vascular Compromise

(5.2) Treatment of Vascular Compromise:

(iii.) Medicines (Standing Order) Regulations 2002, Ministry of Health.

(iv) How it would be viewed by our peers.

3. Summary of Clinical Events:

30/10/20 4.30 pm Patient presented to the beauty clinic for first dermal filler treatment (lips). Immediate blanching and sluggish capillary refill noticed by RN while injecting lower lip. Lip massaged, treatment completed (1ml Juvéderm) and patient sent home.

30/10/20 5.50pm Patient reports increasing pain, purple/black bruising on lower lip and lacey pattern of bruising beneath lip and extending down towards chin. Video and photos sent by patient. 7.17pm. Lip continues to turn purple and black. More photos/ videos sent. 8.47pm. Pain increasing and purple/black area extending. Photos/videos sent. Patient told by RN to come back next day (8.45am) for review.

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31/10/20 9am. Doctor who has issued the Standing Order for hyaluronic acid [Dr C] is in [different city] and is contacted by RN by phone, sent photos and videos. Area was massaged. Patient sent away.

2.45pm. Patient reviewed again, hirudoid creme applied and patient sent home.

4.45pm. Patient reports increasing pain and lip becoming numb. Went back to clinic and 2 vials of hyaluronidase injected by RN. (From texts exchanged [Dr C] advised RN to wait another 24 hours before proceeding with hyaluronidase.)

1/11/20 8.18am Patient reports increasing pain and appearance of white pustules below lip and blisters in mouth. Was told "looks better" but to come in for LED light treatment to "aid healing".

1/11/20 Patient self-presents to ED at the public hospital and is admitted, 2 further vials of hyalase injected. Aspirin 300mg given and Flucloxacillin commenced.

3/11/20 Patient discharged from hospital.

6/11/20 Further pustules and swelling of lip, treated again at ED.

3. Background:

(3.1) Standing Orders

— "Standing Orders" are in fact "prescriptions" given in advance by a doctor to a nurse to administer for a specific set of circumstances when the doctor is not present. They apply only to prescription medicines.

— Dermal fillers, such as Juvéderm, are not listed as prescription medicines in NZ but are "medical devices". A "standing order" therefore, is not required to administer them.

— Hyaluronidase is a prescription medicine, and it is considered mandatory to include it in the "standing orders" of a cosmetic medicine clinic. It is regarded as an "emergency" drug to be used immediately in the event of vascular compromise as it will immediately dissolve the filler so normal blood flow can resume.

(3.2) Vascular Compromise/Occlusion

— "Vascular occlusion" occurs when dermal filler is inadvertently injected into an artery. The filler immediately moves (embolises) into very small vessels (microcirculation) compromising the blood supply to the skin which may result in scarring and tissue loss. Conversely it may continue as an embolus into the vessels supplying the eye with catastrophic consequences (blindness or stroke).

— While vascular occlusion affecting the skin is rare (approx. 1:1000), it is a potentially devastating complication of treatment.

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— It is expected that all injectors (doctors and nurses) are able to competently diagnose and manage a vascular occlusion.

— Due to the devastating sequelae of failing to quickly recognise and reverse this complication a low threshold for administering hyaluronidase (to dissolve the filler) should always be followed.

(3.3) Role of Doctor Issuing Standing Order: (NZSCM Protocol)

The Ministry of Health states "the issuing doctor is completely liable for all aspects of the use of the standing order".

The Medical Council's expectation in paragraph 32 of Good Prescribing Practice is that the doctor signing the standing order is responsible for the effects of that prescription. "Effects" would include how the patient reacts to a treatment or medicine that a doctor prescribes.

The doctor who writes the Standing Order ("the issuer") has responsibility to:

— ensure the legislative requirements for the Standing Order are met;

— ensure that anyone operating under the Standing Order has the appropriate training and competency to fulfil the role;

— countersign, audit and review the Standing Order;

— review the nurse's competency annually;

— document the results of audit and review.

(3.4) Diagnosis of vascular compromise:

1. Early signs:

a) Immediate blanching;

b) Delayed capillary refill;

c) Dusky or purple discolouration;

d) Typical lacey pattern, mottled appearance (anywhere on face).

(2) Late signs: (indicate impending necrosis/tissue loss):

a) Dark colour/blackened area

b) Pustules/blisters.

NB. Vascular compromise may or may not be painful.

