Accident and Medical Clinic

Registered Nurse, RN B

A Report by the

Deputy Health and Disability Commissioner

(Case 14HDC00958)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. On 25 March 2014, Mrs A disturbed a wasp nest and was stung approximately 10–15 times on her face, neck, and right arm. Mrs A had experienced a delayed skin reaction to wasp stings in the past.

2. Within 15 minutes of her arrival at an accident and medical clinic (the Clinic), Mrs A was attended to by physician Dr C. Dr C recorded: "[N]o hypotension, asthma or throat swelling." He prescribed intravenous (IV) promethazine 25mg and hydrocortisone 200mg. He also wrote: "[M]onitor vital signs."

3. Registered nurse (RN) RN B then administered 25mg of promethazine. Promethazine must be diluted before administration, to reduce the risk of vein irritation. However, RN B did not dilute the promethazine, and injected an undiluted form of promethazine into the cannulation site on Mrs A's hand.

4. Mrs A became drowsy and, 10 minutes after the administration of promethazine, she was unable to be roused. She was monitored closely by RN B for one hour, with stable vital signs noted. As there had not been a significant improvement in Mrs A's ability to be roused, Dr C contacted the registrar at the public hospital.

5. Mrs A was transferred to the public hospital by ambulance, and was discharged the next day. Mrs A's discharge summary recorded her primary diagnosis as: "Allergy to wasp stings." Her secondary diagnosis was recorded as "a reduction in consciousness secondary to promethazine". It was also noted that Mrs A is not allergic to promethazine.

6. On 31 March 2014, Mrs A was diagnosed with thrombophlebitis (vein inflammation).

Findings

7. RN B did not provide Mrs A with services with reasonable care and skill, and breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code) by failing to comply with the Clinic's IV Manual, in that she did not double check the IV medications with another qualified person prior to administering them, and by administering an undiluted form of promethazine to Mrs A.[1] This was a significant departure from the accepted standards of safe medication administration.

8. The Clinic did not breach the Code.

9. Other comment is made about Dr C.

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

Complaint and investigation

10. The Commissioner received a complaint from Mrs A about the services provided by RN B at the Clinic. The following issues were identified for investigation:

- *The appropriateness of the care provided by the Clinic to Mrs A in 2014.*
- *The appropriateness of the care provided by RN B to Mrs A in 2014.*

11. An investigation was commenced on 12 January 2015.

12. This report is the opinion of Ms Theo Baker, Deputy Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

13. The parties directly involved in the investigation were:

Mrs A	Consumer/complainant
The Clinic	Provider
RN B	Provider
Dr C	Provider

14. Independent expert advice was obtained from registered nurse Ms Dawn Carey (**Appendix A**) and general practitioner Dr David Maplesden (**Appendix B**).

Information gathered during investigation

Background

15. On 25 March 2014, Mrs A disturbed a wasp nest and was stung approximately 10–15 times on her face, neck, and right arm. Mrs A had experienced a delayed skin reaction to wasp stings in the past.

16. Mrs A attended her local pharmacy and was given Telfast (fexofenadine), a non-sedating antihistamine, paracetamol, and ice packs to apply. Mrs A's husband collected her from the pharmacy and drove her to the Clinic.

The Clinic

Triage

17. Mrs A arrived at the Clinic just after 10am. According to the patient management system, Mrs A was triaged by RN B within six minutes of her arrival (at 10.15am). RN B obtained Mrs A's history and recorded: "Swollen right arm and right side of face … recordings satis[factory], O_2 sat[uration]s 100% in air, pulse 67 regular, appearing a little shocked with some slightly catatonic movements and very jumpy …"[2] Mrs A subsequently told HDC that she was a little shocked but denied being jumpy or having catatonic movements.

[2] Mrs A was initially assigned triage category 4 but this was crossed out and changed to category 3. Triage code 4 is assigned when assessment and treatment should be started within 60 minutes. Triage category 3 is assigned when assessment and treatment should be started within 30 minutes.

Assessment by doctor

18. Within 15 minutes of her arrival, Dr C[3] attended Mrs A. Dr C recorded: "[N]o hypotension, asthma or throat swelling." He prescribed intravenous (IV) promethazine[4] 25mg and hydrocortisone[5] 200mg. He also wrote in the clinical notes: "[M]onitor vital signs."

19. Prescriptions for IV medications do not usually specify the dilution rate or speed of administration. However, Dr C said that he instructed RN B to administer a diluted form of promethazine as a slow push (slowly). In contrast, RN B does not recall any verbal instruction from Dr C to dilute the promethazine. Dr C stated that he advised Mrs A of the potential side effects of drowsiness and stinging related to the use of IV promethazine, and that Mrs A consented to the injection. Subsequently, Mrs A told HDC that Dr C gave her "no advice about IV promethazine burning or asked to consent — he just said he was giving me some IV Antihistamines & I thought ok that sounds harmless enough".

Promethazine

20. Promethazine is highly caustic and, as such, should be administered into a large vein (see further information from Medsafe below). It usually comes in ampoules of 25mg, and must be diluted before being administered to reduce the risk of vein irritation. The Clinic's IV Manual (discussed further below) requires that promethazine be diluted 1:10 with water.

Administration of promethazine

21. Dr C said that his preference for a cannulation site[6] is the antecubital fossa[7] at the elbow. However, he inserted the cannula into Mrs A's hand because "the best veins were present on the dorsum of [her] hand".[8]

22. RN B told HDC that the promethazine came in the form of a promethazine hydrochloride injection BP 25mg/1mL (a single ampoule). She said that she drew the ampoule contents into a syringe, and then checked the prescribed IV medications with Dr C before administering them. In contrast, Dr C says that the IV medications were not brought to him to be checked, and that, if he had checked it, "it would have prompted me to order its dilution".

23. RN B first administered hydrocortisone. She then administered 25mg of promethazine (the amount prescribed). However, she did not dilute the promethazine, and injected it in an undiluted form into the cannulation site on Mrs A's hand. RN B stated: "Whilst I know that I failed to dilute the drug I clearly recall that I administered the syringe contents very slowly. I deliberately sat down, facing [Mrs A] whilst doing this to enable me to administer the drug very slowly and to better observe her for any signs

[3] Dr C is a vocationally registered urgent care physician.
[4] Promethazine acts as an antihistamine and is used to treat allergic reactions, nausea and vomiting. It blocks the effects of the naturally occurring chemical histamine in the body.
[5] A steroidal drug used to treat inflammatory skin conditions.
[6] Where the cannula or luer is placed for the purpose of administering intravenous (directly into the vein) fluids or medication.
[7] The elbow pit.
[8] The back of the hand.

of an untoward reaction." RN B told HDC that, at the time of administration, she believed that her knowledge of how to administer the drug was correct and safe, which is why she did not consult any of the medication resources available.[9]

24. Mrs A stated that the infusion really hurt and she was in tears. She told HDC that it hurt so much that she was screaming, and she asked RN B to stop. In response to the "information gathered" section of my provisional opinion, Mrs A stated:

> "I gave every indication it was intolerable, I was crying, with my face screwed up saying it's burning & stop! I'm not sure what else she expected from someone to alert her it was intolerable, if the Doctor had advised me about burning as he said he did, obviously I would've ordered her to stop immediately."

25. Mrs A also said that RN B did not administer the IV promethazine slowly and, when she asked RN B to stop, she "seemed to go faster".

26. Mrs A's husband was present at the time, and told HDC that his wife told RN B to stop because it was burning. RN B recalls Mrs A saying that the infusion was tender, but says that Mrs A did not ask her to stop, and gave no indication that the infusion was not tolerable. RN B told HDC that Mrs A's discomfort during the infusion did not rise to a level that would have caused her to stop the administration. RN B said that she would have terminated the administration instantly if she had believed Mrs A was suffering a tissue reaction.

