Registered Nurse, RN A
Medical Centre

A Report by the Deputy
Health and Disability Commissioner

(Case 19HDC01647)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns the care provided when a nurse administered a baby his six-week vaccinations. In particular, it concerns the nurse administering the incorrect vaccination to the baby, failing to report her error, and then attempting to cover it up by amending the documentation.

Findings

2. The Deputy Commissioner found that by failing to identify and administer the correct vaccine to the baby, the nurse did not provide services with reasonable care and skill, and, accordingly, breached Right 4(1) of the Code.

3. In addition, the Deputy Commissioner found that by failing to report her vaccine administration error, and by attempting to cover up her mistake, the nurse failed to comply with her ethical and professional obligations, in breach of Right 4(2) of the Code. The Deputy Commissioner also found that the nurse breached Right 6(1) of the Code for failing to disclose her error to the family openly.

4. The Deputy Commissioner was satisfied that the medical centre had taken reasonably practicable steps to prevent the nurse's acts and omissions, and that the medical centre is not vicariously liable for the nurse's breaches of the Code.

Recommendations

5. The Deputy Commissioner recommended that the nurse undertake training on documentation and safe administration of medications, and provide the baby's family with a written apology for her breaches of the Code.

6. The Deputy Commissioner also recommended that the Nursing Council of New Zealand note HDC's findings and consider whether a review of the nurse's competence and/or any further action is warranted. In addition, the nurse was referred to the Director of Proceedings.

Complaint and investigation

7. The Health and Disability Commissioner (HDC) received a complaint from Ms B about the services provided to her son, Baby B, by Registered Nurse (RN) A. The matter was also referred to HDC by the Nursing Council of New Zealand. The following issues were identified for investigation:

- *Whether RN A provided Baby B with an appropriate standard of care in July and August 2019.*
- *Whether the medical centre provided Baby B with an appropriate standard of care in July and August 2019.*

8. This report is the opinion of Deputy Health and Disability Commissioner Rose Wall, and is made in accordance with the power delegated to her by the Commissioner.

9. The parties directly involved in the investigation were:

Ms B	Complainant/mother of consumer
RN A	Provider/registered nurse
Medical centre	Provider/primary healthcare provider

10. Also mentioned in this report:

RN C	Registered nurse
Ms D	Support worker
Ms E	Community Services Manager
Ms F	Support Worker Team Leader

11. Independent expert advice was obtained from RN Fiona Blair (Appendix A).

12. Relevant standards are attached as Appendix B.

Information gathered during investigation

Background

13. This report concerns the care provided to Baby B by RN A, when RN A administered Baby B with his six-week vaccinations. In particular, it concerns an alleged vaccination error.

14. RN A qualified as a registered nurse in 2006 and gained her qualification as an independent registered vaccinator in 2016. As an independent registered vaccinator, RN A was authorised in accordance with the Medicines Regulations Act 1984 to administer vaccines for the purposes of immunisation programmes.

15. At the time of these events, RN A had worked part time as an immunisation nurse for the community service of a medical centre[1] since 2018. Her job involved providing vaccinations for children aged up to five years in the community — predominantly Māori and Pasifika populations — in line with the national childhood immunisation schedule.

16. The key accountabilities for an immunisation nurse, as set out in the job description, included "administer[ing] vaccinations according to the National Immunisation Schedule and the Immunisations Standards 2006 once consent is obtained from the parent", and "ensur[ing] accurate records are kept of the immunisation event according to the Immunisation Standards 2006".

[1] A Non Government Organisation that provides free community and primary health, social, and whānau ora services.

Vaccine details

17. At the time of these events, Baby B (aged eight weeks) was overdue for his six-week vaccinations, which included the pneumococcal conjugate vaccine[2] (PCV), the hexavalent[3] (Hexa) vaccine, and the rotavirus (Rota) vaccine.[4]

18. The vaccine for rotavirus used at the medical centre, called "Rotarix", is stored in a small container with a black lid, and is intended to be given orally. At the time of these events, the medical centre had two brands of PCV: PCV10 (also called "Synflorix"), and "Prevenar 13". Both PCV vaccines are intended to be given into the muscle, and have needle adapters. The PCV10 vaccine syringe is green, whilst the Prevenar 13 vaccine syringe is dark blue, with a dark blue lid.

19. On 29 July 2019, the team leader of the community service, RN C, had sent an email to the nurses at the medical centre advising them to use the remaining doses of Prevenar 13 instead of PCV10, as they were due to expire in August 2019.

30 July 2019 — vaccination administration

20. RN A was accompanied for the day by support worker Ms D, and, after preparing the portable cooler box with that day's vaccinations, they left the office to commence their day at approximately 8.30am.

21. RN A stated that her normal checking routine included counting the vaccines required, and checking the expiry date and batch number, before placing the vaccines in the appropriate cooler box.

22. RN A told HDC that when she and Ms D reached the residence in the afternoon, she removed the appropriate vaccines — 1x Hexa, 1x PVC10, and 1x Rota — from her cooler box and placed them into her transporting container to take inside. RN A stated that just before shutting the lid of her cooler box, she remembered that they were supposed to use up the Prevenar 13 as it was due to expire, and so she also placed this into her transporting container.

23. Present at the residence on this afternoon were Baby B's mother, Ms B, and Ms B's older daughter, who was 19 years old.

24. RN A told HDC that she undertook the 7 Rights of Medication Administration[5] prior to administering the vaccines to Baby B. However, she stated that she did these checks collectively at the beginning, and did not do the check individually for each vaccine. She said that for the "right medication" check, the vaccines were all checked for name, batch number, and expiry date, at the time of opening her transporting container. As noted above,

[2] A vaccine given to protect against pneumococcal disease (a bacterial infection).
[3] A vaccine containing a combination of six vaccines conjugated into one, including diphtheria and tetanus.
[4] A vaccine given to protect against rotavirus, a highly contagious virus that causes diarrhoea and vomiting.
[5] Right patient, right medication, right dose, right route, right time, right documentation, and right reason.

RN A had four vaccines in her storage container — 1x Hexa, 1x PVC10, 1x Rota, and 1x Prevenar 13.

25. RN A told HDC that the PCV and Hexa vaccinations were given first, and both were injected into the arm without issue. She stated:

> "Initially I was going to give the Prevenar 13 in replacement of the PVC[10] [as per [RN C's] advice the previous day], but I had already uncapped the PVC[10] vaccine, so I administered it instead."

26. The oral Rota vaccination was administered last; however, there are differing versions of events as to whether RN A gave Baby B the Rotarix vaccination, or whether she administered the Prevenar 13 vaccination orally, in error.

27. RN A told HDC that she believes she gave Rotarix to Baby B because of the fluid consistency. She stated that Rotarix has a thick consistency whilst Prevenar 13 is watery, and also, Rotarix does not have a needle adaptor, whereas Prevenar 13 has quite an obvious and large needle adaptor.

28. Ms D recalled the events of Baby B's vaccinations as follows:

> "[RN A] prepared the vaccines and gave the PCV and Hexa before preparing the rotavirus vaccine. [RN A] held the baby and asked the daughter to unscrew the lid on the vaccine, I noticed what the vaccine looked like and distinctively remember the dark blue colour [the colour of the Prevenar 13 vaccine] and that it didn't look familiar even though I have seen the rotavirus vaccine given a couple of times during my days on the road."

29. In a subsequent meeting with the family, the Clinical Director asked Ms B and her teenage daughter if they could remember the lid colour of the vaccine that was given orally to Baby B. The daughter advised that it was blue, and stated that she remembered as she had taken off the lid of the vaccine for RN A. RN A told HDC that she cannot recall this. Ms B and her daughter were then given a lineup of vaccine photographs, and both were able to identify Prevenar 13 as the vaccine that was given orally.

30. RN A discarded the containers of all four vaccines that were taken into the residence after administering them. She said that she discarded the Prevenar 13 vaccine because she "had probably uncapped both PCV vaccines".

Documentation

Well Child book[6]

31. In the row for rotavirus on the "immunisation record" page of Baby B's Well Child Health Book, RN A documented "Prevenar 13", along with the Prevenar 13 batch number and the

[6] A Well Child book is a health book given to parents to provide them with important health information and space to record their child's development in the first five years. The book contains a page entitled "immunisation record", which lists all of the vaccines needed for the child at each stage of life (eg, birth, six

expiry date, August 2019. However, these details have been crossed out and, next to them, it is documented "error Rotarix", in the same colour of pen. No batch number or expiry date for the rotavirus vaccine has been documented. The batch number and expiry dates for both the Hexa and the PCV10 vaccines have been completed in their respective rows.

32. RN A told HDC that she completed the documentation in the Well Child book prior to vaccinating Baby B. She stated that initially she was going to give the Prevenar 13 in place of the PVC10, and so documented the same, but, as she had already uncapped the PVC10, she used this instead.