(3.5) Protocol for Treatment of Vascular Occlusion:

a) Stop injecting immediately;

b) Inform patient of your concern;

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c) Immediately prepare hyaluronidase as per protocol and inject entire area with 1/2 to one vial to all symptomatic areas. Repeat **hourly** until capillary return has returned to normal;

d) Consider use of aspirin — 100mg under the tongue immediately then 100 mg daily;

e) Give analgesia if required;

f) Review the patient daily and repeat hyaluronidase injections if any sign of vascular compromise such as delayed capillary return, skin discolouration or pustules are present;

g) This pulsed dosing regimen should prevent any cases of vascular occlusion progressing to necrosis;

h) Hyperbaric Oxygen should be considered to assist tissue healing in established cases of tissue necrosis.

4. <u>Expert Advice Requested by the Commissioner:</u>

(4.1) Comment on the clinic's standing orders:

The standing order for hyaluronidase has been issued by Dr C and is dated 1/8/20 and is therefore up to date at the time it was implemented. The relevant documentation is complete.

It is accepted practice and would be regarded as acceptable by my peers.

It is commendable that the beauty clinic had a Standing Order in place at the time of this complaint (October 2020). Hyaluronidase was reclassified as a Prescription Medicine May 2021, following a submission by NZSCM.

(4.2) Is it preferable to have a doctor on site to supervise the RN?

Dermal fillers are currently listed as "devices" not prescription medicines. As such their use is not confined to registered Medical Practitioners.

Botulinum toxins and hyaluronidase are now listed as prescription medicines and therefore require a doctor to issue a "standing order" for use by a suitably trained and competent RN when the doctor is not present. It is not regarded as necessary to have a doctor on site to supervise the RN provided their training and ongoing competency has been confirmed by the issuing doctor.

NZSCM advises a suitable period of direct observation by the issuing doctor of the nurse performing assessment and treatment is necessary to properly assess their competence.

(4.3) Comment on the adequacy of the advice provided by [Dr C].

While appropriate protocols have been put in place by the beauty clinic these don't appear to have been followed by either [Dr C] or [RN B].

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[RN B] rightly recognised the typical signs of vascular occlusion while injecting the patient. “During injection of the right lip tubercle blanching was seen.” “Sluggish capillary refill” was noticed. Four hours after treatment the patient sent photos and complained of a “strange lace-like bruising”.

All of these signs are typical of vascular compromise (see 3.4).

My impression is that [RN B] successfully identified vascular compromise but failed to act on it. According to [Ms A] she was sent home from the clinic despite [RN B] “feeling unsure if the lip was occluded”.

Accepted practice is that hyaluronidase is immediately injected if vascular compromise is suspected. Injections are repeated hourly (pulsed dosing) thereafter with the patient kept at the clinic for observation. In this case hyaluronidase was not commenced until nearly 24 hours after the first signs appeared.

The beauty clinic protocol rightly states “Immediate action is required” and “the medical director should be immediately contacted”. [Dr C] appears to have only been contacted the following day.

I have reviewed the beauty clinic Protocol for the management of vascular occlusion and find it is consistent with best practice.

I have reviewed the images sent by the patient and believe these should have been recognised as showing signs of vascular compromise requiring immediate attention.

Once hyaluronidase was eventually commenced, the continued clinical deterioration of the vascular compromise doesn’t appear to have been recognised by [Dr C]. The patient was being reassured that the situation was improving while that was not reflected in the images sent by the patient.

[Dr C] did not seem to recognise that the appearance of pustules indicated impending necrosis and needed immediate attention (hyaluronidase). When [Dr C] was asked about the pustules her texted response was “it’s actually looking a lot better”.

There is a failure to recognise the signs of vascular compromise which started at the time of injecting and were progressive. This would be regarded as below the accepted standard by my peers.

This failure resulted in delayed treatment with hyaluronidase, allowing the effects of the vascular compromise to become more serious and prolonged than may otherwise have occurred.

Conclusion: The standard of care is below that of accepted best practice.

Considering the patient’s delayed and prolonged treatment course, resultant hospital admission and residual problem (skin discoloration) I would describe this as a moderate departure from the accepted standard of care.