27. Dr C was not present during the administration of the promethazine.

Deterioration and hospital transfer

28. The medications are recorded as being administered at 10.30am. The nursing notes indicate that Mrs A became drowsy and was unable to be roused 10 minutes after the administration of promethazine. Mrs A said that she was unable to communicate with her husband within three to five minutes after the administration, and it was one of the most frightening experiences of her life. RN B stated that she fetched Dr C immediately, and he elected to continue observing Mrs A at the Clinic. Close monitoring was continued over one hour, with stable vital signs noted.[10] At approximately 11.40am, Dr C reviewed Mrs A and recorded that there had been no significant improvement in her ability to be roused.[11] He assessed her as having a Glasgow Coma Scale score of seven.[12]

29. Dr C contacted the registrar at the public hospital and discussed the possibility of an adverse reaction to promethazine. Dr C decided to transfer Mrs A to the public

[9] The resources available included the Clinic's IV Therapies Manual, which stated that promethazine must be diluted and injected slowly.

[10] Mrs A's vital signs were taken at 10.20am, 10.45am, 11am, 11.20am, and 11.45am. All were within the normal range.

[11] Dr C was not aware at this time that RN B had administered an undiluted form of promethazine. He first became aware of this sometime between 30 August 2014 and 3 September 2014.

[12] The Glasgow Coma Scale is a neurological scale that aims to give a reliable, objective way of recording the conscious state of a person for initial as well as subsequent assessment. A patient is assessed against the criteria of the scale, and the resulting points give a patient score between three (indicating deep unconsciousness) and 15 (fully awake).

hospital, and an ambulance arrived at 11.47am. Mrs A was monitored overnight and discharged the next day. Mrs A's discharge summary recorded her primary diagnosis as: "Allergy to wasp stings." Her secondary diagnosis was recorded as a reduction in consciousness secondary to promethazine. It was also noted that Mrs A is not allergic to promethazine.

Subsequent events

30. On 27 March 2014, Mrs A presented to the Clinic as she was feeling weak and shaky and not quite right. She was seen by a doctor who recorded his impression as "prob[able] panic attack from fainting after shower due to being hot". In contrast, and in response to the "information gathered" section of my provisional opinion, Mrs A stated: "I was weak & shaky & found it difficult to keep my eyes open & it was causing me to panic after my experience the previous day, I most certainly did not faint in the shower as it was too hot …" Mrs A said that over the next two days she had trouble getting around, as her legs were shaking and felt as if they could not hold her up. Her arms were weak, and the veins in her left lower arm were hard, raised and tender to touch.

31. On 30 March 2014, Dr C telephoned Mrs A's family to see what had happened and to apologise for the hospital admission. He said that they had a lengthy discussion, including his request to present the case to a peer group. Mrs A stated that she was happy for Dr C to discuss her case to help ensure that this did not happen to someone else.

32. Dr C also stated that during the telephone call, Mrs A did not mention any injection site symptoms, any unhappiness that the injection had been painful, or that RN B had refused to stop the injection. He told HDC: "These assertions are all new to me, and were not raised at any time by either the nursing staff or family." In response to the "information gathered" section of my provisional opinion, Mrs A said:

> "I did mention my veins were hard in the conversation & he never commented … I never mentioned to the Doctor the issue with the Nurse or the injection as to me it happened & it was a horrible experience but was over now, I never realised the part it played in all of this.
>
> Also the IV Line was dislodged at [the Clinic] by me when I was unconscious & they were unable to stop me from moving my arms around — I was described as unresponsive but combative on the Ambulance report."

33. On 31 March 2014, Mrs A consulted with a general practitioner, as she had been having trouble walking and had pain in her left arm. Mrs A was diagnosed with thrombophlebitis (vein inflammation). The Clinic stated:

> "We note that the diagnosis of thrombophlebitis subsequently made by [Mrs A's] GP is one of the known adverse effects of intravenous promethazine, (and potentially also from trauma to the vein following insertion and subsequent dislodgment of the iv luer [at the public hospital]), and would explain her symptoms of arm pain within the first week."

34. In addition, Dr C told HDC that even though the promethazine was administered slowly, as it was not diluted, "this may have contributed to the discomfort [Mrs A] experienced and the subsequent development of thrombophlebitis".

35. Mrs A told HDC that, since being administered promethazine, she has suffered from a weak left arm, and continues to have "swelling and burning pain" if she knocks her arm.

Training provided to RN B

36. The Clinic stated that RN B has worked at the Clinic on a casual basis since September 2012.

37. The Clinic told HDC that, at the commencement of her employment, RN B received 21 hours of one-to-one orientation with its lead nurse. In addition to that orientation, the Clinic advised that it holds a separate IV therapy session, which involves the review of the Clinic's IV Therapies Manual (IV Manual) and the IV Calculations Booklet. The session is followed by an assessment of IV medications competency and IV drug calculation. RN B's orientation records that she completed the IV medications competency assessment successfully on 9 May 2012, and the IV drug calculation assessment on 6 June 2012. RN B re-sat and passed these assessments in 2013.

38. The Clinic advised that there have been no competence concerns raised about RN B prior to or following this incident.

IV Manual

39. The IV Manual provides the following:

> "The administration of Medications is a potentially high risk activity that requires the person giving it to have good clinical judgment, a sound knowledge base skilled assessment and safe administration technique. Any IV medication therapy given by nurse or medical staff is required to be administered in accordance with these standards as set by the Clinic Medical …
>
> Consideration of accountability should guide practice and the decision *to or not to* administer the prescribed drug. **If in doubt, do not give**. …
>
> All infusions, intravenous medications, intramuscular injections, and controlled drugs much be **double-checked** by two qualified persons." (Emphasis in original.)

40. In relation to promethazine, the IV Manual states:

> "In emergency situations [promethazine] may be given by slow IV injection. Dilute each ml of dose to 10ml with Water for Injection … immediately before use. Inject slowly … Venous irritation may occur with intravenous administration."

New Zealand Medicines and Medical Devices Safety Authority (Medsafe) publication

41. Medsafe's publication *Intravenous promethazine — reports of serious tissue injuries* provides the following information about promethazine and its administration:[13]

> "Promethazine injection is highly caustic to the intima of blood vessels and surrounding tissues.
>
> Reports from the United States describe serious tissue reactions including thrombosis, nerve damage, tissue necrosis and gangrene in patients who have received intravenous promethazine. In rare cases surgical intervention such as skin graft, fasciotomy or amputation has been required.
>
> In New Zealand promethazine injection is approved for the treatment of vomiting, allergic reactions (including anaphylaxis) and to induce sedation.
>
> After reviewing the published literature, assessing the New Zealand case reports and consulting with healthcare professionals, Medsafe has concluded that there remains a clinical need for intravenous promethazine in New Zealand.
>
> Medsafe however recommends that intravenous promethazine should only be used if the benefits clearly outweigh the risks in each patient. This may include emergency situations (such as treatment of anaphylaxis) or situations where intramuscular or oral administration is contraindicated.
>
> To maximise the safe use of this medicine, Medsafe offers the following advice:
>
> 1. Deep intramuscular injection is the preferred route of administration of promethazine injection.
> 2. Promethazine must not be administered subcutaneously or intra-arterially.
> 3. An alternative medicine should be considered if intravenous administration is required.
> 4. Promethazine should be administered through large patent veins. Veins in the hand and wrist should be avoided if possible.
> 5. If intravenous administration is required, the maximum recommended concentration is 25mg/mL and the maximum recommended rate of administration is 25mg/minute. Further dilution and administration over 10–15 minutes may reduce the risks even further.
> 6. The injection should be stopped immediately if pain or a burning sensation occurs.
> 7. Patients should be advised to seek medical assistance if pain, a burning sensation, swelling or blistering occurs at any time after the administration of intravenous promethazine."

