Registered Nurse, RN B

Medical Centre

A Report by the

Deputy Health and Disability Commissioner

(Case 15HDC01397)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

Factual background

1. On 2 September 2015, Mrs A took her son, Master A, aged 23 months at the time, to a Medical Centre for a vaccination.

2. Mrs A discussed the vaccination with registered nurse (RN) B and requested that Master A receive the Infanrix®-IPV vaccination instead of the Infanrix®-hexa vaccination listed on the New Zealand National Immunisation Schedule.

3. RN B failed to take the time to listen to Mrs A properly and understand that Master A was to receive the Infanrix®-IPV vaccination rather than the Infanrix®-hexa vaccination.

4. Instead of administering Infanrix®-IPV, RN B administered Infanrix®-hexa to Master A.

5. On 14 September 2015, Mrs A identified the vaccination administration error and reported it to the Medical Centre.

Deputy Commissioner's findings

6. By failing to administer the correct vaccination to Master A, RN B failed to provide Master A with services with reasonable care and skill and breached Right 4(1)[1] of the Code of Health and Disability Services Consumers' Rights (the Code).

7. Overall, the Medical Centre had appropriate processes in place to support safe and accurate immunisation practices. RN B's error in administering the incorrect vaccination to Master A was an individual clinical error. Accordingly, the Medical Centre did not breach the Code.

Recommendations

8. It was recommended that RN B undertake training with regard to effective communication with consumers, in conjunction with the Nursing Council of New Zealand, within three months of the date of this report; and report to HDC regarding the outcome of the above training and the changes she has made to her practice as a result of this case. The report is to be provided to HDC within four months of the date of this report.

9. In the provisional opinion, it was recommended that the Medical Centre train staff on the new procedures in its Immunisation Protocol and report back to HDC on the completion of this training. The report was to be provided to HDC within two months of the date of the final report. The Medical Centre has since advised that it has trained all staff on the new procedures in its Immunisation Protocol.

[1] Right 4(1) 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 to her son, Master A, by RN B at the Medical Centre. The following issues were identified for investigation:

- *Whether RN B provided Master A with an appropriate standard of care in September 2015.*
- *Whether the Medical Centre provided Master A with an appropriate standard of care in September 2015.*

11. An investigation was commenced on 5 February 2016. This report is the opinion of Meenal Duggal, Deputy Commissioner, and is made in accordance with the powers delegated to her by the Commissioner.

12. The parties directly involved in the investigation were:

Mrs A	Complainant
RN B	Provider, registered nurse
Medical Centre	Provider

13. Information was also obtained from:

Ms C	Regional General Manager, Medical Centre
RN D	Registered nurse, Medical Centre

14. Clinical advice was obtained from in-house nursing advisor RN Dawn Carey **(Appendix A)**.

Information gathered during investigation

Background

15. RN B has been a registered nurse for many years. She commenced employment with the Medical Centre in 2010 on a part-time basis as a practice nurse.

16. Prior to her commencement at the Medical Centre RN B had completed a vaccinator update course.

17. The Medical Centre told HDC that RN B had completed a verbal induction, instead of its typical written induction, as she was employed as "a highly experienced nurse".

Immunisations

18. The New Zealand National Immunisation Schedule (the Schedule) outlines the series of vaccinations (including boosters) that are offered free of charge to babies, children, adolescents and adults at specific times.

19. Infanrix®-hexa is a vaccination used to immunise against diphtheria, tetanus, pertussis (whooping cough), poliomyelitis, hepatitis B and *Haemophilus influenzae* type b. Diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B and *Haemophilus influenzae* type b are life-threatening diseases caused by bacterial and viral infections. The Schedule states that Infanrix®-hexa should be administered when a child is six weeks old, three months old and five months old.

20. Infanrix®-IPV is a vaccination used to immunise against diphtheria, tetanus, pertussis and poliomyelitis. Infanrix®-IPV is listed on the Schedule as a booster vaccination given at the age of four years after a child has received all three Infanrix®-hexa vaccinations (detailed above).