33. RN A did not explain why she documented the information for Prevenar 13 in the row for the rotavirus vaccination. She stated that when she realised that she had written Prevenar 13 in the row for the rotavirus vaccination, she crossed it out and documented "error Rotarix".

Field Team Vaccination sheet

34. A copy of RN A's "Field Team Vaccination" sheet[7] for 30 July 2019 was provided to HDC.

35. Under Baby B's name, RN A had documented "Hexa", "PCV", and "Rota" in the "vaccine" column. In the batch number and expiry columns, she documented the Hexa and PCV10 vaccine batch numbers and expiry dates in their respective rows. However, in the "batch number" row for the rotavirus vaccine, there is a sticker for the Prevenar 13 vaccine, which noted its batch number and expiry date of August 2019. In addition, under the "batch expiry" column for the rotavirus vaccine, RN A had written the Prevenar 13 vaccination expiry date of August 2019 (the expiry date for the rotavirus vaccine was November 2020).

36. RN A stated that she completed the vaccination form before administering the vaccinations. Again, she said that initially she was going to use the Prevenar 13 vaccination instead of the PCV10, and so placed the Prevenar 13 sticker on the form. RN A did not explain why she placed the sticker in the row for the rotavirus vaccine. She told the medical centre during a subsequent interview that she "didn't think to correct it [the sticker error]", and that she placed the sticker for the rotavirus vaccine in her sharps box.

MedTech

37. RN A documented Baby B's vaccination details in Medtech, the patient management system, on return to the office after her day of vaccinating. In Baby B's profile, she documented:

> "Introduced self + organisation. Child seen at home. MOC [mother of child] states child is well and there are no contraindications to immunisations. Verbal informed consent obtained. Imms [immunisations] given, waited 20 min[utes]. After care explained and post care leaflet given. NO reaction observed."

weeks, three months, etc). The immunisation record also provides room for the vaccine administrator to document the batch number, site, date given, and signature for each vaccination given.

[7] This sheet records the vaccination details for each child vaccinated by a specific vaccinator on a certain day.

38. RN A then documented that both the PCV10 and Hexa immunisations were given. However, for the rotavirus vaccine, she documented that Prevenar 13 had been given as an alternative to Rota, as follows:

> "Rotavirus mono Dose1 — AG [alternative given] — Prev[enar] 13 — S2753 [the batch number for Prevenar 13, minus the last number]."

39. RN A explained that this was a documentation error caused by multiple factors, such as the lack of attention in inputting the data, and various events having occurred during the day, such as a car accident and handling stressful clients. She stated that she also input this data in the early evening under stress.

40. The healthcare service told HDC that "it is not credible that [RN A] did not realise her error". The healthcare service explained that when entering into Medtech that an alternative vaccine has been given, as RN A did, Medtech will prompt the user with valid alternatives. The healthcare service said that as there is no valid alternative for a rotavirus vaccine, there would have been no alternative to pick, and noted that RN A then entered the Prevenar 13 vaccination as a comment. The healthcare service stated: "These should have been red flags to an authorised vaccinator, as this is not standard practice."

41. RN A subsequently added an amendment to the Medtech entry for Baby B's six-week vaccination, approximately a week later on 6 August 2019. She documented:

> "Error in recording of paperwork by [RN A] of Rota vs Prev.13 on 30/7. Entry incorrect for Rota. Initially was going to give Prev.13 as pneumococcal but decided against it and gave PCV[10] instead. Instead of replacing the sticker I left the Prev13 in-situ ..."

Actions following vaccine administration

42. At approximately 10am the following day, Ms D emailed the Community Services Manager, Ms E, alerting her to the potential vaccination error. Ms D wrote:

> "I was doing my feedback from 30/07/2019 on the road with [RN A] … 6w[eek] imm[unisations] for [Baby B] were given at around 3pm, the Hexa and PCV messaged through to the NIR [National Immunisation Record] fine. I noticed the Rotavirus Vaccine hadn't messaged through and looked at the [Field Team Vaccination sheet] for details — I noticed the sticker with batch number and expiry in the Rotavirus space was a PCV sticker.
>
> Whilst we were giving the imm[unisations] at home yesterday, I remember having a good look at the vaccine before it was given and thinking 'okay so that's what a rotavirus oral vaccine looks like'.
>
> This morning when I found the PCV sticker in the rotavirus place, I looked in the vaccine fridge to see what a Rotavirus vaccine looks like, it looks very different to what I remember the vaccine looked like yesterday. I distinctively remember the dark blue on the PCV vaccine while it was held by the nurse before administration.

> It appears to me that the PCV was given orally instead of the rotavirus vaccine, but I am not 100% sure of this as I did not administer the vaccine myself."

43. RN A told HDC that she was alerted to this potential vaccination error by Ms F, the Support Worker Team Leader at the medical centre. RN A stated that it was sometime in the morning, but she is not sure what time. The medical centre told HDC that RN A did not report to Ms F.

44. RN A stated that she informed Ms F that she would contact the Immunisation Advisory Centre (IMAC) to seek advice, just in case she had made an error, and then stated that she would visit Baby B. During this telephone call, RN A told Ms F that she was not sure whether she had given the wrong vaccination.

IMAC call

45. RN A told HDC that she contacted IMAC following the call from Ms F, solely for reassurance and guidance.

46. A copy of the IMAC call was provided to HDC. In the recording, RN A begins the call by saying: "Hi [IMAC staff], just a quick question, its [RN A] speaking … Just a quick question, can you give Prevenar 13 and the PCV at the same time?"

47. When questioned by the IMAC staff member as to why the two vaccines would be given at the same time, RN A said: "Yeah, that was just my question, no you wouldn't. Would anything happen babe? No?" She then stated: "I was just wondering if you did, um you know, could it be like really dangerous, that's all."

48. The IMAC staff member then answered that the administration of the two similar vaccines at the same time would not be dangerous, and shortly afterwards the call was terminated.

Visit to Baby B

49. RN A told HDC that approximately 20–30 minutes after the telephone call from Ms F, and after the call to IMAC, she visited the residence. She stated that she did so to ensure Baby B's safety, and to give herself peace of mind.

50. The medical centre told HDC that RN A did not inform either her manager, the Clinical Lead Nurse, or the Clinical Director, of this visit, and noted that it was also RN A's day off. In addition, RN A did not inform the family in advance that she was going to visit Baby B. RN A told HDC that she regrets that she did not seek permission from Ms B before she went to her home, and acknowledged that she showed Ms B disrespect by doing this.

51. RN A told HDC that when she presented to the residence, there were two teenagers at home with Baby B, but Ms B was at work. RN A stated that she asked how Baby B was and whether she could come inside, as she may have made a mistake with the injections. She then asked the older daughter if she could see the baby's Well Child book.

52. RN A told HDC:

> "I checked the book and noticed that I had left out the batch number and expiry date of the Rotarix. I informed the teenager that everything was ok and told her I had missed entering the numbers (batch and expiry numbers). I was in the house for probably less than a minute."

53. In contrast, Ms B told HDC:

> "When I came home from work [on 31st July, 2019], my daughter told me the nurse had been back in the morning when I wasn't home. The nurse told my daughter she had done something wrong, and she (the nurse) borrowed a pen from my daughter and crossed out something in the well-child book. She stayed about five minutes and then she left."

54. Ms B stated that RN A was at the house in the morning, sometime between 10.00am–12.00pm, but that her daughter could not remember the exact time. She said that she returned from work at 3pm that day.

55. RN A denied crossing out anything in the Well Child book during this visit, and stated that if she was going to change the documentation in the Well Child book, she "would have definitely made sure the batch number was there". She said that she had crossed out the Prevenar 13 information at the time of administering the vaccination.

56. Ms B told HDC that she was angry that RN A had come to her house to see her baby without telling or asking her.

57. In contrast with RN A's recollections about the timing of the call to IMAC and the visit to Baby B, the medical centre told HDC that RN A in fact visited the residence in the morning, and then called IMAC in the afternoon. The medical centre stated:

> "[RN A's] call to IMAC in the afternoon is totally inconsistent with her claim that she had only committed a documentation error, and that she confirmed that upon seeing the Well Child book. [RN A] phoned IMAC after visiting the home to ask what would happen if a child reacted to PCV doses. She must have known that this is what occurred."

58. Details of the call were provided to HDC from IMAC, and show that RN A rang them for advice at 11.59am on 31 July.

Subsequent events

59. After being alerted by Ms D to the potential vaccine error on 31 July, the medical centre commenced an internal investigation.

60. The family was advised by the medical centre of the potential vaccination error on 1 August, and notification of an "adverse reaction or event" was sent to the Centre for Adverse Reactions Monitoring (CARM) on 15 August, documenting that "a nurse administered

Prev[enar] 13 orally and PCV10 by [intramuscular injection] to an 8 week old baby during the same visit".