[13] Prescriber Update 30(4): 24 November 2009, See: http://www.medsafe.govt.nz/profs/PUArticles/Intravenous%20promethazine%20-%20reports%20of%20serious%20tissue%20injuries.htm.

Justification for promethazine use

42. Dr C provided HDC with a detailed response outlining his clinical rationale and his research of the literature about antihistamines use in treating anaphylaxis.

43. Dr C told HDC that he considers the use of IV promethazine was justified because Mrs A's presentation might have developed into a "potentially life-threatening event" and, in his view, it is possible that this treatment may have either saved her life or reduced the risk of her losing her life. He stated:

> "[Mrs A] had a history of severe and prolonged swelling after a single previous sting, so that a history of 15–20 stings on the face and neck was of considerable concern and I believe risk to her. I gave promethazine intravenously because I wanted to prevent her deterioration and there was no other drug available that was indicated then that would do something useful to prevent anaphylaxis with an onset of action of less than an hour."

44. In response to my provisional opinion, Mrs A said that she did not think she presented as an emergency situation. She said: "I was stung at 9am, given antihistamines at Pharmacy 9.30am & seen by the Doctor as a precaution an hour later with no issues other than large swelling on right side of face & arm …"

Action taken since complaint

45. The Clinic advised HDC that it sent a detailed email to its clinical staff regarding the prescribing and administration of medication in its clinics. The Clinic also advised that, in response to HDC's nursing advisor's report, it has:

a) ordered an up-to-date copy of the drug manual notes on injectable drugs, and this is now available at both of its clinics;

b) reviewed its anaphylaxis protocol; and

c) run an anaphylaxis teaching scenario as part of an audit of its resuscitation facilities.

46. Dr C stated that Mrs A's case was peer reviewed by a number of colleagues prior to the complaint being received. He has also reflected on the incident and advised HDC that he will:

a) work on improving his communication;
b) be less likely to use IV promethazine;
c) if he does use IV promethazine in the future, he will administer it personally via a large vein and with dilutions and timeframes in excess of what is recommended; and
d) use paediatric formulations of oral antihistamines instead.

47. RN B told HDC that she apologises for any shortcomings in the treatment she provided to Mrs A, and she has completed a self-review and update of her pharmacological knowledge. She stated that it is now her custom always to check drug resources and references for any drugs that she has not administered on a

frequent basis. RN B also re-sat and passed the IV medications competency and IV drug calculation assessments on 5 May 2014.

Responses to provisional opinion

48. A response to the "information gathered" section of my provisional opinion was received from Mrs A, and has been incorporated above.

49. In response to my provisional opinion, RN B advised that she had no further comments to make.

50. In response to my provisional opinion, the Clinic stated:

> "Having reviewed [the provisional opinion] we have nothing further to add, though would like to again note the impact this case has had on our clinic and to reaffirm our ongoing commitment to continuous quality improvement.
>
> …
>
> We also note that [the Clinic] is in the final stages of reviewing and updating our IV Therapies Manual and tests which will shortly be available for [RN B] to complete."

51. The Clinic also provided the following comments on behalf of Dr C:

> "He has confirmed his lasting regret for not administering the medication personally, and that he will use IV promethazine with increased caution. He also commented on how much he has learnt from this case, and how it has modified his practice 'without a doubt'.
>
> He has also had some useful reflections in regard to the internal management of this process which [we] will continue to discuss with him to ensure any further learning opportunities from this case have been explored."

Opinion: Dr C — Other comment

52. On 25 March 2014, Dr C reviewed Mrs A within 15 minutes of her arrival at the Clinic. In light of her triage category (which categorised her as needing to be assessed and treated within 30 minutes), Mrs A was seen promptly.

53. Dr C prescribed IV promethazine and hydrocortisone and requested that Mrs A's vital signs be monitored. Dr C told HDC that he considers that his use of IV promethazine was justified because Mrs A's presentation might have developed into a "potentially life-threatening event", and because she had had a previous severe reaction to a single wasp sting.

54. Medsafe recommends that promethazine be administered through large patent veins, and that veins in the hand and wrist should be avoided if possible. Dr C said that his

preference for a cannulation site is the antecubital fossa at the elbow. However, he inserted the cannula into Mrs A's hand because "the best veins were present on the dorsum of [her] hand".

55. Dr C stated that he advised Mrs A of the potential side effects of drowsiness and stinging related to the use of IV promethazine, and that Mrs A consented to the injections. In response to my provisional opinion, Mrs A said that she was given "no advice about IV promethazine burning or asked to consent". Mrs A said that she was aware she was being giving IV antihistamines, and thought that it "sounded harmless enough". Due to the conflicting accounts, I am unable to make a finding as to exactly what information Dr C gave Mrs A.

56. In relation to Dr C's prescription of promethazine, my expert clinical advisor, Dr David Maplesden, advised:

> "[W]hile [Dr C's] management of [Mrs A] was not consistent with recommended best practice, it was consistent with common practice … I feel also that the potential local toxicity of IV promethazine is under-recognised in primary care, and that a significant number of my peers may have chosen to manage [Mrs A] as [Dr C] did, including placement of the IV line in the peripheral vein."

57. Dr Maplesden also advised me that the management of Mrs A at the Clinic was otherwise satisfactory. She was monitored appropriately, and it was reasonable to attribute her drowsiness initially to an expected side effect of promethazine. The hospital review was also appropriate, and he considered that there was no need to arrange an admission during the hour she was being observed at the Clinic. I accept Dr Maplesden's advice.

58. Dr C has reflected on Dr Maplesden's comments, and has amended his practice accordingly.

Opinion: RN B — Breach

59. Under Right 4(1) of the Code, Mrs A had the right to have services provided to her with reasonable care and skill. I have concerns about the services provided by RN B to Mrs A, in particular, her failure to administer IV promethazine safely.

60. On 25 March 2014, Dr C prescribed IV promethazine. My expert nursing advisor, RN Dawn Carey, stated that prescriptions for IV medications do not usually specify the dilution rate or the speed of administration.

61. Dr C said that he instructed RN B to administer a diluted form of promethazine as a slow push. In contrast, RN B does not recall any verbal instruction from Dr C to dilute the promethazine.

62. RN Carey advised that safe medication practice requires and expects that a registered nurse will use appropriate organisational resources to check or inform his or her knowledge when involved in medication administration. Therefore, irrespective of whether or not Dr C verbally instructed RN B to dilute the promethazine, it was RN B's responsibility to check the available medication resources prior to administering promethazine.

63. The IV Manual provides that all intravenous drugs must be double-checked by two qualified persons. RN B told HDC that she checked the prescribed IV medications with Dr C before administering them. In contrast, Dr C says that the IV medications were not brought to him to be checked, and that, if he had checked the medications, "it would have prompted me to order its dilution". RN Carey advised: "In my experience in an emergency situation, the practice of double checking can be reduced to checking the vial of the medication with another practitioner rather than the more comprehensive check that occurs when checking a medication in a non emergency situation …"

64. In my view, for the following reasons, I am inclined to accept Dr C's account that RN B did not check the IV medications with him:

a) It was an emergency situation.

b) Dr C stated that if the IV medications had been brought to him, it would have prompted him to order the promethazine to be diluted (and it was not diluted).

c) Dr C was not present at the time of the administration.

d) Dr C was unaware until late August/early September 2014 that RN B had administered the promethazine without diluting it.

65. RN B then administered an undiluted form of promethazine into the cannulation site on Mrs A's hand. RN B told HDC that, at the time of administration, she believed that her knowledge of how to administer the drug was correct and safe, which is why she did not consult any of the medication resources available.

66. RN Carey advised: "It was inappropriate for [RN B] to have administered IV promethazine in an undiluted form to [Mrs A] and … the failure to utilise the available medication resources demonstrates a significant departure from the accepted standards of safe medication administration." I accept RN Carey's advice.

