Registered Nurse, RN A

Medical Centre

A Report by the

Health and Disability Commissioner

Case 17HDC01754

Health and Disability Commissioner

Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. On 3 July 2017, Master B presented to a medical centre for his varicella vaccine (chickenpox vaccine). A registered nurse (RN), RN A, administered the varicella vaccine as well as Master B's 15-month vaccinations. Prior to administering the vaccines, RN A did not check Master B's immunisation record, which showed that he had already received the 15-month vaccinations at a previous visit.

Findings

2. By administering three vaccinations to Master B in error on 3 July 2017, RN A did not provide Master B services with reasonable care and skill and, therefore, breached Right 4(1) of the Code.[1]

3. The medical centre had not taken reasonably practicable steps to prevent RN A's breach of the Code. It did not have a formal policy for the practical administration of vaccines, and it did not monitor RN A's compliance with the vaccinator standards in which she was trained. Accordingly, the medical centre was found vicariously liable for RN A's breach of the Code.

Recommendations

4. It was recommended that RN A provide a written apology to the family. As recommended in the provisional opinion, RN A attended the Immunisation Advisory Centre refresher vaccinator training course.

5. It was recommend that the medical centre:

   a) Provide a written apology to the family for its breach of the Code.

   b) Provide HDC with an audit of vaccination-related documents from 1 June 2018 until 31 August 2018 to ascertain compliance with the vaccination administration policy. If the audit does not indicate 100% compliance, the medical centre is to consider further improvements to ensure compliance with the policy.

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

Complaint and investigation

6. The Commissioner received a complaint from Mrs B about the services provided to her son, Master B, by a registered nurse, RN A, at the medical centre. The following issues were identified for investigation:

- *Whether RN A provided Master B with an appropriate standard of care on 3 July 2017.*
- *Whether the medical centre provided Master B with an appropriate standard of care on 3 July 2017.*

7. The parties directly involved in the investigation were:

RN A	Provider/registered nurse
Master B	Consumer
Mrs B	Complainant/consumer's mother
Medical centre	Provider

8. Also mentioned in this report

Mr B	Consumer's father

Information gathered during investigation

9. On 3 July 2017, Mr B took his son, Master B, aged 26 months at the time, to the medical centre for his varicella vaccination.[2]

10. RN A told HDC that she thought that Master B was coming in for his 15-month immunisations.[3] At the time of the event, RN A was an authorised vaccinator. Although varicella is part of the 15-month vaccine schedule, it was not funded for that age group until 1 July 2017, and so was not always administered at the same time as the other three 15-month vaccines.

11. RN A told HDC that the appointment book said only "vaccine", but she had a discussion with Mr B, who agreed that Master B was there for his 15-month vaccinations including the chickenpox vaccine. However, when Mrs B spoke to the medical centre about her complaint, she said that her husband was not made aware of the vaccines to be given in addition to the chickenpox vaccine, and he did not think they were part of the other 15-month vaccines, as he was aware that Master B had already had these.

[2] Chickenpox vaccine.
[3] The 15-month vaccine schedule is comprised of *Haemophilus influenzae* type b, measles/mumps/rubella, pneumococcal, and varicella vaccines.

12. RN A documented in Master B's clinical notes:

> "[H]ere for 15 [month] [immunisations] with Dad, now 25 [months]. Also requests non funded [varicella]. Well today. No contraindications as per immunisation handbook. Side effects explained. Time for questions allowed. Verbal consent obtained for vaccine ..."

13. RN A stated that when she gathered the 15-month vaccines from the practice's vaccination fridge she checked them against the New Zealand Immunisation Schedule[4] on the outside of the fridge. RN A reported that she also checked the name and expiry dates of the vaccines.

14. A second check of the vaccinations was not undertaken before they were administered. RN A told HDC that "it was rare to have two nurses available at the same time to check the vaccines".

15. RN A stated that she told Mr B that there were four vaccines to give. She explained where each vaccine would be administered, and then she proceeded to administer them. She said that she had the front page of Master B's medical records up on the computer screen, and that when she entered the immunisation details into Master B's immunisation record, she discovered that Master B had already had his 15-month vaccinations (other than varicella).