61. The medical centre stated that after meeting with RN A as part of the investigation, it was unsatisfied with RN A's explanations and believed that, on balance, the allegations were substantiated. The medical centre also noted that RN A's recollections differed from the recollections of Ms D, Ms B, and Ms B's daughter. On 16 August, RN A opted to resign, and her resignation was accepted. Subsequently, the investigation was concluded.

62. Baby B was given the rotavirus vaccine by medical centre staff on 30 August 2019.[8]

Further information

RN A

63. RN A maintains that she gave Baby B the correct vaccination, but acknowledged that she made an error in the records. She stated:

> "Since this incident and after much soul searching, I have not vaccinated any pepe's [babies] or tamariki [children] since July 2019, despite about 1 year validity remaining on my certificate. I am no longer an Independent Vaccinator or wish to be one and have allowed my certification to expire."

64. RN A told HDC that she felt that she had been "crucified without proper redress" during the medical centre's investigation, and stated that she has lost confidence, and is conscious of the fact of these accusations despite believing that she was not treated or heard fairly.

Medical centre

65. The medical centre told HDC that this is the first incident of its nature in many years of operating the community service. The medical centre stated that prior to administering any medication, staff are required to complete several checks, which are also standard nursing practice,[9] and that the medical centre is confident that this was an isolated event. However, the medical centre stated that it will continue to review any further steps that can be suggested to prevent this type of event occurring.

66. The medical centre also supplied HDC with RN A's orientation and training records. In addition, it stated that for somebody in a position such as RN A, there is a role-specific orientation that includes nurses being observed in a team working in the community, where they are supported by the clinical lead nurse. The medical centre said that this also involves a gradual handover of responsibilities, and that the nurse does not practise in the community without onsite clinical support until the clinical lead nurse is comfortable with their practice and the nurse is feeling confident. The medical centre stated that this role-specific orientation occurred in RN A's case.

[8] The delay in Baby B receiving the rotavirus vaccination occurred because he was hospitalised for an unrelated infection.

[9] See Appendix B, paragraph 2, for the New Zealand Nurses Organisation (NZNO) "Guidelines for Nurses on the Administration of Medicines" (2018).

67. In September 2019, the medical centre notified the Nursing Council of New Zealand (NCNZ) of RN A's actions.

Responses to provisional opinion

68. Ms B was provided with the opportunity to comment on the "information gathered" section of the provisional opinion, and had no comments to make.

69. The medical centre was provided with the opportunity to comment on the provisional opinion. It stated:

> "We believe our investigation process was fair and appropriate, and gave [RN A] ample opportunity to contribute to a positive process, with hopes of achieving a remedial outcome (both for [the family] and for [RN A])."

70. RN A was provided with the opportunity to comment on the sections of the provisional opinion that related to her, and accepted the findings and recommendations. She stated:

> "Upon much reflection, I am conscious of the fact that establishing trusting relationships with health providers and health consumers and recording accurate documentation is imperative and the pinnacle of the nursing profession.
>
> I have much regret and sincerely hope all parties concerned find I genuinely apologise for any of my shortcomings."

Opinion: RN A — breach

71. This opinion relates to the care provided to Baby B by RN A on 30 July 2019. In particular, the main concern is whether or not Prevenar 13 was given orally to Baby B instead of the rotavirus vaccine, and the actions taken by RN A after the vaccination. There are conflicting versions of events as to whether or not this error occurred.

72. On 30 July 2019, RN A and support worker Ms D presented to the residence to administer Baby B with his overdue six-week vaccinations. Baby B's mother, Ms B, and her teenage daughter were at the house when they arrived. The PCV10 and Hexa vaccinations were given first, and the third vaccine, which was intended to be the oral Rotarix, was given last.

Whether RN A administered Prevenar 13 instead of Rotarix

73. RN A told HDC that she believes she administered Baby B Rotarix, as she recalls the vaccination not having a needle adapter and the fluid being thick (both features consistent with Rotarix). On the other hand, both Ms D and Ms B's daughter recall Prevenar 13 being administered. Ms D stated that she distinctly recalls the lid being dark blue in colour (the colour of Prevenar 13). Ms B's daughter confirmed this, and was able to identify Prevenar 13 as the vaccine given to her brother in a line-up of vaccination photos.

74. In addition, when RN A was confronted by Ms F about the possibility of an error, RN A stated that she was not sure whether or not she had given the wrong vaccination, and that she would contact IMAC to seek advice just in case she had made an error.

75. Regarding Baby B's six-week vaccinations, the documentation, as described in the "information gathered" section above, is inconsistent with RN A's recollection that she administered Rotarix orally.

76. In particular, in Baby B's Well Child book, RN A had documented "Prevenar 13" along with the Prevenar 13 batch number and the expiry date in the row for the rotavirus vaccine. Although these details were crossed out, this may not have occurred at the same time as the initial entry (discussed below). On the Field Team Vaccination sheet, under Baby B's name, RN A had placed the sticker for the Prevenar 13 vaccine, which noted its batch number and expiry date, in the "batch number" row for the rotavirus vaccine.

77. RN A did not provide any explanation for why, on the above two occasions, she documented the information for the Prevenar 13 vaccine in the rotavirus section, instead of in the space for the PCV information.

78. When RN A entered Baby B's vaccination details in Medtech, she documented that Prevenar 13 had been given as an alternative to rotavirus, as follows:

> "Rotavirus mono Dose1 — AG [alternative given] — Prev[enar] 13 — S2753 [the batch number for Prevenar 13, minus the last number]."

79. RN A explained that this was a documentation error caused by multiple factors, and that she input this data in the early evening under stress.

80. My expert nursing advisor, RN Fiona Blair, advised that "it takes quite an extra amount of effort to enter an alternative vaccine into the MedTech system and could not be done accidently". I accept this advice, and note the medical centre's similar comments. I agree that having to choose that an alternative vaccine had been given, and specifically type in "Prevenar 13" indicates a level of concentration and intentional effort on RN A's behalf.

81. I have considered RN A's explanations for her incorrect documentation. When looking at each apparent documentation error in isolation, they could be seen as genuine human error. However, the combination of the three documented entries by RN A recording that she had given Prevenar 13 to Baby B instead of the Rotarix vaccine, makes the explanation of a simple documentation error seem unlikely.

82. Documenting, on two occasions, the information for the Prevenar 13 vaccine in the space allowed for the rotavirus vaccine, in conjunction with recording in Medtech that Prevenar 13 had been given as an alternative to Rotarix, in addition to the contemporaneous documentation corroborating Ms D's and Ms B's recollections, I find it more likely than not that RN A administered Prevenar 13 orally to Baby B instead of Rotarix on 30 July 2019.

83. RN Blair advised:

> "In the case that [RN A] administered PCV13-1 vaccine orally instead of Rotavirus monovalent, this would be considered a serious deviation from accepted practice. Three of the five essential checks for any medicine (right patient, right medication, right dose, right time, and right route) would have been incorrect. Thus the consumer, [Baby B] would have been exposed to potential harm; the wrong medication and dose administered by the wrong route, with potential adverse effects on his health."

84. I accept this advice. Standard three of the Ministry of Health's "Immunisation Standards for Vaccinators" section of the *Immunisation Handbook 2017* states that the vaccinator "visually checks the vaccine, checks expiry date, prepares vaccine as appropriate and uses vaccines within the recommended period after preparation".[10] In addition, the NZNO "Guidelines for Nurses on the Administration of Medicines" state that prior to the administration of medication, the registered nurse "checks the five rights …: the right medicine in the right dose must be administered to the right person at the right time by the right route".[11]

85. RN A stated that her normal checking routine included her counting the vaccines required, and checking the expiry date and batch number, before placing them in the appropriate cooler box. She also stated that that she undertook the 7 Rights of Medication Administration prior to administering the vaccines to Baby B; however, she said that she did these checks collectively at the beginning, and did not do the check individually for each vaccine. As RN A had taken two PCV vaccines into the residence, she should have checked each one prior to administration to ensure that the intended vaccine was used.

86. By failing to check each vaccine individually prior to administration, RN A did not check adequately that the correct vaccine was being used, which led to her administering the incorrect vaccine to Baby B.

87. In administering the wrong vaccine, this was a clear failure to provide appropriate and safe care. Compliance with guidelines reduces the risk of errors occurring and ensures patient safety. RN A did not comply with the above guidelines, or with accepted practice as a registered nurse. RN A had been a registered nurse since 2006, and an independent registered vaccinator since 2016, and should have been familiar with the checks that she was required to undertake prior to vaccination in order to reduce the chance of such an error. I find that by failing to identify and administer the correct vaccine to Baby B, RN A did not provide Baby B services with reasonable care and skill, and, accordingly, breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[12]

[10] See Appendix B, paragraph 1.
[11] See Appendix B, paragraph 2.
[12] Right 4(1) of the Code states: "Every consumer has the right to have services provided with reasonable care and skill."