67. In her complaint to HDC, Mrs A stated that the infusion really hurt and she was in tears. She subsequently told HDC that it hurt so much that she was screaming. Mrs A said that she asked RN B to stop. Mrs A's husband was present at the time, and told HDC that his wife told RN B to stop because it was burning. RN B stated that she recalls Mrs A saying that the infusion was tender, but that Mrs A did not ask her to stop, and gave no indication that the infusion was not tolerable. RN B told HDC that Mrs A's discomfort during the infusion did not rise to a level that would have caused her to terminate the administration, and that she would have stopped instantly if she had believed Mrs A was suffering a tissue reaction. Dr C told HDC that when he spoke to Mrs A on 30 March 2014, she did not mention that the injection had been

painful or that RN B had refused to stop the injection. He stated: "These assertions are all new to me, and were not raised at any time by either the nursing staff or family."

68. I note that stinging at the cannulation site is a known side effect of the administration of IV promethazine. Both Mr and Mrs A stated that Mrs A told RN B to stop the administration because of the pain it was causing her. However, RN B provided a different account. I am satisfied that Mrs A suffered discomfort and pain during the administration of promethazine, and advised RN B of this. I am less persuaded that Mrs A clearly asked RN B to stop. I have considered whether further information would resolve this issue, but have decided that my main concern is RN B's failure to meet the standard of care expected of a registered nurse administering an IV medication. I therefore make no finding on this issue.

69. In my view, RN B failed to provide Mrs A with services with reasonable care and skill by failing to comply with the Clinic's IV Manual, in that RN B did not double check the IV medications with another qualified person, and administered an undiluted form of promethazine to Mrs A. This was a significant departure from the accepted standards of safe medication administration. Accordingly, RN B breached Right 4(1) of the Code.

Opinion: The Clinic — No breach

70. RN B works at the Clinic. Under section 72(3) of the Health and Disability Commissioner Act 1994 (the Act) an employing authority may be vicariously liable for any act or omission of its agent. Under section 72(5) of the Act, it is a defence for an employing authority if it can prove that it took such steps as were reasonably practicable to prevent acts or omissions leading to an employee's breach of the Code. This Office has previously found providers not liable for the acts or omissions of staff, when those acts or omissions clearly relate to an individual clinical failure made by the staff member.[14]

71. RN Carey stated that there were suitable medication resources available to RN B at the Clinic to support the safe administration of IV promethazine. I accept RN Carey's advice. I also note that the Clinic appropriately inducted RN B into her role as a registered nurse, and ensured that she was trained and tested on IV medications competency and IV drug calculation. In my view, the failing in this case was due to an individual clinical failure rather than deficiencies in the processes at the Clinic. Accordingly, I do not find the Clinic liable for RN B's breach of the Code.

[14] Opinion 12HDC01483, available at www.hdc.org.nz.

Recommendations

72. I recommend that RN B:

a) Provide a written apology to Mrs A. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Mrs A.

b) Undertake further professional training on the administration of IV medications and report to HDC with evidence of the course being completed, within three months of the date of this report.

Follow-up actions

73.
- A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the Nursing Council of New Zealand, and it will be advised of RN B's name.
- A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the CEO of the DHB, and it will be advised of RN B's name.
- A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to Medsafe, the Medical Council of New Zealand, and the Royal New Zealand College of Urgent Care.
- A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A — Independent expert advice to the Commissioner

The following expert advice was obtained from registered nurse Ms Dawn Carey on 10 November 2014:

"1. Thank you for the request that I provide clinical advice in relation to the complaint from [Mrs A] about the care provided to her by [the Clinic]. In preparing the advice on this case to the best of my knowledge I have no personal or professional conflict of interest. I agree to follow the Commissioner's Guidelines for Independent Advisors.

2. I have reviewed the following documentation: complaint and correspondence from [Mrs A] and [her husband]; response from [the Clinic] including staff statements and clinical notes for [Mrs A]; [the] DHB clinical notes for [Mrs A]; clinical advice from Dr D Maplesden.

3. [Mrs A's] complaint relates to being administered Promethazine intravenously (IV) via a hand vein as part of her treatment for suspected anaphylaxis. She notes that NZ Medsafe advise against this medication being administered in a hand vein and also that administration should stop if the patient experiences burning. [Mrs A] complains that despite complaining of pain and asking for the IV administration to stop, the nurse didn't do so.

I have been asked to review the nursing care provided to [Mrs A] at [the Clinic] on 25 March and to provide clinical advice in response to the following questions:

- Was it appropriate for an RN to administer the IV Promethazine to [Mrs A]?
- Should the RN have stopped administering the IV Promethazine when [Mrs A] complained of a burning sensation in her arm?

4. [The Clinic] has provided a comprehensive response to all aspects of [Mrs A's] complaint. I have reviewed the response and note that they are supported by the contemporaneous clinical documentation. For the purposes of brevity I have chosen not to reiterate the response details. Relevant to the focus and scope of my advice I note the following:

    - The Patient Registration Form (PRF) has a medication prescription and administration section. This section is completed with *Hydrocortisone 200mg IV* and *Promethazine 25mg IV*. Both medications are signed by the prescriber.
    - [The Clinic's] response reports that ... *[RN B] ... recalls [Mrs A] commenting on discomfort at the time of giving this medication but felt that this was minor rather than distressing and is adamant that there was no request made to stop the administration ...*
    - [Dr C] reports *... the promethazine was given by [RN B] under my verbal and written instructions; my recollection is that this was to be given diluted as a slow push. According to nursing advice the promethazine was given*

undiluted as a slow push over a period of considerably more than one minute, and [Mrs A] did not ask for this to be stopped …

- The second staff statement provided is identified in [the Clinic's] response as being written by [RN B]. The scribe is not identified within the statement except by *… I am a compassionate and experienced Registered Nurse …*
  This statement reports that *… In my clinical judgement I believed that [Mrs A] was experiencing anaphylaxis to her wasp stings* [sic] *… Promethazine was given IV as charted. [Mrs A] said that the infusion was tender but at no time did she ask me to stop or make any inclination that it was not bearable or she was not tolerating the infusion …*

5. Comments
   (i) No intravenous medication policy has been submitted for review and there is no reportage of what medication resources were available to [RN B] on 25 March 2014.
   (ii) The RN response does not report whether [Dr C] had given her any administration advice for the prescribed IV medications.
   (iii) I consider that the prescription of Promethazine for [Mrs A] meets the expected standards. Prescriptions for IV medications do not usually specify the dilution rate or the speed of administration.
   (iv) Safe administration of medications is a basic nursing competency that all nurses are deemed to have achieved following registration. Whilst the administration of intravenous medications is a competency that is usually subject to local (employer) assessment and validation, the professional standards that guide medication administration are the same regardless of the 'route' of administration[1].
   (v) In my opinion, the onus is on the health practitioner to declare any unfamiliarity with a medication and to not administer a medication unless safe and competent to do so. I also consider this to be a professional expectation[1].
   (vi) I consider that safe medication practice requires and expects that a RN will use appropriate organisational resources to check or inform their knowledge when involved in medication administration. Usual available resources in a health clinic would include MIMS medication information either in a hard copy or online format. The MIMS resource identifies that Promethazine *… may be administered by slow IVI (diluted 1:10 with water for inj; max 25mg/min) into large vein (avoid hand, wrist veins) in emergencies or if IM contraindicated …* The requirement for dilution and rate of administration is also specified on the relevant Medsafe data sheet[2].
   (vii) The recollections of [Mrs A] and [RN B] differ in relation to [Mrs A's] pain experience during the administration of IV Promethazine. There is no contemporaneous reportage — [the Clinic], [the ambulance service] or [the DHB] — that references arm pain or signs of pain.