21. The New Zealand data sheet for Infanrix®-IPV states that it may also be given as a series of vaccinations. The data sheet states:

> "Infanrix-IPV is given as a total of three doses in the first year of life from the age of 2 months. Each dose is given on a separate visit with at least 1 month break between doses. In order to maintain protection, a booster dose is recommended which would be given at least 6 months after the third dose."

22. The Immunisation Protocol in place at the Medical Centre at the time of the incident, dated 21 October 2012, required RN B to "[d]iscuss vaccines to be used" and to "[c]onsider any concerns of the caregiver". It also required the vaccination to be checked against the Schedule or catch-up schedule[2] by two qualified vaccinators. The Immunisation Protocol did not require information obtained from the patient or caregiver to be communicated to the second qualified vaccinator responsible for checking the vaccination.

Medication administration error

23. On 2 September 2015, Mrs A took her son, Master A, aged 23 months at the time, to the Medical Centre for his third repeated dose of the Infanrix®-IPV vaccination. Master A had been given the Infanrix®-IPV vaccination on the two previous occasions as it included the vaccination components that Mrs A had chosen for Master A to receive. A catch-up schedule was in place for Master A as he was presenting late for his repeat vaccination.

24. Mrs A said that she told RN B that she had chosen for Master A to receive the Infanrix®-IPV vaccination instead of the Infanrix®-hexa vaccination.

25. RN B acknowledged that Mrs A told her that Master A was not to receive the hepatitis B or *Haemophilus influenzae* type b vaccinations. However, RN B said that, owing to the busyness of the practice that day and the pressure she was under at the time, she failed to take the time to listen properly to Mrs A and understand that Master A was to receive the Infanrix®-IPV vaccination rather than the Infanrix®-hexa vaccination that was listed as given at five months of age on the Schedule.

[2] This refers to a schedule created when an individual presents later than the Schedule for a vaccination.

26. After discussing which vaccination was to be administered with Mrs A, RN B left to obtain the vaccination and have it checked by another vaccinator. RN B stated:

> "[Mrs A] told me that she had decided not to have the HIB and Hep B. She didn't give any reason why. I left the room to get the vaccine and was thinking why would another professional not follow the Immunisation Protocol? I was also thinking how to separate the Hib[3] and Hep B[4] out as it is all in one injection."

27. RN B selected the Infanrix®-hexa vaccination instead of the Infanrix®-IPV vaccination. RN D[5] checked the vaccination against the Schedule. RN B did not discuss Mrs A's request for Master A to receive Infanrix®-IPV instead of Infanrix®-hexa with RN D. RN B told HDC:

> "[RN D] checked the 5 month immunisation with me. I asked [her] to check a 5 month immunisation and didn't discuss the vaccine with her."

28. RN B returned to Mrs A and Master A and administered Infanrix®-hexa to Master A.

29. RN B documented in the clinical notes:

> "Informed verbal consent for part of 5 mth imms obtained from parent/guardian before injection given following full explanation … Possible side effects discussed. Observed for 20 minutes post vaccination. No side effects apparent. Information given. Checked by [RN D] mother present. Only [Infanrix®-hexa] given declined other imms."

30. RN B told HDC:

> "When I put the [vaccination] stickers in the [Well Child Health] book[6] I did not notice that [Master A] had previously been given the 4 yr imms to exclude the Hib and Hep B. I did not look at the other stickers. I did not comment to the mother as I had not given the wrong 5 months imms."

31. Mrs A told HDC that she identified the error a few days later when she was looking through Master A's Well Child Health Book. Mrs A stated:

> "I noticed that the vaccination label/sticker for this most recent injection was different to the first two. The first two labels are for 'Infanrix IPV' and the last one is for 'Infanrix Hexa'. I have discovered that the last one is the vaccine that includes HepB and Hib, specifically what I did not consent for."