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(4.4) Further comments:

I would like to comment on the concerns [Ms A] expressed about the beauty clinic staff members attempting to discourage her from attending ED. I agree that a beauty clinic is typically better placed to manage a vascular occlusion than an ED, as an ED does not stock hyaluronidase and is often unfamiliar with the presentation of a vascular occlusion and the current protocols for treatment. I agree that there are frequently cases presented at conferences, plus anecdotal reports discussed at Peer Review meetings of delayed or inadequate ED treatment for vascular compromise. I believe the staff concerns in this regard were understandable.

(4.5) Recommendations for improvement that may help to prevent a similar occurrence in the future:

1. Vascular occlusion is a rare but potentially devastating risk of dermal filler injection.
2. Numerous injecting techniques have been suggested to reduce the risk, but it is not possible to remove the risk completely.
3. As such it is an important consented risk of procedure and should be highlighted during the consent process.
4. It is considered mandatory that all injectors are able to diagnose and treat a vascular occlusion.
5. All injectors must be familiar with the pathophysiology, clinical progression and treatment of vascular events.
6. A low threshold is expected for initiating treatment with hyaluronidase. The earlier treatment is started the more favourable the outcome.
7. In this case the correct clinic protocols appear to be in place but were not followed.
8. This highlights the importance of ongoing education, peer review and staff audit within all clinics as well as a full understanding of the professional obligations associated with issuing a Standing Order.’

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Appendix B: Independent clinical advice to Commissioner

The following independent advice was obtained from RN Emma Lindley:

'I, Emma Lindley, have been tasked with providing impartial clinical guidance to the Health and Disability Commissioner regarding the appropriateness of the care administered to [Ms A] by [RN B]. The assessment encompasses several key aspects.

1. The risks and benefits discussed with the consumer prior to treatment.

a) The standard of care/accepted practice would be to discuss with the patient all the potential risks and benefits of the proposed procedures and then verbally run through the written informed consent form with the patient together. This written informed consent would cover all potential risks and benefits and appropriate aftercare information that the patient would need to consider before consenting to the treatment.

b) There appears to be a mild departure of standard of care.

- While the consent form for the dermal filler addressed potential risks such as Ischaemia/necrosis, it lacked detailed descriptions. Furthermore, the absence of an aftercare form (I wasn't provided this) and incomplete documentation of the consultation/after care information in the clinical notes (only in the statement) signify a mild deviation from the standard of care. However, despite this it clearly seemed that the patient was aware of signs and symptoms of a VO as she was sending videos of cap refill and reporting appropriate signs of deterioration. Additionally, that [RN B] mentioned that [Ms A] was aware of VO and potential risk of blindness before having the procedure (in her statement).
- Regarding the Dysport — I wasn't provided a consent form or documentation regarding the consultation conversation. There was documentation regarding batch, expiry, and general location of the Dysport.
- The standard of care/accepted practice by NZSCM doctors (and the nurses they prescribe for) would be to not treat the patient with dermal filler on the same day as the initial consultation — particularly if the patient is filler naïve. I am aware that there are variations from this if there is a justified reason and that there are numerous clinics that don't follow this standard of care.

c) The care would be reviewed as a mild departure of the standard of care/accepted practice by peers. The main issue being that the discussion regarding the consultation and risks and benefits of the procedure haven't been documented in enough detail.

d) It is advisable to meticulously document all patient consultations, including comprehensive discussions on procedure risks and benefits. Additionally, administering Dysport concurrently with filler treatments in the same area is not ideal (but not contraindicated). It would be recommended to wait and review as

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concurrent treatment can make it harder to interpret the relative success of each treatment. Additionally, I noted that [Ms A's] son's birthday party was soon after the filler treatment. Conservatively I don't treat patients before any big events and consider their social schedule and plan for the best time for filler in case of any needle related expected outcomes — these questions are part of my consultation.

2. Whether the treatment was carried out in accordance with expected practice and with appropriate safeguards, including comment on the appropriateness of the clinic's standing orders, and there not being a registered medical practitioner on-site to supervise the RN.

a) The standard of care/accepted practice for dermal filler lip treatments is to perform a consultation to assess the patient's health suitability for treatment and their expectations of treatment and whether this is appropriate. Then to consent the patient, take clinical photographs, complete the treatment with aseptic and best practice techniques in respect to the patient's vascular anatomy first and foremost (this would be to understand depth and location of "normal vascular anatomy, no large boluses when injecting and to keep your needle moving") take immediate after photos and then provide the patient with appropriate aftercare including emergency contact details and what to watch out for in terms of VO — booking a follow up appointment if necessary.