[1] Nursing Council of New Zealand (NCNZ), *Code of conduct for nurses* (Wellington: NCNZ, 2012).
[2] See: http://www.medsafe.govt.nz/profs/datasheet/d/dblPromethazinehydrochlorideinj.pdf

6. Clinical advice
   - Was it appropriate for an RN to administer the IV Promethazine to [Mrs A]?

   It was only appropriate for the RN to administer the IV Promethazine if she was doing so in accordance with her professional competencies, scope of practice and the established standards/guidelines. I have attempted to address the possible different scenarios were I to consider administration to be appropriate or inappropriate:

   (i) If [RN B] checked [the Clinic's] protocol for IV Promethazine and the resource specified that this medication was safe to administer undiluted, I would consider it appropriate for [RN B] to have administered the medication in this format.

   (ii) If [RN B] did not check an IV medication resource as none were available I would be critical of her medication practice and also [the Clinic] organisational standards. In this instance I would consider it inappropriate for [RN B] to have administered the medication.

   (iii) If [RN B] administered the Promethazine to [Mrs A] without checking a medication resource prior, I would consider it inappropriate for [RN B] to have administered the medication. In my opinion such practice is unsafe and contrary to the expected standards of nursing care during medication administration. I would view such practice to be a significant departure from expected standards.

   - Should the RN have stopped administering the IV Promethazine when [Mrs A] complained of a burning sensation in her arm?

   During IV administration it is usual for the RN to be observing for signs of pain and to be responsive to them. If [Mrs A] did report a significant burning sensation during administration then [RN B] should have stopped administration of the medication. As [Mrs A] received IV Promethazine in an undiluted form it is reasonable to conclude that the caustic nature of this medication would have caused her to experience pain.

   However, I am unable to determine whether her experience and reportage was such that [RN B] should have ceased administration immediately.

Addendum entry:

I have received and reviewed further response and documentation from [the Clinic], including a copy of the Intravenous therapies manual (May 2012), Promethazine information sheet and RN Orientation Book. I note that [the Clinic] report that the following resources were available to [RN B] on 25 March 2014 — MIMS information in hard and electronic copy, notes on injectable drugs from New Zealand Healthcare Pharmacies Association, internet access, and other members of the Clinical team.

In my opinion, the submitted manual is clinically robust and supports safe clinical practice. It rightly acknowledges RN accountability during IV medication administration and advocates ... ***if in doubt do not give*** [emphasis in original

document]. I note that the manual reports that all IV medications … *must be **double-checked** by two qualified persons* … [emphasis in original document]. It is not reported whether this occurred in this case or not.

The submitted copy of the Promethazine hydrochloride information sheet (dated 1999[3]) specifies … *Direct IV injection: (into vein or side arm). In emergency situations may be given by slow IV injection. Dilute each ml of dose to 10ml with Water for Injection (concentration = 2.5mg/ml) immediately before use. Venous irritation may occur with intravenous administration …*

In my opinion, whilst the available Promethazine information sheet does not caution [RN B] that IV administration should be into a large vein, it does acknowledge the need to dilute Promethazine prior to administration. Following a review of the further documentation I am of the opinion that there were suitable medication resources — hard copy MIMS or Promethazine information sheet — available to support the safe administration of IV Promethazine to [Mrs A]. In my opinion, it was inappropriate for [RN B] to have administered the Promethazine to [Mrs A] without a suitable volume of diluent. As expressed in section 6(iii) of this advice I view [RN B's] failure to utilise the available medication resources to be a significant departure from expected standards of safe medication administration.

I would encourage [the Clinic to] ensure that the available Information Sheets for injectable drugs is the most up-to-date version available or to ensure that MIMS is the medication resource utilised.

Dawn Carey (RN PG Dip)
Nursing Advisor
Health and Disability Commissioner
Auckland"

Further expert advice was obtained from registered nurse Ms Dawn Carey on 19 February 2015:

"1. Thank you for the request that I provide further clinical advice in relation to the complaint from [Mrs A] about the care provided to her by [the Clinic]. In preparing the advice on this case to the best of my knowledge I have no personal or professional conflict of interest. I agree to follow the Commissioner's Guidelines for Independent Advisors.

2. I have reviewed the following documentation: my clinical advice dated 10 and 12 November 2014; responses and supporting documentation from [RN B] dated 9 December 2014 and 9 February 2015; responses and supporting documentation from [the Clinic] dated 5 February 2015.

3. [RN B's] response and supporting documentation: I note that [RN B] reports double checking the prescribed intravenous (IV) medications with [Dr C] in accordance with [the Clinic's] IV therapies manual. The requirement to check IV medications such as Promethazine is a [Clinic] organisational

[3] Promethazine Injection NZ Healthcare Pharmacists Notes on Injectable Drugs 9th ed 1999.

policy rather than a legislative requirement. In my experience in an emergency situation, the practice of double checking can be reduced to checking the vial of the medication with another practitioner rather than the more comprehensive check that occurs when checking a medication in a non emergency situation e.g. Actrapid insulin and normal saline infusion. Therefore I can accept that [RN B] could have complied with the organisational requirement to have the medication 'checked' by another qualified practitioner without a discussion of the need for a diluent being voiced. Within the relevant literature, the act of 'double checking' a medication has not been proven to prevent medication administration errors[i].

[RN B] also reports that she does not recall hearing any verbal instruction from [Dr C] to dilute the IV Promethazine. She notes that if she had heard she would have done so or at least have questioned the instruction. She reports that at the time of administration she held the belief that her knowledge of how to administer the drug was correct and safe, which was why she did not utilise the available resources. [RN B] reports amending her nursing practice to ensure that she now consistently checks resources/references for any drugs that she has not administered on a regular or recent basis. Further actions relating to comprehensively updating her pharmacology knowledge are also reported as being completed. I consider [RN B's] practice changes and knowledge updates to be an appropriate response to the complaint. I have no further recommendations to add.

4. [The Clinic's] response and supporting documentation: I agree with the provider that the orientation programme for nursing staff is comprehensive. I also agree that [RN B] had demonstrated and was up-to-date with relevant education and required competency assessments.

   I note the actions that [the Clinic has] completed in response to this complaint and received clinical advice to date. In my opinion, these are appropriate and I have no further recommendations to add.

5. Clinical advice
   Following a review of the additional responses, I remain of the opinion that it was inappropriate for [RN B] to have administered IV Promethazine in an undiluted form to [Mrs A] and that the failure to utilise the available medication resources demonstrates a significant departure from the accepted standards of safe medication administration.

   In my opinion, the remedial actions and practice changes undertaken by [the Clinic] and [RN B] are appropriate and should reduce the likelihood of a similar error occurring in the future.

Dawn Carey (RN PG Dip)
Nursing Advisor
Health and Disability Commissioner
Auckland"

Appendix B — Independent expert advice to the Commissioner

The following expert advice was obtained from general practitioner Dr David Maplesden on 22 October 2014:

"1. Thank you for providing this file for advice. To the best of my knowledge I have no conflict of interest in providing this advice. I have reviewed the available information: complaint from [Mrs A] and statement from [her husband]; response from [the person in charge of clinical operations at the Clinic]; response from [Dr C] who treated [Mrs A] at [the Clinic]; statement (unsigned and undated) which I presume to be from a RN providing care to [Mrs A] at [the Clinic]; [the Clinic's] clinical notes; the [public hospital's] clinical notes.