32. On 14 September 2015, Mrs A emailed the Medical Centre and informed it that it had made an error by administering a vaccination that included hepatitis B and *Haemophilus influenzae* type b. The Nurse Manager then telephoned Mrs A to

[3] *Haemophilus influenzae* type b disease.
[4] Hepatitis B viral infection.
[5] RN D was also working that day at the Medical Centre.
[6] The Well Child Health Book is produced by the Ministry of Health and is a parent information, health and immunisation record for children.

apologise for the error and to provide her with information on the Infanrix®-hexa vaccination Master A had received.

Actions taken by the Medical Centre

33. On 22 September 2015, the Regional General Manager of the Medical Centre, Ms C, wrote a formal letter of apology to Mrs A and informed her of the subsequent change in procedure implemented at the Medical Centre to minimise the risk of such an error occurring in the future.

34. The Medical Centre's new checking procedure in the Immunisation Protocol requires:

> "2. Right Drug — correct immunisation as per schedule.
>
> — Check back with patient or parent/caregiver that you have a correct understanding of the requested immunisation.
>
> …
>
> — If request from caregiver is out of the normal schedule then document on the encounter slip, confirm the request with the patient, parent/caregiver again and present request to Immunisation champion[7] for confirmation of request with the patient or parent/caregiver and double checking the vaccine with you.
>
> …
>
> 6. Right to refuse — Caregivers/patients have the right to refuse immunisation so adequate education must be given. Document requests."

35. The Medical Centre told HDC that they:

> "… [have] had an immunisation champion for many years, however post this incident changes have been made in the immunisation procedure whereby the immunisation champion or nurse manager must be directly involved with the checking and authorisation with both the nurse and parent/caregiver if there is a variation to the Vaccine Advisory Council of NZ schedule."

36. The Nurse Manager told HDC that the changes made to the Immunisation Protocol were presented in a nurses' meeting. During this meeting, all nurses were asked to read and sign the updated Immunisation Protocol.

37. The Medical Centre provided HDC with a print-out of the appointment books for 2 September 2015. The print-out shows that Master A was allocated a 30-minute appointment for his immunisation, in accordance with the Medical Centre's usual practice for childhood immunisations. However, it is not possible to determine from the print-out how busy the Medical Centre was at the time.

[7] An immunisation champion is a nurse with knowledge and expertise in vaccinations who is available to answer questions from Medical Centre staff and healthcare consumers in relation to vaccinations.

38. The Medical Centre provided evidence that RN B had completed a Vaccinator Update Course in 2010.

Action taken by RN B

39. RN B wrote a letter of apology to Mrs A for her medication administration error. RN B told Mrs A that she could not understand how the error happened, as it was not consistent with her normal practice. RN B stated: "I have learned from this experience and I am now more vigilant in checking with colleagues and patients and/or parents before administering medications." Mrs A confirmed that she received RN B's apology letter.

40. RN B's lawyer told HDC that RN B "double checks on the computer, at the start of her shift, all immunisations that she had to give that day, to see what has been given previously". RN B stated that she could not understand why she did not do this on the day she administered the vaccination to Master A.

41. RN B's lawyer advised that RN B has registered to attend an immunisation update course, and intends to attend a course on rights and responsibilities this year.

Action taken by RN D

42. RN D wrote an apology to Mrs A, in which she stated: "It was unfortunate that I did not have all the information at the time of checking the vaccine for administration."

Response to provisional opinion

43. RN B was provided with an opportunity to respond to the provisional opinion and made no further comment.

44. The Medical Centre was provided with an opportunity to respond to the provisional opinion and made no further comment.

45. Mrs A was provided with a copy of the "information gathered" section of the provisional opinion and added no further information.

Opinion: RN B — Breach

46. On 2 September 2015, Mrs A took her son Master A to the Medical Centre for his third repeated dose of the Infanrix®-IPV vaccination. Master A had been given the Infanrix®-IPV vaccination on two previous occasions, and this was recorded in his Well Child Health Book.

47. Mrs A said that she discussed the vaccination with RN B and requested that Master A receive the Infanrix®-IPV vaccination instead of the Infanrix®-hexa vaccination listed on the New Zealand National Immunisation Schedule (the Schedule).