In terms of accepted practice of the S.O. — as dermal fillers are medical devices, they currently do not need a S.O. However, Hyalase is a medication, and this does require an S.O. Both the standing order doctor and the RN need to have familiarised themselves with these documents and any policy/procedures related to them. The RN needs to know when to escalate care and when to contact the S.O. doctor and the S.O. doctor needs to stipulate when this needs to be. The S.O. and relevant procedure/policy documents need to be up to date and accessible in an emergency.

Accepted practice in NZ is that there doesn't need to be a "registered medical practitioner on-site to supervise the RN". This is not limited to the field of cosmetics. Doctors and Nurses work as colleagues in both primary and secondary health care facilities as part of a multi-disciplinary team.

b. There appears to be both no departure from the standard of care and a moderate–severe departure from the standard of care.

- Regarding the dermal filler treatment itself — a VO is a rare unfortunate consented potential side effect. Dose not product is responsible.
- I note that Ms A has questioned why aspiration was not performed but aspiration is not regarded as "best practice", there is a debate in this industry as to its effectiveness and reliability, and it has an unknown false negative rate so shouldn't be relied on.
- Therefore, in terms of the dermal filler treatment itself — I can comment that there were no contraindications for the patient to treatment. [RN B] consented the patient, performed the treatment, documented the treatment, and provided

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appropriate after care and contact details. I cannot comment on the depth of injection as this wasn't documented or the presence of clinical photographs as I wasn't provided these.

- Regarding the management of the VO and the recognition of this — I would say there has been a moderate–severe departure from the standard of care. [RN B] and [Dr C] failed to administer immediate Hyalase for what I would describe as a "textbook presentation" of a VO and this is a severe departure from the standard of care which could be downgraded to moderate due to their eventual (but delayed) administration of Hyalase.
- I have viewed videos sent from [Ms A] to [RN B] and there was in my opinion a sluggish cap refill from the evening of the 30/10/2020. Progressing on the next day to purpura forming in her right oral commissure with obvious blanching in the centre of her lower lip and a darkened discolouration. Progressing more on the 31/10/2020 to signs of hypoxia with the tissue breakdown.
- [RN B] was correct when she put in her statement that a blanching at the time of injecting can indicate superficial placement of product but a delayed capillary return at this time can indicate VO — unfortunately I have not seen immediately after photos to comment whether this was the case. I also have not seen the videos that [RN B] took and sent to [Dr C] to comment on what they were seeing.
- The VO was eventually recognised and the appropriate treatment of hyalase was implemented on the afternoon of the 31/10/2020 — close to 24 hours after the treatment. Resolution of a VO can be successful days after treatment, but best practice would always be early recognition and intervention for this emergency event. It may not have progressed to pustules if this was the case (1,3).

c) Peers would likely acknowledge the challenges of acute situations and agree that we learn and make changes to our practice from them. However, from viewing the videos, peers would agree that [RN B] and [Dr C] initially failed to act on the textbook VO that required emergency reversal with hyalase and that early recognition and intervention in cases of vascular occlusion are imperative to the best outcome for the patient. (1,3).

In terms of not having a "recognised medical practitioner on site" peers would agree this is standard practice. I work at a different site to my prescribing doctor. I have successfully managed a VO for one of my patients — liaising with my prescribing doctor by sending videos, photos and video calling her. My prescribing doctor is in a 20–30-minute drive from me so I do have the ability for her to review my patients in person if necessary.

d) My recommendation for the future would be to be decisive with the plan when advising the patient, communicate clearly, document everything and if in doubt to Hyalase.

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From reviewing the events that followed the VO, [Ms A] lost confidence in the ability of [RN B] and [Dr C] to manage her complication and that is why she sought treatment elsewhere (at the hospital). I am confident that [Ms A] would not have sought treatment elsewhere if they would have been more decisive about the plan and communicated the process of what the next few days would look like for [Ms A] with her and provided reassurance (e.g., at least daily appointments, more hyalase, potentially antibiotic cover, potentially pustules forming). This may also have alleviated the HDC complaint.