2. [Mrs A's] complaint relates primarily to: the fact she was given IV promethazine at [the Clinic] as part of treatment for suspected anaphylaxis following wasp stings, and that the medication was administered through a vein in her hand which is not recommended by Medsafe; that the infusion was not stopped when she complained of pain; and that a reaction to the infusion has left her with persistent arm symptoms many weeks after the event in question. I do not think it is possible to make an unequivocal determination that [Mrs A's] ongoing symptoms are directly related to the use of IV promethazine, or the precise nature of what is presumed to be a more immediate reaction to IV promethazine, and I will not attempt to do so. This advice relates primarily to the appropriateness of [Mrs A's] diagnosis and management at [the Clinic]. Nevertheless, if [Mrs A] felt inclined to make a claim to ACC for them to consider whether her current persistent symptoms might constitute treatment injury (as an unintended and unusual consequence of IV promethazine administration causing physical harm) this would be a not unreasonable action.

3. The [Clinic's] responses are comprehensive and will not be reiterated in detail here. Some relevant points which I will discuss later in this report include:

(i) On arrival at [the Clinic] [Mrs A] was seen by a triage nurse and given a triage category of 4.

(ii) [Dr C] believes his use of IV promethazine was justified because [Mrs A's] presentation *might develop into a potentially life-threatening event. It is entirely possible that this treatment* (IV promethazine) *may have either saved her life, or if not, certainly reduced the risk of loss of it.*

(iii) [Dr C] also states his belief that *there was no other drug available that was indicated then that would do something useful to prevent anaphylaxis with an onset of action of less than one hour. I do not believe IM adrenaline was in her best interests at that time, but I would have given her that had she developed the more serious signs listed above.*

(iv) [Dr C] recalls charting the promethazine as a stat dose of 25mg IV and giving the RN verbal instructions to give the medication dilutes as a slow push.

(v) The promethazine was given undiluted over more than one minute. The RN recalls [Mrs A] saying the infusion *was tender but at know* [sic] *time did she ask*

me to stop or make any inclination that it was not bearable or that she was not tolerating the infusion.

(vi) The RN statement includes *... although* [Mrs A's] *recordings were satisfactory including her oxygen saturations she stated she was feeling breathless and one side of her face was swollen leading down to her lips. In my clinical judgement I believed that [Mrs A] was experiencing anaphylaxis to her wasp stings.*

(vii) [Dr C] states he inserted the luer into [Mrs A's] hand because *she had good veins there ... You will appreciate these decisions are made rapidly in an emergency.* [Dr C] states he warned [Mrs A] of potential side effects of drowsiness and stinging related to use of IV promethazine, and [Mrs A] consented to the injection.

(viii) Both [the person in charge of clinical operations] and [Dr C] quote, as support for the use of IV promethazine, the Medsafe information: *intravenous promethazine should only be used if the benefits clearly outweigh the risks in each patient. This may include emergency situations (such as the treatment of anaphylaxis)...*

4. Brief clinical synopsis from information on file

(i) 25 March 2014 0900hrs — [Mrs A] disturbed a wasp nest and wasp stung many times including face and arm. She had apparently had skin reaction to single wasp stings in the past, usually delayed. [Mrs A] attended the local pharmacy where she was administered oral fexofenadine (non-sedating antihistamine) and paracetamol and ice packs were applied to the stings. She states by this stage she had 'calmed down' and had no breathing issues. Her husband collected her and took her to [the Clinic] arriving around 1000hrs.

(ii) At [the Clinic] [Mrs A's] registration form was loaded at 1009hrs. Triage time is recorded as 1000hrs on the registration form (1015hrs in the Clinical notes) — on this form a triage category of 4 is recorded then crossed out with category 3 circled.

(iii) In the nurse triage notes the current history of wasp stings and previous local reaction to stings is recorded. Observations include *swollen right arm and right side of face ... recording satis, O_2 sats 100% in air, pulse 67 regular, appearing a little shocked with some slightly catatonic movements and very jumpy ... Triage code:4.* There was no blood pressure recorded in the narrative notes page but there is a separate observation chart, with blood pressure (1020hrs) recorded as 147/8? (obscured) and respiratory rate 14. I note further observations (pulse, blood pressure, respiratory rate, oxygen saturations) were taken at 1045hrs, 1100hrs, 1120hrs and 1145hrs and all were within the normal range.

(iv) [Mrs A] was evidently placed in a resus bay and attended promptly by [Dr C]. He noted the history and nurse recordings and *no hypotension, asthma or throat swelling. Rx iv line, promethazine 25mg iv, hydrocortisone 200mg, monitor vital signs.* The medications are recorded as being administered at 1030hrs. There is no reference to complaints of pain.

(v) Nurse notes indicate [Mrs A] became drowsy and then unrouseable about 10 minutes after administration of the medications. Close monitoring was continued over one hour with stable vital signs noted (see above). It was initially felt the situation was a common if somewhat marked reaction to promethazine (drowsiness). Around 1140hrs [Dr C] reviewed [Mrs A] noting there had been no significant improvement in her rouseability over the preceding hour. He queried an adverse reaction to promethazine and spoke with the medical registrar at the public hospital including discussion over whether it could be a dystonic reaction requiring administration of benztropine (I note this was the retrospective diagnosis by an immunologist, but benztropine was not administered at any stage in [the Clinic] or the public hospital). Ambulance transfer to the public hospital was arranged so [Mrs A] could be reviewed and monitored further.

(vi) Ambulance arrived at [the Clinic] 1147hrs and transported [Mrs A] to the public hospital ED arriving 1223hrs. Ambulance officers replaced her luer which had been previously dislodged, siting it in the right antecubital fossa. [Mrs A] had stable observations en route although she remained drowsy and was noted to be quite combative. In ED [Mrs A] became hypotensive and was given IV fluid bolus and IM adrenaline at 1245hrs. Differential diagnoses recorded include anaphylactoid reaction to sting or reaction to promethazine. [Mrs A] was observed in ED overnight and discharged on paracetamol and ibuprofen at 1225hrs 26 March 2014.

(vii) There was no specific reference to IV related arm pain in the the public hospital notes. I understand [Mrs A] was subsequently diagnosed and treated for a thrombophlebitis of vessels used for initial luer placement (lower left arm) and her current symptoms are related to this area.

5. Medsafe product data and advice regarding IV promethazine

(i) Product data[1] includes the following information

a. *Indications … Treatment of allergic reactions such as uncomplicated allergic conditions of the immediate type, eg. Pruritus, urticaria and angioedema, when oral therapy is impossible or contraindicated*

b. *Precautions … Intravenous Use: Promethazine is highly caustic to the intima of blood vessels and surrounding tissues. Intravenous administration can cause severe tissue injury … Severe tissue injury may result from perivascular extravasation, unintentional intra-arterial injection, and intraneuronal or perineuronal infiltration … Prescribers should be aware of early sign of tissue injury including burning or pain at the injection site, phlebitis, swelling and blistering. Injections should be stopped immediately if any of these symptoms occur. If venous administration is required, a large vein should be used. Administration via a venous site in the hand or wrist should be avoided if possible due to an increased risk of tissue injury.*

c. *All routes of administration can cause damage to tissues … The preferred route of administration of DBL™ Promethazine Hydrochloride Injection BP is by deep*

[1] See: http://www.medsafe.govt.nz/profs/datasheet/d/dblPromethazinehydrochlorideinj.pdf

intramuscular injection. Intramuscular injection may be painful … Promethazine should only be administered intravenously if the benefits outweigh the risks in an individual patient. This may include emergency situations or situations where IM injections are contraindicated … Extreme care must be taken to avoid extravasation or intra-arterial injection. Injections should be stopped immediately if a patient complains of pain during injection … If venous administration is required, a large vein should be used. Administration via a venous site in the hand or wrist should be avoided if possible due to an increased risk of tissue injury.

d. *When given intravenously DBL™ Promethazine Hydrochloride Injection BP 25mg/1mL should be diluted 1 in 10 with water for injections or preferably given through the tubing of a freely flowing I.V. infusion. It should be injected slowly at a rate of administration not greater than 25mg/minute (ie. 10mL/minute of dilute solution. Rapid intravenous infusion may cause a transient fall in blood pressure and may increase the risk of severe tissue injuries.*