48. RN B acknowledged that Mrs A told her that Master A was not to receive the hepatitis B or *Haemophilus influenzae* type b vaccinations. RN B said that, owing to the busyness of the practice that day and the pressure she was under, she failed to take the time to listen to Mrs A properly and to understand that Master A was to receive the Infanrix®-IPV vaccination, which excluded the hepatitis B and *Haemophilus influenzae* type b vaccinations, rather than the Infanrix®-hexa vaccination listed on the Schedule as the vaccination to be given at five months of age.

49. RN B selected the Infanrix®-hexa vaccination and asked RN D to check it against the Schedule without discussing any of the particulars with her. RN B then administered Master A with Infanrix®-hexa instead of Infanrix®-IPV.

50. RN B acknowledged that she failed to notice that Master A had been given the Infanrix®-IPV vaccination previously, at the request of Mrs A.

51. As a registered nurse, RN B is responsible for ensuring her adherence to professional standards. The Nursing Council of New Zealand's "Competencies for registered nurses" (December 2007) state:

> "Competency 1.1
>
> Accepts responsibility for ensuring that his/her nursing practice and conduct meet the standards of the professional, ethical and relevant legislated requirements.
>
> Indicator: Practises nursing in accord with relevant legislation/codes/policies and upholds health consumers rights derived from that legislation.
>
> …
>
> Indicator: Demonstrates knowledge of, and accesses, policies and procedural guidelines that have implications for practice.
>
> …
>
> Competency 2.1
>
> Provides planned nursing care to achieve identified outcomes.
>
> …
>
> Indicator: Administers interventions, treatments and medications, (for example: intravenous therapy, calming and restraint), within legislation, codes and scope of practice; and according to authorised prescription, established policy and guidelines."

52. The Nursing Council of New Zealand's "Code of Conduct" (June 2012) states:

> "Principle 4.

> Maintain health consumer trust by providing safe and competent care
>
> …
>
> 4.9 Administer medicines and health care interventions in accordance with legislation, your scope of practice and established standards or guidelines."

53. My in-house nursing advisor, RN Dawn Carey, advised:

> "In my opinion, [RN B] failed to administer the 'correct' vaccine to [Master A] as in consent was not granted for him to receive the combined vaccine as per the immunisation schedule. In my opinion, [RN B's] practice on 2 September 2015 was a moderate departure from accepted standards of nursing care."

54. I accept RN Carey's advice and find that, by failing to identify and administer the correct vaccination to Master A appropriately, RN B failed to provide Master A with services with reasonable care and skill and, as such, breached Right 4(1) of the Code.

55. I note that RN B has apologised to Mrs A for her error, and that she intends to attend an immunisation update course and a course on rights and responsibilities this year. I consider these to be appropriate steps in response to her error.

Opinion: Medical centre — No breach

56. RN B is 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. In addition to vicarious liability, the Medical Centre may also be held directly liable for the services it provides.

57. Protocols provide a set procedure that assists staff to comply with their legal and professional obligations. The Medical Centre's Immunisation Protocol in place at the time of this incident clearly required a discussion of the vaccinations to be used, and stated that any concerns of the caregiver must be considered.

58. When Mrs A presented with her son, Master A, for his third repeated dose of the Infanrix®-IPV vaccination on 2 September 2015, RN B discussed the vaccination with Mrs A, as required by the Immunisation Protocol. Mrs A said that she told RN B of her decision for Master A to receive the Infanrix®-IPV vaccination instead of the Infanrix®-hexa vaccination.

59. RN B acknowledged that Mrs A told her that Master A was not to receive the hepatitis B or *Haemophilus influenzae* type b vaccinations. RN B said that owing to the busyness of the practice and the pressure she was under at the time she failed to take

the time to listen to Mrs A properly and understand that Master A was to receive the Infanrix®-IPV vaccination instead of the Infanrix®-hexa vaccination. As a result, RN B selected the incorrect vaccination and administered it to Master A.