16. RN A told HDC that when she realised she had administered three additional vaccinations in error she immediately informed Mr B, and reassured him that receiving extra vaccinations would not cause Master B harm. She added that following the vaccinations Master B stayed in the waiting room for 20 minutes for observation, and no adverse reaction occurred.

17. RN A told HDC that she did not think Master B's doctor was present on the day of the event, and that the other doctors were busy, and therefore she advised the doctor of the event the following day.

18. The medical centre advised that two doctors were present on the day of the event, and one of them should have been consulted immediately.

The medical centre's immunisation policy

19. The medical centre told HDC that it ensured that RN A was "fully trained and certified as an independent vaccinator and [it] relied on her expertise as a registered nurse to be able to administer vaccines in a competent and safe manner, consistent with best practice guidelines and nursing standards in place".

20. The medical centre advised HDC that in the first half of 2017, it moved through the process of gaining The Royal New Zealand College of General Practitioners Cornerstone

[4] The National Immunisation Schedule is the series of vaccines that are offered free of charge to babies, children, adolescents, and adults.

Accreditation,[5] which involved a comprehensive review of its clinical and administrative practices and policies. The medical centre said that RN A was involved in the process from the outset in relation to clinical policy formulation pertaining to nursing, and was allowed time off her other duties to draft nursing-related indicators, including vaccination and cold chain processes[6] and policies. It said that when another nurse took over these policy reviews, RN A continued to be consulted throughout the process, and was required to read and comment on all policies and indicator statements. She was also involved in one-on-one discussions with the Cornerstone assessors. The medical centre told HDC that it considers that its policies and procedures in place at the time of the incident were appropriate.

21. At the time of the incident, the practice had in place an immunisation policy[7] entitled "The practice maintains an effective [immunisation] programme", which refers to Cornerstone Policy Indicator 26 and criteria 26.1,[8] 26.2,[9] and 26.3.[10] The policy focused on how the practice would maintain an effective immunisation programme, but did not contain a written procedure for the administration of vaccines.

22. The medical centre told HDC that the "policy incorporates the Ministry of Health standards[11] on immunisations", noting that it was its understanding that the standards[12] required the vaccinator to obtain a pre-vaccination history. It said that the standards were incorporated in criterion 26.2 of the policy, which states: "General practice team members responsible for performing immunisations hold current authorization." Therefore, by way of RN A being currently authorised and therefore trained using the standards, it considers that the policy incorporated the Ministry of Health standards. There is no direct reference or link to the Ministry of Health standards for the practical steps or process for the administration of vaccinations.

23. The medical centre told HDC:

> "While it is not formally recorded in our [p]olicy, it was our recommended practice that the vaccinator administering the immunisation have an independent person check the vaccines to be given to ensure they were the correct vaccines according to the Immunisation Schedule and that the [v]accine had not expired."

[5] A quality improvement and quality assurance process in which GP practices measure themselves against a set of defined standards.
[6] The process that ensures that vaccines are kept at the optimal temperature from manufacturing until administration.
[7] Effective 9 February 2017.
[8] The practice identifies and recalls all patients requiring immunisations on the national schedule.
[9] General practice team members responsible for performing immunisations hold current authorisation.
[10] The practice regularly reviews immunisation recall activities to identify effectiveness in reaching eligible target populations.
[11] Appendix 3 of *The Immunisation Handbook 2017*, published by the Ministry of Health, contains "Immunisation standards for vaccinators and guidelines for organisations offering immunisation services". The Handbook also provides clinical guidelines for health professionals on safe and effective use of vaccines.
[12] Standard 3.7 states: "[B]efore vaccinating, the vaccinator undertakes an appropriate clinical assessment (pre-vaccination screen)."

24. The medical centre also said that at the time of the incident, it did not recommend that an independent person sight the National Immunisation Register[13] to check the immunisation status of the person being immunised.

25. The medical centre told HDC that it accepts responsibility for not ensuring that RN A was adhering to the vaccinator practice standards she had been instructed in to become a vaccinator, and in failing to follow the medical centre's additional practices in having a second person check the vaccines.

26. The medical centre advised that since this incident it has given "clear and unequivocal direction" to its vaccinators that they must have an independent person check the immunisation status of the person being immunised, and that the vaccinations to be given are consistent with the National Immunisation Register.