Whether RN A attempted to conceal her error

88. The day after Baby B's vaccinations, RN A was alerted to a potential error. In response to this, she presented to Baby B's home, unannounced and on her day off, without telling her supervisors. The events that follow this are disputed.

89. Whilst it is not disputed that RN A rang IMAC, whether she telephoned before or after her visit to the home is. The records show that RN A called IMAC at 11.59am. RN A states that this call was made prior to her visit, whereas Ms B told HDC that RN A went to her house "in the morning" when she was not at home.

90. Ms B's daughter stated that during RN A's visit, RN A asked to borrow a pen. Ms B's daughter said that she witnessed RN A crossing out something in Baby B's Well Child book. Notably, the details for the Prevenar 13 vaccine have been crossed out in the Well Child book, and "error Rotarix" has been written.

91. RN A denies crossing out anything in the Well Child book. She advised that she went to see Baby B only to check that he was all right, and that upon seeing the paperwork she saw that she had not made an error, although she noted that she had left out the batch number and expiry date of the Rotarix.

92. RN A stated that if she was going to change the documentation in the Well Child book, she "would have definitely made sure the batch number was there". However, I consider that if RN A had crossed out the Prevenar 13 information at the time of administering the vaccination and documented "error Rotarix", she would have added the batch number and expiry for the Rotarix, as she had done for the other vaccines. Additionally, RN A would not have been able to enter the batch number and expiry date for the Rotarix vaccine when she presented to the residence the following day, as she had already discarded the vaccine.

93. Accordingly, I find it more likely than not that RN A called IMAC after her visit to the residence to understand whether a vaccination error was potentially harmful to Baby B. Further, I find it more likely than not that when RN A visited the residence, she saw that she had documented that she had administered Prevenar 13 instead of Rotarix. I also find it more likely than not that upon noting this error, she crossed out the Prevenar 13 information and wrote "error Rotarix" in an effort to conceal it.

94. RN Blair stated:

> "The scale of the seriousness of this deviation would depend on [RN A's] response to the error. Human error is inevitable and medication errors occur … Accidently administering the wrong vaccine … would be considered a mistake, a moderate error which is multi-factorial. A professional with integrity who identified a mistake would be expected to report the error, or suspected error and follow the organisation's processes for taking remedial action, investigating root causes, and instigating actions to prevent future occurrence … If the incorrect vaccine were given and the documentation deliberately falsified, I believe I and my peers would consider this to be severe wrongdoing which would bring discredit to the profession."

95. I accept this advice, which is also mirrored in the Nursing Council of New Zealand's Code of Conduct. In my view, RN A's actions in this case do not uphold principles 4, 7, and 8 of the NCNZ Code of Conduct.[13]

96. In addition, the NZNO "Guidelines for Nurses on the Administration of Medicines" stipulates expectations for reporting adverse events such as errors or incidents, and states that if an error is made in the administration of a medicine, the nurse must take every action to prevent any potential harm to the client, and report the error as soon as possible.[14]

97. I am critical that RN A did not follow this guideline in relation to the vaccination error with Baby B, and that she failed to uphold the behaviour that was expected of her as a registered nurse. Errors act as a means to further learn and understand where one can improve, and to identify ways to prevent the future occurrence of such errors. Instead of owning up to her mistake, RN A went to significant efforts in an attempt to cover up her error. In my view, she acted wholly inappropriately by presenting to the residence unannounced and on her day off, in order to amend the records in Baby B's Well Child book. In the spirit of open disclosure, RN A should have alerted Baby B's family to her mistake, and her failure to report it led to a delay in the error being rectified. This meant that Baby B was left unprotected from rotavirus, and placed at risk of the illness unnecessarily. It also meant that his family were not alert to signs of possible reaction to the drug error in the young infant.

98. By failing to report her vaccine administration error, and by attempting to cover up her mistake, RN A failed to comply with her ethical and professional obligations as stated in both the NCNZ Code of Conduct, and the NZNO "Guidelines for Nurses on the Administration of Medicines". Accordingly, I find that RN A also breached Right 4(2)[15] of the Code.

99. In addition, RN A failed to openly disclose her error to the family. As the individual provider with overall responsibility for the consumer's care, it was RN A's responsibility to disclose that the incorrect vaccination had been given. As such, I also find that RN A breached Right 6(1)[16] of the Code.

Family assistance for removal of vaccine lid — adverse comment

100. Both the support worker, Ms D, and Ms B's 19-year-old daughter stated that before RN A administered Baby B with the third vaccine, RN A asked Ms B's daughter to unscrew the lid while she held the baby. RN A told HDC that she cannot recall this. Considering the evidence, I find it more likely than not that this did occur.

101. RN Blair advised that it is not unusual in her experience, in a domiciliary situation, for a nurse to ask the family to assist with an individual's cares. However, she stated that this is with the proviso that there is no other suitable solution that can be carried out safely by the

[13] See Appendix B, paragraph 4.
[14] See Appendix B, paragraph 3.
[15] Right 4(2) states: "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards."
[16] Right 6(1) states: "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive."

health professional, that it is safe for the client/patient, and that suitable training or coaching is provided to the family member in order to maintain hygiene standards and keep the family member safe. She made the following three comments about this situation:

> "[I]f this was Rotavirus oral vaccine, it would be easy, and usual for the Registered Nurse to remove the lid and administer the vaccine without assistance.
>
> If assistance were required the support worker may have been a more appropriate person to do so, and this would be another opportunity to visually and verbally check the vaccine.
>
> Any person who handled the live Rotavirus vaccine should be instructed to complete hand hygiene, both before and after handling the vaccine."

102. I accept this advice. Ms D was present during Baby B's vaccinations, and, as such, I would expect that she would have been a more appropriate person to remove the lid from the vaccine safely, in the event that RN A was unable to do so herself.

Opinion: Medical centre — no breach

103. As a healthcare provider, the medical centre is responsible for providing services in accordance with the Code. RN A was employed by the medical centre to provide vaccinations for children aged up to five years in the community, in line with the national childhood immunisation schedule.

104. In this case, I consider that the failings identified in this report were matters of individual clinical judgement, ethics, and practice, and did not indicate broader systems or organisational issues at the medical centre. Therefore, I consider that the medical centre did not breach the Code directly.

105. In addition to any direct liability for a breach of the Code, under section 72(2) of the Health and Disability Commissioner Act 1994 (the Act), an employing authority is vicariously liable for any acts or omissions of its employees. A defence is available to the employing authority of an employee under section 72(5) if it can prove that it took such steps as were reasonably practicable to prevent the acts or omissions.

106. In July and August 2019, RN A was an employee of the medical centre. Accordingly, the medical centre is an employing authority for the purposes of the Act. As set out above, I have found that RN A breached Rights 4(1), 4(2), and Right 6(1) of the Code by erroneously administering Baby B with a Prevenar 13 vaccine instead of the Rotarix vaccine, attempting to cover up her mistake by changing the documentation in the Well Child book, and failing to disclose her error to the family.

107. The medical centre supplied HDC with RN A's orientation and training records, and stated that for somebody in a position such as RN A, there is a role-specific orientation. It stated that this includes nurses being observed in a team working in the community, where they are supported by the clinical lead nurse, and that the nurse does not practise in the community without onsite clinical support until the clinical lead nurse is comfortable with the nurse's practice and the nurse is feeling confident. The medical centre said that this role-specific orientation occurred in RN A's case.

108. RN Blair advised that the supplied documentation of RN A's orientation and training record shows a "thorough and safe orientation policy and process". RN Blair stated that there is clear evidence of the information RN A was expected to receive or seek, and noted that a week-long supervised orientation would be considered "at least accepted practice and probably generous".

109. The medical centre also told HDC that this is the first incident of this nature in many years of operating the community service. The medical centre stated that prior to administering any medication, staff are required to complete several checks, which are also standard nursing practice, and that the medical centre is confident that this was an isolated event. I note that RN A had been a registered nurse since 2006, and had been a qualified independent registered vaccinator for three years at the time of these events. I consider that identifying and administering the correct vaccine is a basic requirement of someone in RN A's role, and that the medical centre should have been able to rely on RN A's experience in this regard.

110. I note the above information, and the advice I have received from RN Blair. I am satisfied that the medical centre had taken such steps as were reasonably practicable to prevent these acts and omissions occurring. Accordingly, I do not find the medical centre vicariously liable for RN A's breaches of the Code.

111. I note that the medical centre conducted an investigation as soon as it was made aware of the error, that staff administered Baby B with his missed rotavirus vaccination once the investigation had been completed, and that the medical centre had good communication with the family. In addition, the medical centre reported the incident to CARM, and notified the Nursing Council of New Zealand of RN A's actions. I commend the medical centre for these actions.