1. **The adequacy of the safety netting advice provided to the consumer and the appropriateness of the follow up communication/advice.**

   a) Standard practice dictates providing patients with comprehensive aftercare information, including potential complications and instructions on post-treatment care. This would include after-hours contact details. It is not uncommon for patients to contact a practitioner on a social media platform via their business account as this can be how they make bookings etc. It is not uncommon for them to continue to communicate over this platform and to use it to send videos/photos etc.

   b) There appears to be a mild departure from the standard of care. There were no issues with the initial post care information provided as [Ms A] knew what to look for in terms of a VO and how to check her Cap refill — this is evident on the videos that she sent to [RN B] and submitted as evidence. There appears to be regular communication between [RN B] and [Ms A], however, as mentioned above the plan and implementation of the plan was not clear and decisive enough and I believe this led [Ms A] not to feel confident in this care provided by [RN B] and [Dr C].

   c) I believe peers would agree on the above. They would also agree that because Cosmetic medicine is very specialised that the advice on the hospital not being the best place to go to manage a VO is justified. Dermal filler complication management isn't something that most acute care facilities will have seen or have procedures in place to manage. Hyalase is always the critical factor in the resolution of the VO. (2)

   d) Recommendations include providing clear plans to patients, maintaining consistent communication, and ensuring follow-through on proposed actions to instill patient confidence and manage expectations effectively.

      Another recommendation would be that [RN B] and [Dr C] partake in further education about the presentation and management of a VO as they failed to immediately recognise and act on the videos sent by the patient that evening. This should have been immediately hyalased and their failure to do so indicates that their knowledge (at that time) was insufficient. VO is a well-recognised, much feared, adverse event that injectors should expect to encounter at some time during their career and it is therefore crucial that it is diagnosed correctly

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and in a timely manner to optimise the patient's recovery. In the paper (3) it showed that 62% of injectors had encountered one or more vascular occlusions.

2. **Any other comments you wish to make on the care provided.**

I noted that [Dr C] mentioned in her communication with [RN B] that "patients with a VO usually experience Gnarly pain". I wanted to comment on this as this is in fact quite incorrect. VO can have pain and an absence of pain may also be present. In this article (3) mildness/absence of pain was a feature of 47% of the VO events.

References

1. **Murray G, Walker L, Davies, E. Guideline for the safe use of Hyaluronidase in Aesthetic Medicine, including modified high dose protocol. *J Clin Aesthet Dermatol.* 2021;14(8): E69–75.**
2. **DeLorenzi C. New High Dose Pulsed Hyaluronidase Protocol for Hyaluronic Acid Filler Vascular Adverse Events. *Aesthetic Surgery Journal.* 2017; 1–12.**
3. **Goodman GJ, Roberts S, Callan P. Experience and Management of Intravascular Injection with Facial Fillers: Results of a Multinational Survey of Experienced Injectors. *Aesth Plast Surg.* 2016; 40: 549-555.'**

The following further advice was received from RN Lindley on 16 September 2024:

'I am Emma Lindley (BNurs, PGCertHSc) of Auckland, New Zealand. I have almost 16 years' experience as a Registered Nurse and 11 of those years have been in cosmetic medicine. I worked in a busy cosmetic clinic before I became a National Nurse Trainer for two large corporations in New Zealand, educating over 100+ nurses during this time. For the last four years, I have been a faculty member for Teoxane ANZ whereby I have trained another 100+ nurses, doctors and dentists during this time and continue to do so. I have had a patient base and been in a clinical injecting role also for the last 11 years. I am an active member of NZANA group and have held a position of a board member for CANN in its establishment in 2019–2020 prior to it becoming CANNZ (which I am no longer involved with).

I, Emma Lindley, have been tasked with providing further impartial clinical guidance and clarification to the Health and Disability Commissioner following [RN B's] response to the advice report and the covering letter provided by [her legal representative]. This was specifically regarding whether the following points caused me to change or amend any of my previous advice:

1. **[RN B's] submissions regarding her inexperience as a cosmetic injector at the time of events and the "few other options for clinical support available to her" paragraph 19.**

I acknowledge the difficult position that [RN B] was in at the beauty clinic, as I have too worked in a busy clinic as my introduction to the industry. Not having a clinical nurse specialist role at the beauty clinic present at the time of this complication would have made it more challenging for RN B in this situation.

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However, there was a clear protocol (the beauty clinic protocol) for VO recognition that wasn't followed. It was initially the responsibility of the RN to act on the patient's clinical symptoms and escalate to her prescribing doctor, who then would have shared responsibility for establishing a management plan.