(ii) In 2009 Medsafe reiterated the manufacturer advice regarding use of IV promethazine following reports of serious tissue injury associated with such use. Extracts from the advice[2] include:

a. *In New Zealand promethazine injection is approved for the treatment of vomiting, allergic reactions (including anaphylaxis) and to induce sedation … After reviewing the published literature, assessing the New Zealand case reports and consulting with healthcare professionals, Medsafe has concluded that there remains a clinical need for intravenous promethazine in New Zealand. Medsafe however recommends that intravenous promethazine should only be used if the benefits clearly outweigh the risks in each patient. This may include emergency situations (such as treatment of anaphylaxis) or situations where intramuscular or oral administration is contraindicated.*

b. *To maximise the safe use of this medicine, Medsafe offers the following advice: Deep intramuscular injection is the preferred route of administration of promethazine injection … Promethazine must not be administered subcutaneously or intra-arterially … An alternative medicine should be considered if intravenous administration is required … Promethazine should be administered through large patent veins. Veins in the hand and wrist should be avoided if possible … If intravenous administration is required, the maximum recommended concentration is 25mg/mL and the maximum recommended rate of administration is 25mg/minute. Further dilution and administration over 10–15 minutes may reduce the risks even further … The injection should be stopped immediately if pain or a burning sensation occurs.*

6. To give a local perspective on recommended best practice diagnosis and management of suspected anaphylactic and anaphylactoid reactions I present excerpts from a 2008 BPAC article[3]:

[2] Medsafe. Intravenous promethazine — reports of serious tissue injuries. Prescriber Update. November 2009. 30(4): 24 Available at: http://www.medsafe.govt.nz/profs/PUArticles/Intravenous%20promethazine%20-%20reports%20of%20serious%20tissue%20injuries.htm

(i) *Signs and symptoms of anaphylaxis may vary … Symptoms usually occur within five to 30 minutes after exposure to a trigger, however reactions can occur up to several hours later, or symptoms can build up over time, beginning as a mild allergic reaction. Exposure to an intravenous trigger usually results in a more rapid onset of symptoms, followed by stings, then orally ingested allergens. If untreated, anaphylaxis can cause death within minutes due to cardiovascular collapse (more common in adults) or respiratory tract obstruction (more common in children) … Risk factors for mortality include … Delayed or no administration of adrenaline.*

(ii) *Criteria for suspecting anaphylaxis: Anaphylaxis is likely when all three of the following criteria are met:*

1. *Sudden onset and rapid progression of symptoms*
2. *Life threatening airway, breathing or circulatory problems*
3. *Skin and/or mucosal changes*

Exposure to a known allergen supports the diagnosis. Note that: Skin or mucosal changes alone are not a sign of anaphylactic reaction; Skin or mucosal changes can be subtle or absent in some reactions (approximately 12%); Gastrointestinal symptoms may also be present.

(iii) *Adrenaline is the core treatment of anaphylaxis). Adrenaline (also called epinephrine) should be given immediately to all patients with life threatening features of anaphylaxis. Adrenaline prevents and relieves laryngeal oedema and circulatory collapse, provides bronchodilation and reduces the release of histamine and other mediators. It is important not to give adrenaline inappropriately e.g. for allergic reactions just involving the skin, vasovagal reactions or panic attacks. However many cases of fatal anaphylaxis are caused as a result of the reaction not being recognised and adrenaline not delivered promptly enough or not used at all.*

(iv) *Mild to moderate allergic reaction: Swelling of lips, face or eyes; Hives or welts; Tingling mouth; Abdominal pain, vomiting … If life-threatening respiratory and cardiovascular features of anaphylaxis are not present, but there are other features of a systemic allergic reaction (e.g. skin changes, abdominal pain or vomiting), the patient should be closely observed for deterioration and given symptomatic treatment such as oral antihistamines and if clinically indicated, oral steroids (e.g. prednisone 20 mg).*

(v) *H1-antihistamines (e.g. loratadine or cetirizine) are sometimes used for anaphylaxis to down-regulate the allergic response and minimise [[the Clinic]]al impact of histamine release. H1-antihistamines may relieve itching, hives, other cutaneous symptoms and rhinorrhoea. After oral administration, onset of action is one to two hours. First generation sedating antihistamines (e.g. promethazine) should be avoided. IM preparations are not generally used.*

[3] BPAC. The management of anaphylaxis in primary care. Best Practice Journal. 2008; Issue 18

7. The Australasian Society of Clinical Immunology and Allergy includes the following information in their 2013 guidelines on management of anaphylaxis[4]:

(i) *Antihistamines have no role in treating or preventing respiratory or cardiovascular symptoms of anaphylaxis ... Do not use oral sedating antihistamines as side effects (drowsiness or lethargy) may mimic some signs of anaphylaxis.*

(ii) ***Injectable promethazine should not be used*** *in anaphylaxis as it can worsen hypotension and cause muscle necrosis* [emphasis from source].

(iii) *The benefit of corticosteroids in anaphylaxis is unproven ... It is common practice to prescribe a 2-day course of oral steroids (e.g. oral prednisolone 1 mg/kg, maximum 50 mg daily) to hopefully reduce the risk of symptom recurrence after a severe reaction or a reaction with marked or persistent wheeze*.

8. A literature review service[5] includes some relevant points regarding current anaphylaxis diagnosis and management recommendations (emphases from source):

(i) *Accepted diagnostic criteria: Anaphylaxis is highly likely when any* ***ONE*** *of the following three criteria is fulfilled:*

Criterion 1 *— Acute onset of an illness (minutes to several hours) involving the skin, mucosal tissue, or both (eg, generalized hives, pruritus or flushing, swollen lips-tongue-uvula)* ***and at least one of the following****: Respiratory compromise (eg, dyspnea, wheeze-bronchospasm, stridor, reduced peak expiratory flow, hypoxemia) OR Reduced blood pressure (BP) or associated symptoms and signs of end-organ dysfunction (eg, hypotonia [collapse] syncope, incontinence). Note: Skin symptoms and signs are present in up to 90 percent of anaphylactic episodes. This criterion will therefore frequently be helpful in making the diagnosis.*

Criterion 2 *— Two or more of the following that occur rapidly after exposure* ***to a LIKELY allergen for that patient*** *(minutes to several hours): Involvement of the skin-mucosal tissue (eg, generalized hives, itch-flush, swollen lips-tongue-uvula); Respiratory compromise (eg, dyspnea, wheeze-bronchospasm, stridor, reduced peak expiratory flow, hypoxemia); Reduced BP or associated symptoms and signs (eg, hypotonia [collapse], syncope, incontinence); Persistent gastrointestinal symptoms and signs (eg, crampy abdominal pain, vomiting).*

Note: Skin symptoms or signs are absent or unrecognized in up to 20 percent of anaphylactic episodes. Criterion 2 incorporates gastrointestinal symptoms in addition to skin symptoms, respiratory symptoms, and reduced BP. It is applied to patients with exposure to a substance that is a likely allergen for them.

[4] Available at: http://www.allergy.org.au/health-professionals/papers/acute-management-of-anaphylaxis-guidelines

[5] Simons F et Camargo C. Anaphylaxis: Rapid recognition and treatment. Uptodate. Last updated June 2014. www.uptodate.com

Criterion 3 *— Reduced BP after exposure* ***to a KNOWN allergen for that patient*** *(minutes to several hours): Reduced BP in adults is defined as a systolic BP of less than 90 mmHg or greater than 30 percent decrease from that person's baseline*

Note: Criterion 3 is intended to detect anaphylactic episodes in which only one organ system is involved and is applied to patients who have been exposed to a substance to which they are known to be allergic, for example, hypotension or shock after an insect sting. There will occasionally be patients who do not fulfill any of these criteria, but for whom the administration of epinephrine is appropriate. As an example, it would be appropriate to administer epinephrine to a patient with a history of near-fatal anaphylaxis to peanut who presents with urticaria and flushing that developed within minutes of a known or suspected ingestion of peanut.