112. I commend the initiative shown by support worker Ms D the following day when she emailed the Community Services Manager, Ms E, alerting her to RN A's potential vaccination error.

Recommendations

113. I recommend that RN A:

a) Undertake training on documentation and safe administration of medications. Evidence that this has been done is to be sent to HDC within six months of the date of this report.

b) Provide Baby B's family with a written apology for her breaches of the Code. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to the family.

114. I recommend that the Nursing Council of New Zealand note HDC's findings and consider whether a review of RN A's competence and/or any further action is warranted.

Follow-up actions

115. RN A will be referred to the Director of Proceedings in accordance with section 45(2)(f) of the Health and Disability Commissioner Act 1994 for the purpose of deciding whether any proceedings should be taken.

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

117. 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 Nurses Organisation, the Centre for Adverse Reactions Monitoring (CARM), and the Health Quality & Safety Commission, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Addendum

118. The Director of Proceedings decided not to issue proceedings.

Appendix A: Independent clinical advice to the Commissioner

The following expert advice was obtained from RN Fiona Blair:

"Thank you for your request for advice regarding complaint reference C19HDC01647; [RN A] and [the medical centre] regarding care provided to [Baby B] on 30 July 2019.

Please review the enclosed documentation and advise whether you consider the care provided to [Baby B] by [RN A] was reasonable in the circumstances, and why.

In particular, please comment on:

1. In the event that [RN A] administered [Baby B] with PCV13-1 instead of Rotavirus Monovalent, whether the care provided was consistent with accepted practice;
2. In the event that [RN A] administered PCV13-1 instead of Rotavirus Monovalent, **and** altered the documentation to reflect administration of the latter immunisation, whether the care provided was consistent with accepted practice;
3. Whether [RN A's] keeping of immunisation and clinical records met the accepted standard of practice;
4. The adequacy of [the medical centre's] actions once they were notified of the event; and
5. Any other matters in this case that you consider warrant comment.

For each question, please advise:

1. What is the standard of care/accepted practice?
2. If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be?
3. How would it be viewed by your peers?
4. Recommendations for improvement that may help to prevent a similar occurrence in future.

As you will note, there are different versions of events in the information provided. Please provide your advice in the alternative. For example, whether the care was appropriate based on scenario (a), and whether it was appropriate based on scenario (b).

Introduction

I am a New Zealand registered Nurse Practitioner. I have worked in General Practice and primary health organisations since 1989, in roles including: Practice Nurse, Nurse Educator, Nurse Manager, Team Leader, Humanitarian worker, roles in Primary Care Governance, and Practice Facilitator. I have been an Authorised Vaccinator for at least 15 years. My curriculum vitae and qualifications are available for review.

I have no conflicts of interest with any organisation or person in this case. I am, however familiar with the geographic and socio economic environment of [the area] having worked in this area as a District nurse and Practice Nurse in the past.

I have read the 'Guidelines for Independent Advisors' provided by the Office of the Health and Disability Commissioner, and agree to abide by these guidelines.

This case is complex due to the conflicting evidence supplied. My comments will be based on the information supplied and additional material requested by me.

In order to complete this report I have received and reviewed:

- A copy of the Complaint from [Ms B], parent
- A response from [the] Clinical Director, [the medical centre]
- A statement from [RN A]
- A copy of MedTech Clinical Notes from [the medical centre]
- A copy of the report to the Centre for Adverse Reactions Monitoring (CARM)
- [The medical centre's] Continuous Improvement Form (CIF)
- A transcription of [the medical centre's] disciplinary meeting with [RN A]
- A colour copy of an Immunisation record, assumed to be that of [Baby B]
- A 'log of Interactions and Conversations Regarding Potential Vaccine Error', recorded by Support Worker (SW) [Ms D]
- [Medical centre] Policies 'Adverse Event Management', 'Complaints Management', 'CIF Guidelines', 'Open Disclosure', 'National Immunisation Register (NIR) and [the community service] Manual, June 2019', 'Medication Management Manual, Youth Health Hub, August 2018'; and 'Draft August 2019'
- Clinical Records for [Baby B] from [the] DHB

Additional resources requested and received:

- Image of the MedTech entry for 30th July [RN A] showing the 'alternative given' entry — Prevenar 13 instead of Rotarix
- Organisation Chart for [the medical centre] 2019

…

- A copy of the internal Immunisation record for [Baby B] showing the Prevenar 13 sticker in the space allocated for recording Rotarix

Summary of events

Registered Nurse and Authorised Independent Vaccinator [RN A] attended the home of 8 week old [Baby B] with National Immunisation Service and Immunisation Support worker [Ms D] on 30th July 2019 to administer the vaccines scheduled for 6 weeks of age. It is alleged that [RN A] administered Pneumococcal 13 Vaccine (PCV13-1) via the oral route, instead of Rotavirus vaccine (Rotarix).

This allegation was raised as a concern the next day (**Day one post vaccination**) by [Ms D] on reviewing [the medical centre's] immunisation record, and the National

Immunisation Register (NIR) record. [Ms D] first raised the concern to [Ms E] (Community Services Manager), and then [Ms D's] manager, [Ms F] (NIR/[the community service] Co-ordinator and Supervisor). [RN A] was called by [Ms F] to ask for her view of events, and consequently reported that nurses had been advised by [RN C] Clinical Lead, [community] immunisation Service and [community] immunisation Service Nurse) to give PCV 13 orally as Rotarix, and that the 'case was closed'. Later that day [RN A] reported via [Ms F], that she had visited the home, checked the baby and checked the Plunket book, where Rotarix was correctly recorded. Other concerns about [RN A's] work were raised at the same time, but consequently documented separately. The Immunisation Advisory Centre (IMAC) were contacted the same day to check if any harm were anticipated if the Prevenar 13 vaccine were administered orally, the response was in the negative, however the Rotavirus vaccine still needed to be administered.

Day two post vaccination [RN A] was spoken to by [Ms E] and asserted that she had given the correct vaccine orally (Rotarix), but had made a paperwork error. [RN A] reported she had been to the house the previous day (her day off) to check the book. It was noted that in the MedTech electronic record Prevenar 13 was recorded as having been given as an alternative to Rotarix.

The advice of the New Zealand Nurses Organisation (NZNO) was sought with regard to correct procedure for the investigation. Two senior staff met with the Mother and elder sister of [Baby B], advised them of the possible error, the advice that no harm was expected, their evidence was collected and they were given information regarding the complaint process.

On **day 6 post vaccination** advice was received from NZNO that the RN should receive a formal letter inviting her to a review meeting, and what topics that meeting would cover. Other senior staff were informed of this via email, and the Human Resources (HR) [lawyer] copied in. At this stage, a 'cover up' was suggested.

Day 9 post vaccination two senior staff met with [RN A] to deliver the letter prepared by the HR Lawyer, explained its contents and presented the evidence collected. [RN A] became upset and threw her keys and identification on the desk, verbally resigned, and left. A further letter and the evidence to date was couriered to her with an invitation to a disciplinary meeting on day 14 post vaccination.

Day 10 post vaccination [RN A's] letter of resignation was received by email.

Day 13 post vaccination, [RN A] came in to collect belongings and agreed to attend the disciplinary meeting.

Day 14 post vaccination, Disciplinary meeting held and conversation transcribed.

Day 15 post vaccination, transcription of [RN A's] call to IMAC sought and received.

Day 17 post vaccination, Mother of [Baby B] calls to advise that he has been in hospital and asked for a meeting with the two staff who came to her home to advise of the possible error. She also requested to meet with [RN A] — this was declined as [RN A] had resigned. [Ms B] was offered support to make a complaint.

Day 20 post vaccination [Medical centre] staff visit Mother, [Ms B], in [the public hospital], accompanied by an interpreter. [Ms B] was advised that [Baby B's] admission was not related to the possible vaccination error, and that he still needed a dose of Rotavirus vaccine. Support to make a complaint was again offered. Day 31 post vaccination; Rotavirus vaccine administered at home to [Baby B].