60. The Medical Centre provided the appointment books for 2 September 2015. I am unable to make a factual finding in relation to how busy the Medical Centre was that day, but I note that Master A's appointment was scheduled for 30 minutes, in accordance with the Medical Centre's usual practice for childhood immunisations.

61. The Medical Centre also told HDC that RN B had completed a verbal induction instead of its typical written induction, as she was employed as "a highly experienced nurse". The Medical Centre provided evidence that RN B had completed a Vaccinator Update Course in 2010.

62. RN Carey advised:

> "It needs to be acknowledged that administration of medications is a basic nursing competency which includes obtaining consent, patients' rights, and the necessary medication checks that underpin safe practice … In my opinion the submitted [Medical Centre] documentation [Immunisation Protocol] is consistent with the organisational guidelines specified in the Ministry of Health Immunisation Handbook."

63. Guided by RN Carey, I am satisfied that the Medical Centre had in place an appropriate Immunisation Protocol to support safe and correct immunisation practices.

64. In my view, the error in administering the wrong vaccination to Master A was an individual error by RN B, rather than a result of the Medical Centre's processes. Accordingly, I find that the Medical Centre did not breach the Code.

Recommendations

65. I recommend that RN B:

a) Undertake training with regard to effective communication with consumers, in conjunction with the Nursing Council of New Zealand, within three months of the date of this report.

b) Report to HDC regarding the outcome of the above training and the changes she has made to her practice as a result of this case. The report is to be provided to HDC within four months of the date of this report.

66. In my provisional opinion, I recommended that the Medical Centre train staff on the new procedures in its Immunisation Protocol and report back to HDC on the completion of this training. The report was to be provided to HDC within two months

of the date of the final report. The Medical Centre has since advised that it has trained all staff on the new procedures in its Immunisation Protocol.

Follow-up actions

67. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the District Health Board and the Nursing Council of New Zealand, and they will be advised of RN B's name.

68. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the New Zealand Nursing Organisation, and the Health Quality and Safety Commission, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: In-house nursing advice to the Commissioner

The following expert advice was obtained from in-house nursing advisor RN Dawn Carey:

"1. Thank you for the request that I provide clinical advice in relation to the complaint from [Mrs A] about the immunisation administered to her son [Master A], at [the Medical Centre]. On 2 September 2015 [Master A] was administered Infanrix hexa, which is a combined Diphtheria /Tetanus/Pertussis/Polio/Hepatitis B/Haemophilus influenza type b vaccine. His mother had requested and consented for him to receive Infanrix, which is the combined Diphtheria/Tetanus/Pertussis/Polio vaccine. In preparing the advice on this case to the best of my knowledge I have no personal or professional conflict of interest. I have read and agree to follow the Commissioner's Guidelines for Independent Advisors.

2. I have reviewed the following information available on file: complaint from [Mrs A]; response from [the Medical Centre] including statement from [RN B], copy of response and apology letters sent to [Mrs A], copy of current immunisation policy which includes practice changes, [Master A's] clinical notes.

3. Provider responses

   [The Medical Centre was] notified of this complaint directly by [Mrs A]. The response reports their acknowledgement of the error and expresses regret. Following notification of the error, [the Medical Centre reports] completing an incident form, interviewing the staff involved, communicating with [Mrs A] and implementing changes to their immunisation policy and procedure. In my opinion, these actions are appropriate.

   The response from [RN B] reports that on the day in question, the clinic was busier than usual. She reports that [Master A] was booked to have his five month 'off schedule' immunisation and that [Mrs A] told her *... that she had decided not to have the Hib and Hep B ...* [RN B] reports asking [RN D] to check a 5 month immunisation vaccine but not discussing the vaccine with her. [RN B] also reports learning from this experience and that there was never any intention to override [Mrs A's] instructions. She reports being more vigilant in checking medications with colleagues and patients/parents prior to administering medications.