27. As a result of this incident, the medical centre developed a written policy for the administration of vaccines, which was adopted in September 2017. The policy incorporates a pre-check of what the patient requires before arrival, discussion with and consent from the patient, the process of administration, the selection of the correct vaccine, a second check of the vaccine, and a check of the expiry dates.

Further information — Mrs B

28. Mrs B told HDC that her husband told RN A that he was there for Master B's chickenpox vaccine. When RN A administered additional vaccines he queried what she was giving, which was when she checked the National Immunisation Register and found that Master B had already received the additional vaccines.

29. Mrs B told HDC:

> "[W]e hope this complaint will act as a prompt for other children and families to not receive this type of care in the future. It was probably an honest mistake — but had a major impact on our family …"

Further information — RN A

30. RN A told HDC: "I am so very sorry that the family have had this experience … I wish to express my sincere apologies."

31. RN A said that as a result of this incident she has made improvements to her practice:

> "… I bring up on the screen the child's immunisation page before I call the patient into the room. I now clarify with the parents what they had brought their infant in for by specifically asking what immunisation they are coming in for. I wait for them to tell me which one rather than asking whether they are here for a specific immunisation and relying on their agreement …"

[13] Computerised information system holding immunisation details of New Zealand children.

Further information — medical centre

32. The medical centre stated that it is "very distressed at what has happened and the impact on [Master B] and his family", and apologises unreservedly to Master B and his family. It acknowledged:

> "[I]t was this complaint that b[r]ought to our attention the need to have consistent application of our standards rigorously applied and of the critical importance of the constant monitoring of our standards."

33. The medical centre has trained further staff to be second checkers for the vaccines against the New Zealand Immunisation Schedule and National Immunisation Register to ensure that the patient is receiving the correct vaccination.

34. An updated policy was introduced in May 2018 to reflect the following additional changes:

- Confirmation that the safety checking process has taken place is now documented on the patient record, and the second staff member who provides the safety check is identified on the record by his or her initials.
- The clinical documentation is audited monthly to ensure compliance with the policy.

Responses to provisional opinion

Mrs B

35. Mrs B was given an opportunity to comment on the "information gathered" section of the provisional opinion. Where relevant her comments have been incorporated into the report.

RN A

36. RN A was provided with an opportunity to comment on the provisional opinion, as it related to her.

37. RN A told HDC that she is happy to provide an apology to the family, and advised that she has completed the Immunisation Advisory Centre refresher vaccinator training course.

The medical centre

38. The medical centre was provided with an opportunity to comment on the provisional opinion. It advised HDC that its aim is to provide safe and excellent care, and it will take any opportunity to improve the quality of the service it provides.

Opinion: RN A — breach

39. Mr B took his son, Master B, for his varicella vaccine when he was 24 months old. Varicella is part of the 15-month vaccination schedule but it became funded only on 1 July 2017. Prior to 1 July 2017, due to the cost, the vaccine was not always administered at the same time as the other 15-month vaccinations.

40. There are differing accounts between RN A and Master B's parents regarding the discussion that took place about the vaccines Master B was to receive. However, either way, RN A erroneously administered three vaccinations that Master B had received already, in addition to the varicella vaccination. Prior to administering the vaccines, RN A did not check to see which vaccinations Master B was due to receive. This would have indicated that Master B had already received the 15-month vaccinations (other than varicella) when he was 15 months old.

41. This office has previously found providers in breach of the Code for failing to identify and administer the correct vaccine.[14]

42. By administering three vaccinations to Master B in error on 3 July 2017, RN A did not provide Master B services with reasonable care and skill and, therefore, breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[15]

Disclosure of adverse event within medical centre: adverse comment

43. With regard to event notification, I am concerned that RN A waited until the following day to notify one of the doctors that an adverse event had occurred within the practice. I remind RN A of the importance of full disclosure, not only to the patient but also to relevant colleagues who may be able to offer useful support and assistance to both the patient and the practitioner following an adverse event.

Opinion: The medical centre — breach

44. RN A was an employee of the medical centre. Under section 72(2) of the Health and Disability Commissioner Act 1994 (the Act), an employing authority may be vicariously liable for any act or omission by an employee. 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.