In the event that [RN A] administered [Baby B] with PCV13-1 instead of Rotavirus Monovalent, whether the care provided was consistent with accepted practice:

In the case that [RN A] administered PCV13-1 vaccine orally instead of Rotovirus monovalent, this would be considered a serious deviation from accepted practice. Three of the five essential checks for any medicine [1] (right patient, right medication, right dose, right time, and right route) would have been incorrect. Thus the consumer, [Baby B] would have been exposed to potential harm; the wrong medication and dose administered by the wrong route, with potential adverse effects on his health. Additionally this would mean he would not have received the correct vaccine, leaving him exposed to infection with Rotavirus. The scale of the seriousness of this deviation would depend on [RN A's] response to the error. Human error is inevitable and medication errors occur. A third of harm from medication errors occur in primary care and 25% of these occur at the administration phase [1,2]. Information from [the medical centre] suggests that incorrect information was understood by [RN A] about using PCV13-1 orally instead of Rotavirus monovalent. [RN A], as an authorised independent vaccinator, could have been expected to have been aware this was the incorrect vaccine and route, and questioned the information, if indeed this was circulated [3]. Accidently administering the wrong vaccine by the wrong route would be considered a mistake, a moderate error which is multi-factorial. A professional with integrity who identified a mistake would be expected to report the error, or suspected error and follow the organisation's processes for taking remedial action, investigating root causes, and instigating actions to prevent future occurrence [1,4–6]. This is dependent not only on the individual nurse's self-awareness, knowledge and conscience, but on the policies and the thoroughness of the orientation and familiarisation to these the nurse received when employed, and the workplace culture. A culture of no-blame, openness and collective responsibility, a 'Just and Fair Culture' as described by the Health Quality and Safety Commission [5] is most likely to result in mistakes being reported. There are contributory factors to a potential medication error in the evidence provided; [RN A] notes that 'through the entirety of our visit, Mum and I were talking' ([RN A] statement) and '… cause I sort of had opened up both of them — and then we were just talking away' (Disciplinary meeting transcription) before, during and after the vaccination process, raising the possibility of distraction from the task. Distractions and interruptions have been recognised as a contributor to medication administration errors [4].

In the event that [RN A] administered PCV13-1 instead of Rotavirus Monovalent, and altered the documentation to reflect administration of the latter immunisation, whether the care provided was consistent with accepted practice:

If the incorrect vaccine were given and the documentation deliberately falsified, I believe I and my peers would consider this to be severe wrongdoing which would bring discredit to the profession. This would be contrary to Principles 4, 7 and 8 of the Code of Conduct for Nurses, set out by the Nursing Council of New Zealand, which are standards Nurses in New Zealand are expected to uphold [6].

PRINCIPLE 1. Respect the dignity and individuality of health consumers

PRINCIPLE 2. Respect the cultural needs and values of health consumers

PRINCIPLE 3. Work in partnership with health consumers to promote and protect their well-being

PRINCIPLE 4. Maintain health consumer trust by providing safe and competent care

PRINCIPLE 5. Respect health consumers' privacy and confidentiality

PRINCIPLE 6. Work respectfully with colleagues to best meet health consumers' needs

PRINCIPLE 7. Act with integrity to justify health consumers' trust

PRINCIPLE 8. Maintain public trust & confidence in the nursing profession

Deliberately falsifying records or denying wrongdoing would comprise a violation of accepted practice [4].

Within the records I have received there is contradictory evidence presented by [RN A] regarding her actions and the order of events. In her interview of August 13 she agrees that the drug she gave for the Rotavirus vaccine was indeed Prevenar 13. It is documented in her entry into Medtech records that she gave an alternative vaccine to Rotavirus vaccine, and that this was Prevenar 13. This was reflected in the messaging to the NIR. It takes quite an extra amount of effort to enter an alternative vaccine into the MedTech system and could not be done accidently. In her statement [RN A] notes that she re checked the vaccines, wrote in the WCTO book, and talked to the family, all at the same time, prior to administering the vaccines. She does not state the reason for her crossing out 'Prevenar 13', batch and expiry date, and writing 'error Rotarix' instead, nor the lack of batch and expiry date for the latter.

[RN A's] verbal and written accounts of her return to the home of [Baby B] the day after immunisation differ from that of [the whānau] who were present. [RN A] states she checked the book and that Rotavirus was correctly documented but she had forgotten the batch number and expiry date. There is a clear picture of the Immunisation record page of the WCTO book showing Prevenar 13, batch number and expiry crossed out, and 'error, Rotarix' written in, in apparently the same handwriting. It is reported on the CIF Form that [the whānau] stated that [RN A] altered the record when she came back the next day. In the interview of August 13th (page 14) [RN A] denies altering the book. If the record were indeed altered in order to disguise a medication error, at a visit to

the whānau home without permission, this would comprise a serious violation of accepted practice.

Whether [RN A's] keeping of immunisation and clinical records met the accepted standard of practice:

[RN A] has failed to keep adequate records in a number of areas, representing a moderate departure from expected practice. Best practice is prescribed in the standards set out for vaccinators in the Immunisation Handbook, and available as a resource guide to all vaccinators from the Immunisation Advisory Centre [7,8]. These standards are essential knowledge for all Authorised Vaccinators:

- It is recommended best practice that the Vaccines are recorded in the Well Child Tamariki Ora book (WCTO) after administration. [RN A] states she placed the vaccine stickers and completed the book prior to administering the vaccines
- There is discrepancy in the needle size recorded by [RN A] in the immunisation entry in MedTech (5/8th") and her response letter (1")
- The Correction of the immunisation record in the 'My Health' Well Child Tamariki book to 'Rotarix' does not state the batch number, expiry date or route of administration of the vaccine, as is recommended best practice
- [RN A] did not document her visit to [Baby B's] home on the 30th of July until August 6th. She writes '[RN A] visited house' but not the date and time, who was present, whether there was consent, her observations or actions, and that she was not working for [the medical centre] at the time of the visit.

The adequacy of [the medical centre's] actions once they were notified of the event:

I find there are some failures in [the medical centre's] processes and investigation, which may be reviewed in order to prevent future events and improve response to events when they occur:

- [The medical centre] [has] provided copies of their policies for managing adverse events. They have designated this incident to be an 'Adverse Event': 'Events with negative or unfavourable reactions or results that are unintended, unexpected or unplanned …' rated 'Moderate Risk': 'Consequences of not being addressed would put clients/staff at moderate risk of harm'. The [medical centre's] policy is for this to be notified to the CEO on the day received, with an investigation timeframe of 10 working days. There is no record of this notification occurring, and the time frame is exceeded.
- It would have been helpful to use full names and titles at the mention of each person in the CIF. They could thenceforth have been referred to by their initials.
- 'Unable to meet as [RN C] is on leave' — in the case of an incident of this risk rating I would expect this to be delegated so as to meet the organisation's time frames.
- No corrective action has been recorded on pages 10 and 11 of the CIF, although this may be on hold pending the HDC report.

- The response to [RN A's] verbal resignation is not recorded, nor is it recorded that she was officially 'stood down' pending investigation, nor how this was delivered or recorded.
- It is not stated if an interpreter was offered to the whānau at any of the visits by [the medical centre] senior staff to the home following the incident.
- The message alluded to by [Ms F], page 3 of the CIF that [RN C] '… had told the staff they could give PCV in place of Rotarix' and [Ms D] Log for Wednesday 31st July '[RN A] said that [RN C] told the nurses to give the remaining PCV 13's as Rotarix', has not been investigated, nor is there a record of an interview with [RN C] regarding this assertion.
- It also appears the contributory actions of [Ms F] have not been investigated nor has her evidence been included, if sought, despite serious accusations of collusion and cover-up in which it is suggested she is complicit.
- I do not have a record of [the medical centre's] orientation programme, nor [RN A's] participation in it, however this event is an opportunity to consider how adverse event reporting and [the medical centre's] policies are covered in the orientation of new staff.
- I find insufficient evidence of a 'Just and Fair Culture' particularly 'support and respect each other'. Such a culture encourages open disclosure of errors [4]. 'Inadequate organisational culture that does not place value on the importance of the Five Rights as routine, safe administration, can also affect staff adherence' [4]. If the affected staff members had immediately been called together in a collaborative and supportive environment the subsequent investigation and its accusatory tone may have been curtailed or abbreviated and distress to the consumers minimised.
- The organisation may have considered offering [RN A] the opportunity to meet with the parent, [Ms B], as this was her wish and may have offered resolution and relieved distress for this mother and the whānau.
- There are times when it may be difficult to enter the home of some whānau, particularly if staff are unknown to them, as [RN A] has noted. If [the medical centre] agrees with the pragmatic approach that a Nurse may at times enter a home alone, then sufficient systems need to be in place to ensure that the staff member is safe and is able to immediately contact their back up support worker, and key management staff, if they have any safety concerns.

Other matters

[RN A] appears to have deviated from Best Practice for immunisation in other matters:

- It is a requirement that a minimum of two immunisation team members must be present for vaccination; one of whom must be an authorised vaccinator, the other must be a competent adult who is able to call for emergency support and has a current basic life support certificate. In this context the support worker fulfills this

role [8]. This is consistent with [the medical centre's] own outreach immunisation policy.

- It is recommended that oral Rotavirus vaccine is given first, usually with the infant held by the parent or caregiver. The sweet vaccine confers some analgesic properties [7,8].
- It is also best practice for the parent to hold the infant for immunisation, and breast feed if they wish [8].
- [RN A] notes a previous incident where an open needle was left at a home. It is not noted what actions were taken over this incident, however it is best practice to immediately place sharps in an approved safety container and keep these out of reach of young children [8].