2. The submissions from [legal representative] at paragraph 18 of the covering letter.

Whilst treating with filler at the initial consultation is a frequent practice in some clinics, this does not mean it is in the patient's best interests or considered acceptable practice by healthcare professionals.

...

NZSCM is the only body recognised by the Medical Council of New Zealand to train and regulate Cosmetic Medicine doctors. My understanding is they recommend against routinely treating with dermal filler at the initial consultation, except for reasons such as the patient having a deadline or travelling a distance, and the practitioner must be confident that the patient has a good understanding of the risks and benefits. My understanding is that there is no other recognised body that has provided advice on this matter and therefore NZSCM's stance is the "accepted standard".

There are two problems with treating at the initial consultation. Firstly, the patient has not had a "cooling off" period to consider the risks and benefits. Secondly, the initial consultation may not provide enough time to perform both consultation and treatment to an acceptable standard on a new patient. I believe most practitioners would agree at least 60 minutes is required to consult a new patient, identify contraindications and precautions, assess their face, formulate a treatment plan, perform informed consent, allow the patient time to consider the risks and benefits and ask questions, answer questions, take clinical photographs, administer local analgesia, perform filler treatment, and educate the patient on aftercare. All these steps are necessary for an accepted standard of care.

Many clinics only allocate 30–45 minutes for an initial consultation, as this fits their business model. I believe there are few practitioners who would consider this sufficient time for an accepted standard of consultation and filler treatment on a new patient.

3. [RN B's] submission at paragraph 3 & 6–11 of her response where she advises that she was unable to add more detail into the consent form owing to it being provided by the beauty clinic.

I agree with [RN B] that she could not have provided a different consent form to the one provided to patients at the beauty clinic. However, she could have handwritten (or typed, if on computer) a more detailed description of ischemia/necrosis on the form. This is common practice.

Alternatively, she could have verbally explained it to the patient and documented this in the clinical notes. This is also common practice, both routinely and when the written consent form is not sufficient.

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The cosmetic field is always changing. Frequently, we learn new information from conferences, webinars, or peer groups. To keep patients updated about new risks before the written consent form is updated, we may educate the patient verbally before documenting it on the consent form or in the notes.

During an initial consultation, even if no treatment happens, it's important to clearly document that verbal consent was discussed with the patient. This meets the requirement for verbal informed consent, and the written consent form confirms that the patient understands and agrees with what is in the consent form.

4. [RN B's] response at paragraph 13.

I would agree that it is up to the patient to decide if they want to proceed with the treatment in respect to their social schedule. I would however advise and educate the patient about my clinical reasoning, and document it. If I really thought it wasn't in their best interest at this time, I would decline to treat and reschedule for a **later** date. Cosmetic treatments are elective, and a crucial skill for cosmetic practitioners is to be able to sensitively decline to treat when appropriate.

5. [The legal representative's] response at paragraph 5 of the covering letter and paragraph 17 of [RN B's] response, in particular whether you consider responsibility for [Ms A's] care still rested with [RN B] following [Dr C's] involvement from the morning of 31 October 2020.

I agree with [the legal representative's] response and [RN B's] response regarding [Dr C] assuming overall responsibility of the management plan for the patient when she was informed about the situation. However, the "textbook presentation video" was from the evening of the 30th of October and [RN B] failed to recognize this and to follow the protocol set out by the beauty clinic about the management of a VO.

When I completed my initial advice, I was only asked to comment on [RN B's] involvement in the care of [Ms A] not [Dr C].

My advice for [RN B] in the future is to seek a second opinion from a more experienced colleague if she encounters a complication she feels too inexperienced to diagnose or manage. While I recognize that she reached out to another nurse later that night, it would be beneficial to do so sooner rather than relying on a solo decision initially.

6. The mitigating circumstances presented by [the legal representative], or any other information provided by [RN B's] response.

Under the heading "Mitigating circumstances", [the legal representative] quoted that I had only managed this event once. Personally, in my 11-year career, two of my patients have experienced a VO, which I successfully managed with no sequalae. One of these was in my first 24 months of injecting, whilst working at a chain clinic. I have also managed and mentored my colleagues through more than twenty VOs in my roles as training manager, educator, and mentor.

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[RN B's] clinical environment at the beauty clinic is unfortunately not an uncommon one. This doesn't excuse or explain why the beauty clinic Occlusion protocol was not followed. I agree that I am unfamiliar with [the staff member] who the beauty clinic described but do know that they now have a clinical nurse specialist presently working for them.