45. The medical centre told HDC that in the first half of 2017 it underwent the process of gaining The Royal New Zealand College of General Practitioners Cornerstone Accreditation, and that RN A was actively involved in the process. I note that this means that the practice has demonstrated compliance with certain quality indicators and criteria.

46. However, as set out above, the medical centre's immunisation policy in place at the time of the event related only to how the medical practice would maintain an effective immunisation programme to minimise the risk of infection. The policy did not include a written procedure for the administration of vaccines.

[14] 15HDC01397, 17HDC00512.

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

47. I note that the medical centre has said that the policy it had at the time incorporated the Ministry of Health standards on immunisations. However, the policy did not clearly set out or specifically refer the reader to Ministry of Health standards. I do not consider that stating that general practice team members responsible for performing immunisations hold current authorisation means that the Ministry of Health standards have been "incorporated" into the policy in relation to those staff who hold current authorisation.

48. My in-house medical advisor, Dr David Maplesden, advised that the Ministry of Health immunisation standards in relation to organisations require that "the organisation has comprehensive immunisation related policies based on best practice, informed consent, the vaccination process and management of adverse events". He also advised that the immunisation policy in place at the time of the incident was not consistent with common practice (based on limited sampling) and did not represent the Ministry requirement. Dr Maplesden was therefore critical that the medical centre did not have a more detailed immunisation policy in place that reflected the Ministry of Health immunisation requirements. I am guided by this advice.

49. The medical centre also told HDC that it ensured that RN A was fully trained and certified as an independent vaccinator, and relied on her expertise as a registered nurse to be able to administer vaccines in a competent and safe manner, consistent with best practice guidelines and nursing standards in place. However, it has said that it accepts responsibility for not ensuring that RN A was adhering to the vaccinator practice standards she had been instructed in to become a vaccinator. The medical centre also said that it now understands the importance of consistent application of standards, and of the critical importance of the constant monitoring of standards.

50. I note that following this event, the medical centre developed a formal written policy for the administration of a vaccine. The medical centre said that it did so because of the patient safety concerns raised by this incident. The policy was updated in May 2018 to include a second check of intended vaccines against the National Immunisation Register to further ensure that the patient is getting the right vaccinations at the right time.

51. I note Dr Maplesden's comment that a policy for the practical administration of vaccines would not necessarily have prevented this incident from occurring. However, in light of the absence of a formal written policy relating to the administration of vaccinations as required by the Ministry of Health standards, as discussed above, and the failure to monitor compliance with the vaccinator practice standards in which RN A was trained, I am not satisfied that the medical centre had taken reasonably practicable steps to prevent RN A's breach of Right 4(1) of the Code. Accordingly, the medical centre is vicariously liable for RN A's breach of the Code.

52. It is positive to note that as a result of this event the medical centre developed a written policy for the administration of vaccines.

Recommendations

53. I recommend that RN A provide a written apology to the family. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding.

54. In accordance with the proposed recommendation in my provisional opinion, RN A attended the Immunisation Advisory Centre refresher vaccinator training course.

55. I recommend that the medical centre:

a) Provide a written apology to the family for its breach of the Code. The apology is to be sent to HDC within four weeks of the date of this report, for forwarding.

b) Provide HDC with an audit of vaccination-related documents from 1 June 2018 until 31 August 2018 to ascertain compliance with the vaccination administration policy. If the audit does not reflect 100% compliance, the medical centre is to consider further improvements to ensure compliance with the policy. The medical centre is to report back to HDC on this within three months of the date of this report.

Follow-up actions

56. A copy of this report with details identifying the parties removed will be sent to the Nursing Council of New Zealand, and it will be advised of RN A's name.

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

Expert in-house clinical advice from Dr David Maplesden

"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 B]; response from [the medical centre] including copies of [the medical centre] Immunisation Policy in place at the time of the incident in question and a revised version following the incident; [the medical centre] incident report; responses from [RN A].