It is not in the scope of this report to interrogate other matters outside the alleged vaccine error, however there are several other issues brought to the attention of [the medical centre] by Support Worker [Ms D] which would not meet the standards of the Code Of Conduct set out by the Nursing Council of New Zealand [6], nor consistent with reasonable and accepted practice, including allegedly:

- Attending the home without her employer's knowledge and without seeking permission of the parent and homeowner
- Smoking by the Health Provider Vehicle
- Requiring Support Worker [Ms D] to transport a minor without consent, withdraw money and purchase confectionary for the child
- Leaving vaccines unattended in a Health Provider Vehicle with windows down

These matters are for the health provider to investigate and address. All would bring the profession into disrepute if proven.

Recommendations

- There is currently no requirement to check vaccines with another person when delivering [community services] for [the medical centre], however my recommendation is that the vaccines are checked with the accompanying support worker, against a copy of the current immunisation schedule.
- The Immunisation Advisory Centre offer a course 'Introduction to immunisation for non-vaccinating health care workers'. I recommend this course be undertaken by support workers accompanying vaccinators for home visits.
- That laminated copies of: the most recent Immunisation Schedule [9] and the resource 'Successful strategies towards Best Practice for vaccination' [7], and a copy of the latest Immunisation Handbook [8] be carried by all vaccinators to check vaccines and processes against in the home.

- If unaccompanied visits to homes by RNs are permitted in some circumstances, that these circumstances, and safety measures for staff, are clearly laid out in policy.
- It may be useful for Team Leaders such as Clinical Lead [RN C], to accompany staff members on visits as part of annual performance review, to ensure consistent delivery of services and quality of care.
- Regular Peer review meetings of the Immunisation service nurses would be helpful both in discussing cases and sharing information. Each Authorised Vaccinator has an individual renewal date, therefore new information, strategies and techniques may be shared amongst the team.
- That [the medical centre] adopt the 'Just and Fair Culture' framework suggested by the Health Quality and Safety Commission [5]. Review of critical incidents in a no blame atmosphere with all of the team may prevent errors and safeguard consumers from harm.

Nāku iti noa, nā

Fiona Blair NZRGON, MN, NP, PGcert TRav Med

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The following further expert advice was obtained from RN Blair:

"I am in receipt of your further expert advice request re:

[Baby B] HDC Ref: C19HDC01647, accompanying documentation and questions.

1) Whether you have any further comments to make regarding the care provided to [Baby B] by [RN A] and [the medical centre]
2) The adequacy of the policies and procedures in place at [the medical centre], including whether they are consistent with accepted practice and other health care facilities.
3) The adequacy of the training provided to [RN A] by [the medical centre].

If you could please respond to both the points in [the medical centre's] response that are directed towards your report, as well as any relevant points that relate to the below questions.

Thank you for supplying these documents including responses supplied by both [RN A] and [the medical centre].

In response to both, I note that my report was based on the information supplied to me in the original request.

For clarity I have highlighted my response in blue.

1) Whether you have any further comments to make regarding the care provided to [Baby B] by [RN A] and [the medical centre]

I have no additional comments to make regarding the care provided to [Baby B], other than those in my original report.

2) The adequacy of the policies and procedures in place at [the medical centre], including whether they are consistent with accepted practice and other health care facilities.

[The medical centre] [has] provided several new documents, information, and comments in their response to the Commissioner's request for information. I will address each of these appended to [the medical centre's] comments, with my comments below:

[The medical centre's] Response to RN Blair's opinion

[The medical centre] agrees with the conclusions that RN Blair has formed regarding the administration of PCV13 instead of Rotavirus, and also the alteration of documentation. As RN Blair sets out, particularly the alteration of documentation would

constitute severe wrong-doing, and the alteration of the Well Child book in order to disguise a medication error is a serious violation of accepted practice. Those acts are also a violation of expected standards within [the medical centre] and are exactly why [the medical centre] was going through an employment process with [RN A] once these issues were identified.

[The medical centre] does however disagree with what RN Blair has constituted as failures with [the medical centre's] processes and investigation. It must be remembered that the additional details (over and above a medication error) meant that this turned into an employment investigation that needed to follow established procedures for employment related matters.

Despite the CEO being away and travelling overseas, the CEO was informed and advised of what had occurred. She was also kept informed of progress via email and phone conversations. A timeframe of 10 days was unrealistic to complete the investigation. However, [the medical centre] representatives met with [Baby B's] family at an early stage to advise them of the vaccination error despite the ongoing investigation into other matters that arose from that medication error.

I have received documentation that the CEO was advised of the error on day two post vaccination, meeting the timeframe in [the medical centre's] policy.

As is set out above, a situation like this has demonstrated that the timeframe of 10 days set out in our policy is unachievable in many situations and we are looking to amend this.

I agree with the anticipated amendment to extend the timeframe in the adverse events policy.

RN Blair's comment around using full names and titles is taken on board. However, it needs to be considered that the CIF was intended for internal use where the initials are easily identifiable for those that need to know them. We agree that, given this was being sent to an external party, being the HDC, it may have been useful to use the full names and titles at the start. Nonetheless, this does seem to be overly critical.

I note that the CIF was intended for internal use; therefore, the use of initials for the staff involved.

[RN C] was on leave at the time of this event. However, that did not result in any delays. [Ms E], the Community Services Manager, and [the] Clinical Director, had started the investigation, and [Ms E] met with [RN A] on 1 August 2019 which was [RN A's] next working day after the incident.

Noted

RN Blair criticises that there is no corrective action having been recorded. Obviously, the key corrective action in this instance was the correction of [Baby B's] immunisation

status. This corrective action is outlined in the body of the CIF. In terms of any other preventative actions, it is hard at this stage to identify those given that this was a medication error by a very experienced nurse, who has then seemingly tried to cover up that error. If there are any recommendations that HDC makes following this, [the medical centre] would be open to considering them.

Noted

We do not accept any criticism in terms of the employment process that was being adopted based on expert employment advice. We also do not feel it appropriate for RN Blair to be expressing comments on our employment process.

I was asked to comment on [the medical centre's] actions and have done so.

RN Blair also refers to it not being stated if an interpreter was offered to the whānau. If there had been any indication at all that the family was not comprehending the conversation, an interpreter would have been offered and arranged. However, there was no indication of this during the meeting with them. It is also notable that there was apparently no need for an interpreter when [RN A] visited the house (on either occasion).

This was based on the documentation in [the medical centre's] incident report that '[name]' had arranged an interpreter for the meeting with the family at [the public hospital] 19/08/2019, and that the Complaints information had been printed off for the family in [their language]. I accept that during this meeting it may have been clarified that the further use of an interpreter was not required by the family.

RN Blair's criticism around the apparent lack of investigation of the statement attributed to [RN C] is incorrect. The suggestion that was made was clearly erroneous, but this has been confirmed during discussions with [RN C] and is confirmed in her statement. Appendix 11 (attached).

This matter has been clarified by [RN C's] supplied statement dated 28/10/20.

RN Blair also refers to the 'contributory actions' of [Ms F]. A discussion was had with [Ms F] but it is notable that it is [RN A] that is alleging that [the medical centre] is making accusations of collusion and cover-up. Those accusations have never been made regarding [Ms F]. Once again, this does appear that RN Blair is commenting on [the medical centre's] employment processes.

In retrospect, this should have been worded 'alleged' or 'implied' contributory actions. This has been clarified in the interview dated 22/10/2019.

RN Blair also refers to not having a record of [the medical centre's] orientation programme. For somebody in a position such as [RN A], there is a role specific orientation. That includes nurses being observed in a team working in the community where they are supported by the clinical lead nurse. That involves a gradual handover

of responsibilities, and the nurse does not practise in the community without onsite clinical support until the clinical lead nurse is comfortable with their practice and the nurse is feeling confident. That occurred in [RN A's] case. She was a very experienced RN and had been working for [the medical centre] for some time.

The supplied documentation of [RN A's] orientation and training record shows a thorough and safe orientation policy and process. Although not all areas have been ticked by [RN A] there is clear evidence of the information [RN A] was expected to receive or seek, and a week-long supervised orientation would be considered at least accepted practice and probably generous.

It is concerning and surprising that RN Blair considers there is insufficient evidence of a 'just and fair culture' at [the medical centre]. Staff are encouraged to report errors and not to blame and shame at [the medical centre]. This usually leads to identification of what happened, and what can be done to prevent the error from occurring again. The learnings from these processes are then discussed with nurses and other staff in regular team meetings and the input valued in terms of how processes can be improved. It is evident in this case that the support worker did feel able to raise the issue and that was consistent with our just and fair culture encouraging the raising of these issues. What has occurred in this case though is that as soon as that potential issue was raised with [RN A], she has compounded the issue that has placed the process on an employment track given the severity of her conduct.