(ii) *Epinephrine* (adrenaline) *is lifesaving in anaphylaxis. It should be injected as early as possible in the episode in order to prevent progression of symptoms and signs.* ***There are no absolute contraindications to epinephrine use and it is the treatment of choice for anaphylaxis of any severity****. We recommend epinephrine for patients with apparently mild symptoms and signs (eg, a few hives and mild wheezing) … and for patients with moderate to severe symptoms and signs.*

(iii) *Agents that may be given as adjunctive therapies to epinephrine in the treatment of anaphylaxis include H1 antihistamines, H2 antihistamines, bronchodilators, and glucocorticoids. None of these medications should be used as initial treatment or as sole treatment because they do not relieve upper or lower respiratory tract obstruction, hypotension, or shock and are not lifesaving.*

(iv) ***H1 antihistamines*** *— Epinephrine is first-line treatment for anaphylaxis and there is no known equivalent substitute. A systematic review of the literature has failed to retrieve any randomized controlled trials that meet current standards and support the use of H1 antihistamines in anaphylaxis*[6]*. Despite this, H1 antihistamines are the most commonly administered medications in the treatment of anaphylaxis. This suggests overreliance on these agents, which should be considered adjunctive to epinephrine for the purpose of relieving itching and hives. H1 antihistamines relieve itch and hives. These medications DO NOT relieve upper or lower airway obstruction, hypotension or shock, and in standard doses, do not inhibit mediator release from mast cells and basophils. It is probable that the improvement in noncutaneous symptoms that is sometimes attributed to antihistamine treatment occurs instead because of endogenous production of epinephrine and other compensatory mediators, including other catecholamines, angiotensin II, and endothelins. In addition, the onset of action of antihistamines such as cetirizine or diphenhydramine takes 30 to 40 minutes and is too slow to provide any immediate benefit. H1 antihistamines administered intravenously may increase hypotension.*

[6] Sheikh A, Ten Broek V, Brown SG, Simons FE. H1-antihistamines for the treatment of anaphylaxis: Cochrane systematic review. Allergy 2007; 62:830.

9. A review of management of severe anaphylaxis in 58 European centres was published in 2012[7]. Of the 2114 patients reviewed, 8% received adrenaline intravenously, 4% intramuscularly; 50% antihistamines, and 51% corticosteroids. Both antihistamines and corticosteroids were most commonly administered intravenously. The investigators concluded: *There is a distinct discrepancy between current anaphylaxis management guidelines and their implementation. To improve patient care, a revised approach for medical education and training on the management of severe anaphylaxis is warranted.* I have included this reference, together with the comment in 8(iv) above, to illustrate that while antihistamine use as first line treatment in anaphylaxis is not best practice or even recommended practice, it is certainly common practice in many areas.

10. Comments

(i) [Mrs A] was triaged promptly at [the Clinic]. However I am somewhat critical that if anaphylaxis was suspected by the triage nurse (as noted in the response) and [Mrs A] *appeared a little shocked* she was given a triage category of 4. I have assumed [the Clinic] use the ACEM triage guidelines which state category 4 patients should have assessment and treatment starting by 60 minutes. Nevertheless, [Mrs A's] vital signs were normal, she had no breathing symptoms, the categorisation was apparently later changed to 3, and [Mrs A] was seen promptly in any case. Nursing assessment and monitoring was otherwise very reasonable.

(ii) I am concerned that promethazine was apparently administered by the RN in an undiluted form contrary to the instructions [Dr C] recalls giving, and contrary to manufacturer recommendations and expected practice. I would be concerned if administration of the medication persisted when [Mrs A] reported burning in the area of the injections site, particularly as the medication was being administered undiluted. I note the recollections of [Mrs A] and the RN differ in this regard. **I recommend the in-house nursing advisor be asked to comment briefly on the RN involvement in administration of IV promethazine to [Mrs A].**

(iii) It is unclear to me precisely what diagnosis was made by [Dr C] and, if anaphylaxis was not the working diagnosis, why there was sufficient degree of urgency to warrant consideration of IV promethazine. It does not appear [Mrs A] met the Clinical criteria for anaphylaxis (see section 8(i)) so I do not think it is possible to criticize [Dr C] for failing to administer IM adrenaline as per recommended management of this condition. It is most likely [Mrs A] was experiencing a mild to moderate allergic reaction (see section 6(iv)) for which administration of oral antihistamines (which [Mrs A] had taken 30 minutes prior to her arrival at [the Clinic]) is recommended. I am not convinced there was an indication for administration of IV promethazine, or, if [Dr C] truly felt [Mrs A's] life was potentially at risk (as stated in his response), his priority should have been administration of IM adrenaline rather than IV promethazine (see 8(iv)).

[7] Grabenhenrich L et al. Implementation of Anaphylaxis Management Guidelines: A Register-Based Study. Plos One. 2012. DOI: 10.1371/journal.pone.0035778
Available at: http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0035778

(iv) However, there is a huge difference between me calmly and retrospectively analyzing this case compared with the stress the GP experiences when faced with a patient presenting with facial and neck swelling following insect stings, and in whom anaphylaxis needs to be rapidly considered and treated (if suspected) because of the potentially severe outcome of delaying appropriate treatment. As discussed in sections 8(iv) and 9, there is (internationally) an apparent reluctance for providers to use adrenaline when anaphylaxis is suspected even when this is evidence-based recommended first-line treatment. Furthermore, there is apparent overuse of antihistamines, and particularly IV antihistamines, in the same situation when there is little if any evidence for their use in such a situation and some guidelines advise against their use (referring to IV antihistamines in anaphylaxis treatment) as noted above. That is to say, while [Dr C's] management of [Mrs A] was not consistent with recommended best practice, it was consistent with common practice. To confuse the picture more, the 2009 message from Medsafe apparently accepting IV promethazine may be used in an emergency situation 'such as treatment of anaphylaxis' (see section 6(ii)a) does not appear consistent with the current evidence base and directly contradicts the ASCIA guidelines (section 7). I feel also that the potential local toxicity of IV promethazine is under-recognized in primary care, and that a significant number of my peers may have chosen to manage [Mrs A] as [Dr C] did, including placement of the IV line in a peripheral vein. This is not a particularly satisfactory situation and illustrates the need for practices to have management protocols (eg for suspected anaphylaxis) that are readily available, reflect current evidence-based best practice recommendations, and include any specific precautions relating to medications used as part of the protocol.

(v) I think the best outcome in this case may be for [the Clinic] to review their anaphylaxis protocol in relation to my comments above, acknowledging [Mrs A] did not fit the criteria for this diagnosis but to avoid the risk of future patients being subject to sub-optimal management in relation to use of IV promethazine. It is apparent from his response that [Dr C] has reflected on his use of IV promethazine and undertaken some research in this area, and that he has discussed his findings with his peers. This is an appropriate response to the incident. Nursing staff need to be reminded also on the administration recommendations regarding IV promethazine.

(vi) Management of [Mrs A] in [the Clinic] was otherwise satisfactory. She was monitored appropriately and it was reasonable to attribute her drowsiness initially to an expected side effect of promethazine and then to some less common but marked side effect of the drug. Given [Mrs A's] vital signs remained normal and stable during her observation at [the Clinic] I do not feel there was a particular need to arrange hospital admission during the hour of observation, but certainly that hospital review was warranted when it became obvious her degree and length of sedation was outside that normally expected as a consequence of standard dose IV promethazine administration."

[i] Alsulami, Z., Conroy, S., Choonara, I. (2012) Double checking the administration of medicines: what is the evidence? A systematic review. *Archives of Diseases in Childhood,* 97: 833–837