2. The complaint relates to erroneous administration of vaccinations to [Master B] by [RN A] at [the medical centre] on 3 July 2017. The facts established include that prior to administering the vaccines, [RN A] did not check [Master B's] immunisation record that would have confirmed he had already received the vaccinations at a previous visit. There was no adverse outcome as a result of the double administration of the vaccines. The question asked is: *Is it reasonable that [the medical centre] did not have a specific policy/guideline outlining the procedure for the administration of vaccinations?*

3. By 1 July 2017 all New Zealand general practices were expected to comply with the RNZCGP Foundation Standard[1] as a minimum standard. Some practices choose to gain Cornerstone accreditation[2] which involves somewhat more stringent standards in certain areas, although standards relating to immunisation practice do not differ significantly between the two programmes. I understand [the medical centre] was accredited for Cornerstone at the time of the incident in question.

4. The relevant Cornerstone programme indicator with respect to this case Indicator 26.2 which states: *General practice team members responsible for performing immunisations hold current authorization.* This indicator is discussed further in the document as: *Vaccination should be undertaken in compliance with the Ministry of Health's current regulations and standards for authorisation of vaccinators. Your practice should ensure that all your vaccinators meet the quality levels required to ensure they can competently deliver safe and effective immunisation services. Your vaccinators must be competent in all aspects of the immunisation technique, understand Cold Chain requirements, and have the appropriate knowledge and skills for the task. Your general practice team members responsible for performing immunisations must hold current authorisation and evidence of this should be available.*

5. The requirements for vaccinators are listed as a summary of the relevant information contained in the NZ Immunisation Handbook (current version 2017)[3]. Appendix 3 of this publication lists Immunisation standards for vaccinators and guidelines for organisations offering immunisation services. An organizational 'required characteristic' is that *The*

[1] https://www.rnzcgp.org.nz/RNZCGP/I_m_a_Practice/Quality_standards/Foundation_Standard/RNZCGP/Im_a_practice/Foundation_Standard.aspx?hkey=d20c8db4-d2b2-4b50-880f-ee2213049b27 Accessed 17 August 2018

[2] https://www.rnzcgp.org.nz/RNZCGP/Im_a_practice/Aiming_for_Excellence/Aiming_for_Excellence_standard.aspx Accessed 17 August 2018

[3] https://www.health.govt.nz/publication/immunisation-handbook-2017 Accessed 17 August 2018

organisation has comprehensive immunisation-related policies based on best practice, informed consent, the vaccination process and management of adverse events.

6. The [medical centre's] Immunisation Policy document in place at the time of the incident was a reproduction of the Cornerstone Indicator 26.2 (tabulated section only). The section relevant to the incident was: *General practice team members responsible for performing immunisations hold current authorization* with evidence of achievement attached as a log of vaccinators and date of certification (viewed). [RN A] held current certification. The revised [medical centre] Immunisation Policy incorporated a more detailed outline of the expected process of vaccination reproduced from the NZ Immunisation Handbook (section A3.3).

7. [The medical centre has] argued that by having a policy which ensured all vaccinators were currently authorized (meaning they had undertaken appropriate training and been assessed against the Ministry guidelines), the Ministry guidelines were automatically incorporated into the policy. I agree that any authorized vaccinator should be competent in following the Ministry guidelines including awareness that the guidelines are readily accessible electronically should any advice be required.

8. I would expect a practice to have a process in place to monitor when Authorised Vaccinator Certificates are due to expire and require reauthorization. With respect to the immunisation policy, my own practice has had detailed policy/protocol immunisation documents in place since at least 2014 similar to the revised policy provided by [the medical centre]. On contacting several other practices in my network, I suggest provision of such a policy is common practice. I do not feel the [medical centre's] immunisation policy in place at the time of the incident in question is consistent with common practice (based on limited sampling) or represents the Ministry requirement as noted in section 5. However, as noted above I agree that an authorized vaccinator would be expected to be aware of, and to follow, the Ministry requirements. As such, I am mildly to moderately critical that [the medical centre] did not have a more detailed immunisation policy in place in July 2017 in accordance with Ministry requirements. The revised policy is appropriate. However, I do not believe that [the medical centre] having a practice-level comprehensive immunisation policy in place in July 2017 would necessarily have prevented the incident in question given [RN A] had been trained and assessed in the Ministry standards, was up to date with her certification, and should have been aware of and following the standard immunisation process."