I defend this statement for several reasons and note that this is a relatively new campaign with accompanying resources, promoted by the Health Quality and Safety Commission. It will take time for this to reach all areas of the Health System. The presence or absence of a culture cannot be judged solely by those in management or leadership positions, or indeed by myself as an outsider, but by the entire team and each individual employee. You will note that I state that I do not find sufficient evidence and this is the key word. It is not explicit in the Job Description and it was not evident to me in the information that was provided. I am delighted that at [the medical centre] staff are encouraged to report errors and not to blame and shame. My suggestion for [the medical centre] and any other health organisation delivering medicines or treatments is that the Just and Fair training video (https://www.hqsc.govt.nz/our-programmes/medication-safety/publications-and-resources/publication/3651/) be part of future orientation packages.

RN Blair also suggests that [the medical centre] may have considered offering [RN A] the opportunity to meet with the parent [Ms B]. That was never expressed as a wish by [RN A] when she was employed by [the medical centre]. We also do not feel that this would have been appropriate given the actions of [RN A] upon returning to the house and altering the records.

Noted

RN Blair also refers to the issue of entering the homes of some whānau. That was obviously not an issue in terms of [this whānau], but we can confirm that it is not standard practice that a nurse enters a home to vaccinate without a support worker present. [The medical centre] was concerned to discover that [RN A] had been regularly asking support workers to wait in the car while vaccinating. The requirement for a support worker is necessary for safety reasons.

Noted

RN Blair also makes a number of recommendations which we will consider. However, some current comments in relation to her recommendations are set out below.

- The requirements for checking vaccines with another person is dictated by the Ministry of Health guidelines on vaccinations. The support workers that we have present are also non-clinical, and it is questionable how effective and appropriate it would be to be checking vaccinations with a non-clinical person.
- We agree that the introduction to immunisation for non-vaccinating healthcare workers is a useful course, and we will ensure support workers complete this course.
- Our nurses always carry a copy of the immunisation handbook with them.
- Unaccompanied visits to homes are not permitted.
- The Clinical Lead Nurse does accompany the Independent Authorised Vaccinators on visits as part of annual performance reviews and to ensure consistent delivery of services and quality of care. The nurses are also not working in the community until they have been assessed as competent to perform this role without support. There are also regular meetings held with new nurses to discuss their progress and any additional support they may feel they need.
- Information sharing, as is suggested by peer review meetings, occurs on a monthly basis. Accordingly, we already have this in place.

Noted

[The medical centre] does work in a no-blame atmosphere. However, when an employee goes out of their way to cover up issues and actively mislead the organisation about what has occurred, then it is appropriate that these severe violations are addressed. Nonetheless, it was a huge loss to [the medical centre] and the community that we serve when [RN A] left the organisation. She had made some valuable inroads with our high needs patients.

Noted

In summary, I believe that [the medical centre's] policies and procedures are comprehensive and generally sound, consistent with accepted practice, and in my limited experience of such organisations, at least equal to other similar health care facilities.

3. The adequacy of the training provided to [RN A] by [the medical centre].

As noted above, I believe that the training and orientation provided to [RN A] was comprehensive, and appropriately tailored to her qualifications and experience. In particular, the practice of accompanying an experienced practitioner on visits during the orientation period, followed by annual review including home visits and notes audit by the Clinical Nurse Lead would be viewed as best practice by peers and similar health facilities.

I would be happy to provide further response if required.

Yours sincerely

Nāku iti noa, nā

Fiona Blair
NZRGON, PGCertTravMed, MN, NP"

The following further advice was sought from RN Blair:

"Thank you for your further request for advice regarding complaint reference C19HDC01647;

[RN A] and [the medical centre] regarding care provided to [Baby B] on 30 July 2019.

You note a brief request:

'Both the support worker in this case and [Ms B's] teenage daughter have stated that [RN A] asked the daughter to take the lid off third vaccine before it was administered, and that the daughter did so. [RN A] stated that she cannot recall this. I just wanted to obtain your opinion on the appropriateness of [RN A] asking the daughter to do so, and whether this was consistent with accepted standards?'

It is not unusual in my experience, in a domiciliary situation, to ask the family to assist with an individual's cares. This is with the proviso that there is no other suitable solution that can be carried out safely by the health professional, that it is safe for the client/patient, and that suitable training or coaching is provided to the family member in order to maintain hygiene standards and keep the family member safe. This may be the case for District Nurses, paediatric outreach, public health nurses etc.

In the case in question that would mean, to me, checking with the family member that they were happy to assist with the task, ensuring hands were washed prior, that the medicine/vaccine was identified by the Nurse and Family member, and ensuring that the family member did not come in contact with the vaccine.

In the case of [Baby B], I have three comments:

- That if this was Rotavirus oral vaccine, it would be easy, and usual for the Registered Nurse to remove the lid and administer the vaccine without assistance.

- If assistance were required the support worker may have been a more appropriate person to do so, and this would be another opportunity to visually and verbally check the vaccine.
- Any person who handled the live Rotavirus vaccine should be instructed to complete hand hygiene, both before and after handling the vaccine.

I hope this is helpful.

Yours sincerely

Fiona Blair”

Appendix B: Relevant Standards

The Ministry of Health's "Immunisation Standards for Vaccinators" section of the *Immunisation Handbook 2017* (Immunisation standards) sets the quality levels that all vaccinators should achieve to ensure that they can deliver safe and effective immunisation services competently. The standards apply to all vaccinators, and the term "vaccinator" applies to *any* health professional who offers a vaccinator service. The standards include the following:

> "**Standard 3: The vaccinator provides safe immunisation**
> …
> 3.8 The vaccinator uses clean techniques in the preparation and administration of all vaccines, visually checks the vaccine, checks expiry date, prepares vaccine as appropriate and uses vaccines within the recommended period after preparation.
>
> **Standard 4: The vaccinator documents information on the vaccine(s) administered, and maintains patient confidentiality**
> …
> 4.3 Having chosen the appropriate immunisation schedule, the vaccinator documents the following details:
>
> - consent obtained
> - date vaccine administered
> - vaccine type and number in the series
> - batch number and expiry date
> - injection site (eg, 'right deltoid' not 'upper arm')
> - needle length
> - that the patient was observed for 20 minutes post-vaccine …"

The New Zealand Nurses Organisation (NZNO) "Guidelines for Nurses on the Administration of Medicines" (2018) states:

> "**Prior to administration**
> Prior to administration of medication, the regulated nurse or midwife administering the medicine:
>
> - within the limits of the available information, confirms the correctness of the prescription/medication chart, and the information provided on the relevant containers;
> - ensures they are aware of the client's current assessment and planned programme of care; and makes a clinical assessment of the suitability of administration at the scheduled time of administration;
> - ensures appropriate protocols regarding the preparation, administration and documentation of controlled drugs are followed (all controlled drugs must be stored in a locked cabinet);

- checks the five rights + three: the right medicine in the right dose must be administered to the right person at the right time by the right route. The nurse is certain the client is showing the right indications and completes the right documentation before and after administration. The nurse is aware that the person has the right to refuse the medication;
- checks the expiry date of the medicine …"

In addition, the NZNO "Guidelines for Nurses on the Administration of Medicines" (2018) provides guidance for reporting adverse events such as errors or incidents. It states:

"**Reporting adverse events (errors or incidents)**
If an error is made in the administration of a medicine, the RN must take every action to prevent any potential harm to the client, and report the error as soon as possible to the prescribing health professional, the line manager or employer (according to local workplace policy). The RN must document the incident and the action taken. A reportable event form must be completed. If an EN, HCA or student nurse makes an error, this must be reported to the supervising RN as soon as possible so the above actions can be taken.

6.15.1 Implications for nursing

- The RN and EN are accountable for their actions in the administration of medicines to the Nursing Council.
- Any error or incident should be subject to an investigation; this may be internal or, if serious harm has occurred, external.
- NZNO supports a thorough, open and multidisciplinary approach to investigating adverse events. This will ensure improvements in practice can be discussed, identified and disseminated.
- An open culture is important to encourage the immediate reporting of errors or incidents in the administration of medicines."

The NCNZ Code of Conduct (2012) sets out standards defined by the Council describing the behavior or conduct that nurses are expected to uphold. It stipulates eight principles which form the framework for the code, as follows:

"**PRINCIPLE 1**. Respect the dignity and individuality of health consumers
PRINCIPLE 2. Respect the cultural needs and values of health consumers
PRINCIPLE 3. Work in partnership with health consumers to promote and protect their well-being
PRINCIPLE 4. Maintain health consumer trust by providing safe and competent care
PRINCIPLE 5. Respect health consumers' privacy and confidentiality
PRINCIPLE 6. Work respectfully with colleagues to best meet health consumers' needs
PRINCIPLE 7. Act with integrity to justify health consumers' trust
PRINCIPLE 8. Maintain public trust & confidence in the nursing profession"