4. I note that the contemporaneous clinical notes are consistent with the provider's responses.

   I have interpreted this complaint as relating to a medication error. Within the relevant literature medication errors are unfortunately commonplace. Distractions, task overload and lack of concentrated focus are recognised 'human factors' that are contributory issues that lead to errors. Despite the common nature of medication errors, they cannot ever be deemed an acceptable part of nursing practice. As a core competency that all registered

nurses are deemed to have achieved, medication errors are always a departure from accepted standards of safe medication practice.

In my opinion, the error is acknowledged by the providers in this case and their apologies to [Mrs A] appear sincere. I consider that all subsequent actions following the realisation of the error are consistent with the expectations of openness and transparency. I note that the implemented procedure changes for 'variation from schedule' vaccinations minimise the reoccurrence of such an error at [the Medical Centre]. I consider the amendments appropriate and note that they appear consistent with [Mrs A's] reasonable expectations that [the Medical Centre has] improved documentation regarding vaccine administration; that practitioners consistently practise in accordance with the '5Rs' of medication safety and are respectful of the right to refuse consent for a medication. I have no further recommendations to make.

5. I have been asked to specify the degree of departure from accepted standards in this case.

   In my opinion, [RN B] failed to administer the 'correct' vaccine to [Master A] as in consent was not granted for him to receive the combined vaccine as per the immunisation schedule. In my opinion, [RN B's] practice on 2 September 2015 was a moderate departure from accepted standards of nursing care.

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

Further information requested from RN Carey

"1. Thank you for the request that I provide additional clinical advice in relation to the complaint from [Mrs A] about the immunisation administered to her son [Master A], at [the Medical Centre] on 2 September 2015. In preparing the advice on this case to the best of my knowledge I have no personal or professional conflict of interest. I have read and agree to follow the Commissioner's Guidelines for Independent Advisors. I have been asked to review the [Medical Centre's] Immunisation Protocol dated 21 October 2012, which was the protocol in place when [Master A] was immunised.

2. Clinical advice
   The reviewed [Medical Centre] Immunisation Protocol details how to send recalls, actions prior to administering an immunisation vaccine, post immunisation care and actions for managing overdue/non responders to recall letters. I note that the protocol specifies the need to *discuss vaccines to be used; side effects and post vaccination care … consider any concerns of caregiver. Provide caregivers with education about each of the vaccines … check correct immunisation against schedule or catch up, immunisation to be checked by two qualified vaccinators …*

It needs to be acknowledged that administration of medications is a basic nursing competency which includes obtaining consent, patients' rights, and the necessary medication checks that underpin safe practice. In my opinion, [the Medical Centre's] 2012 Protocol fits within the standard of comparable organisations and was not a significant contributory factor in this case.

3. Other comments
   In 2014, the Ministry of Health (MOH) updated the Immunisation Handbook — previous version 2011. This handbook is a set of clinical guidelines detailing the processes for safe immunisation practice including standards for vaccinators and guidelines for organisations offering vaccination services. This includes the process for informed consent. In my experience all vaccinators are familiar and cognisant with the standards especially due to the requirement to complete MOH approved educational updates every two years.

   I note that the MOH Handbook specifies that organisations support vaccinators by having … *comprehensive immunisation-related policies based on … management of adverse events* … As part of my previous advice, I reviewed the protocol changes [the Medical Centre] made in response to this complaint. I note that adverse events are not addressed in this protocol. While I acknowledge that this was not a feature within this case and that it may be addressed in a separate protocol, I would recommend that the provider take the opportunity to have a wider review and ensure that they meet all the organisational guidelines as specified in the Handbook.

4. Further information received
   Documentation provided by [the Medical Centre]:

   - adverse reactions to immunisations protocol — dated 15 August 2014,
   - protocol for treatment of anaphylaxis — dated 15 June 2015, and
   - form for reporting adverse reactions to medicines, vaccines and devices and all clinical events.

In my opinion the submitted [the Medical Centre] documentation is consistent with the organisational guidelines specified in the Ministry of Health Immunisation Handbook.

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

Additional comment received from RN Carey

RN Carey advised that, from the appointment books provided, it is not possible to determine how busy [RN B] was during her shift.