I did refer to the fact that the video I viewed from the evening of the 30/10/2020 showed a sluggish cap refill and a "textbook presentation" of a VO. [The legal representative] spoke about the clinic being closed and [RN B] having a "limited opportunity to provide treatment" and [RN B] spoke about how it "was 9pm and too late to return to the clinic to administer Hyalase". This is not an acceptable reason to deny the patient the urgent treatment they require. Patients are provided with after-hours contact details so they can immediately notify the practitioner of any side effects and receive appropriate management promptly, even after-hours. As mentioned in the previous report, timely recognition, and intervention for the emergency event of vascular occlusion is crucial for proper management (1,2).

[RN B] did reach out to [another nurse whose] response was that it was an occlusion and that she required Hyalase. I disagree that [Ms A] could wait till the morning for Hyalase.

I acknowledge [RN B's] commitment to [Ms A's] care via her actions related to the hospital events, messaging another colleague and communicating (not decisively on a plan however) with the patient. However, the fundamental issue is that [RN B] failed to recognize and act on a "textbook presentation" of a VO in the evening of the 30/10/2020 and possibly even before this (I haven't seen any videos of the patient's capillary refill before the one I have mentioned). Additionally, [RN B] didn't follow the beauty clinic Occlusion protocol and failed to inform her prescribing doctor ([Dr C]) until the morning of the 31/10/2020. [Dr C] then failed to recognize the presentation and at this stage [RN B] was working under [Dr C's] guidance, although still entitled to take part and manage her patient during this time. This has led to [Ms A] losing confidence in both [RN B] and [Dr C] and seeking treatment elsewhere and possibly leading to the HDC complaint.

Any other matter that you consider warrants comment.

[The legal representative] spoke about Redactions — there were no redactions in the reports I received, however I was specifically asked to comment about [RN B's] care not [Dr C's]. You will see in this report I have discussed both where necessary.

Whether you consider the standard of care you described in the initial advice report as the "accepted industry standard", with regard to the following.

a) Treatment on the same day as the initial consultation.

As mentioned in (2.) above, the HDC can approach NZSCM for their official position, but my understanding is that they recommend against routinely treating with dermal filler at the initial consultation, except for reasons such as the patient having a deadline or

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travelling a distance, and only if the practitioner is confident the patient had a good understanding of the risks and benefits. This would be the "accepted standard of care". The time allowed for an initial consultation may not be sufficient to perform consultation and treatment to an acceptable standard. I believe most practitioners would agree that 30–45 minutes isn't enough time to meet a new patient, identify contraindications and precautions, assess their face, formulate a treatment plan, perform informed consent, allow the patient time to consider the risks and benefits and ask questions, answer questions, take clinical photographs, administer local analgesia, perform filler treatment. In addition, they must have time to educate the patient about the importance of returning promptly should the signs or symptoms of vascular occlusion appear.

As mentioned previously, NZSCM is the only body recognised by the Medical Council for the regulation and training of cosmetic medicine doctors. My understanding is that there is no other body that has provided advice on this matter and therefore NZSCM's advice is the "accepted standard".

To summarise, in the current situation it doesn't appear that there was a "deadline" for this patient to receive treatment on the same day as the consultation. However, performing treatment at the initial consultation is unlikely to be the reason that [Ms A] experienced a VO. I'm aware that [RN B] was working under guidelines from the beauty clinic that don't necessarily follow "accepted practice guidelines" from professional healthcare societies.

b. Treatment with Dysport and filler on the same day.

Regarding the advice around administering Dysport concurrently with filler treatments, this was in relation to it being "in the same area of the face is not ideal but not contraindicated". I could have expanded on this further to include new patient and first treatment of both Dysport/Botox and Filler to this area of the face.

Section D was about providing recommendations to help prevent a similar occurrence, which in this circumstance, was related to an unhappy patient putting a complaint through to the HDC.

It wasn't about the "accepted standard of care", more so advice for [RN B] on how to practise conservatively and to prevent other patient complaints or complications in the future, based on my extensive personal and professional knowledge and experience in this industry.

This did not contribute to the VO, but [Ms A] was dissatisfied with "I am left with a smile that isn't mine, and that quite frankly I hate". In a similar circumstance it would be sensible to allow the filler to settle and then assess how much gum and teeth show would be present before injecting Dysport/Botox to alter the smile.

9. Whether [Ms A's] symptoms following treatment on 30th October 2020 warranted immediate action (and not the next day as occurred).

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Unfortunately, I'm not able to comment on this comprehensively and as accurately as I would like, as mentioned in my first report and again now. I have not seen immediate "after" photos of when [Ms A] was treated, or an immediate video of the capillary refill to answer that decisively.

What I can be confident about, is that the video that I did view that was taken around 8:47pm on the 30th of October 2020 is the "textbook VO" that I have commented on, and this required immediate intervention. There was obviously delayed capillary return, violaceous purpura (or purple net-like pattern), and a pale appearance of surrounding area. It could be assumed from this that either the symptoms were present and required immediate action or that it had progressed to now requiring Hyalase. The issue is the lack of recognition and the delay in Hyalase treatment that took place after this video was received until the following afternoon.

It was also concerning that when describing this same video in her first statement [RN B] wrote "From the video, her capillary refill appeared improved from what I had seen in clinic". This implies she had more severe symptoms that had not been acted on at an earlier stage.

10. Clarification of what time period you consider [Ms A] was presenting with "textbook" symptoms of vascular occlusion (paragraph 15 of [RN B's] response).

Please see answers to question 9, as it covers the answers to this question above.

References

1. Murray G, Walker L, Davies, E. Guideline for the safe use of Hyaluronidase in Aesthetic Medicine, including modified high dose protocol. *J Clin Aesthet Dermatol.* 2021;14(8): E69–75.

2. Goodman GJ, Roberts S, Callan P. Experience and Management of Intravascular Injection with Facial Fillers: Results of a Multinational Survey of Experienced Injectors. *Aesth Plast Surg.* 2016; 40: 549–555.'

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Appendix C: The beauty clinic's Vascular Occlusion Policy

'PROTOCOL

Vascular occlusion or intra-arterial occlusions can present immediately following a treatment or occur in the minutes or hours following a treatment. In some cases, even several days later, with this in mind this reiterates the need to ensure client education is given post treatment.

- Signs to look for include blanching of the area while, or immediately subsequent to, injecting filler. Bruising in the injection area may occur, mottling of the skin, colour changes or bruising in the skin away from the injected area may also indicate vascular compromise.

- If a vascular occlusion event is not treated, lack of blood supply to the tissue may lead to necrosis and ulcerated tissue and skin. For this reason, immediate action is required.

- If you suspect vascular compromise:

    1. Do not inject any further product.
    2. Inform the client of your concerns.
    3. Your immediate goal is to restore vascular supply to the area as soon as possible. A number of measures to promote blood supply are detailed. However, the most important is the use of Hyaluronidase (Hylase) to disperse the hyaluronic acid filler. While adjunctive measures may be useful, these should not delay the injection of hyaluronidase. **Follow the Immediate Action below:**

OCULAR OCCLUSION PROTOCOL

Eye strokes occur when blockages (occlusions) occur in arteries or veins in the retina, causing vision loss. The severity of vision loss depends on the extent and location of the occlusion(s) and loss of blood flow. When blood flow is blocked, the eye also may suffer damage when vital structures such as the retina and optic nerve are cut off from nutrients and oxygen flowing through your blood.

- Signs to look for include blurry vision, partial loss of vision, complete loss of vision, loss of vision in one eye while, or immediately subsequent to, injecting filler. Bruising in the injection area may occur.

- Dial 111 and ask for an ambulance, provide clinic address & clear references where to find you. Explain that the client has a possible Ocular Occlusion due to injectable filler. Have another staff member stay on the phone with the call center to liaise client's welfare & provide directions.

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- **Follow the immediate action below.** With the Medical Directors approval for hyaluronidase treatment, commence immediately while waiting for ambulance to arrive.

- Ask ambulance staff which hospital they are taking the client too. Ring the Emergency Department and ask for the On Call Ophthalmologist and calmly provide details of filler product used, client's reaction and amount of Hylase injected.

IMMEDIATE ACTION:

The Cosmetic Injector must immediately contact the [beauty clinic's] Medical Director for approval of hyaluronidase treatment. In the rare event an occlusion occurs when a Doctor is not available; contact the [relevant staff member]. Should the [relevant staff member] not be contactable, immediately send an SMS to the Chief Executive Officer so a [beauty clinic] Medical representative can be contacted:'

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