Pharmacy
Pharmacist
Northland District Health Board

A Report by the
Deputy Health and Disability Commissioner

(Case 18HDC01272)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns the care provided to a five-year-old boy by a pharmacist, a pharmacy, and Northland District Health Board (NDHB) from January to March 2018, inclusive. The boy was dispensed incorrect medication, which he took for several weeks before being admitted to hospital. During his admission, a number of errors resulted in the boy continuing to receive the incorrect medication and dosage on five occasions. This report discusses the initial dispensing error, and the providers' responses following identification of the subsequent errors at NDHB.

2. The Deputy Commissioner found that the pharmacist failed to provide services in accordance with relevant standards and breached Right 4(2) of the Code. The pharmacist did not take sufficient steps to check that she was dispensing the correct medication. The Deputy Commissioner also found that NDHB failed to provide services with reasonable care and skill to the boy and breached Right 4(1) of the Code. Shortcomings included the failure of multiple NDHB staff to check the boy's medication and dose adequately, and to comply with NDHB policy regarding the use of a patient's own medications. In addition, the Deputy Commissioner made adverse comment in relation to the pharmacy's response once it was made aware of the error.

3. It was recommended that the pharmacist, the pharmacy, and NDHB provide a written apology to the boy's family. In addition, the Deputy Commissioner asked that NDHB, amongst other recommendations, conduct an audit of staff compliance with relevant policies, and consider further changes in light of the suggestions from the nursing expert advisor on this case. The pharmacy was also asked to consider amending its procedures in relation to incident management.

Complaint and investigation

4. The Commissioner received a complaint from Mrs A about the services provided to her son, Master A, by the pharmacy and pharmacist Ms B. Following initial review of the incident, concerns were also identified relating to the services provided by Northland District Health Board (NDHB). The following issues were identified for investigation:

- *Whether the pharmacy provided Master A with an appropriate standard of care between January and March 2018 (inclusive).*
- *Whether Ms B provided Master A with an appropriate standard of care in January 2018.*
- *Whether Northland District Health Board provided Master A with an appropriate standard of care in March 2018.*

5. This report is the opinion of Deputy Commissioner Kevin Allan, and is made in accordance with the power delegated to him by the Commissioner.

6. The parties directly involved in the investigation were:

Mrs A	Complainant/consumer's mother
Ms B	Provider/pharmacist
Pharmacy	Provider/pharmacy
Northland District Health Board	Provider

7. Further information was received from:

RN C	NDHB registered nurse
RN D	NDHB registered nurse
RN E	NDHB registered nurse
RN F	NDHB registered nurse
RN G	NDHB registered nurse
Dr H	NDHB senior house officer

8. Also mentioned in this report:

Dr I	Paediatric consultant
Mr J	NDHB senior pharmacist
RN K	Registered nurse
Mr L	Pharmacy director/pharmacist
Dr M	NDHB Clinical Director for Paediatrics

9. Independent expert advice was obtained from registered nurse (RN) Rebecca Conway **(Appendix A)** and pharmacist Ms Sharynne Fordyce **(Appendix B)**.

Information gathered during investigation

Introduction

10. Master A (five years old at the time of these events) had a complex medical background including spastic quadriplegia (a type of cerebral palsy[1]), and epilepsy,[2] for which he was prescribed the anti-seizure medication vigabatrin 500mg.

11. On Friday 26 January 2018, pharmacist Ms B mistakenly dispensed valaciclovir 500mg, an antiviral medication, instead of the prescribed vigabatrin 500mg. The error was discovered over five weeks later by NDHB staff during an admission to the public hospital in March 2018.

[1] Cerebral palsy is a group of disorders that affect movement and muscle tone. It is caused by brain damage during pregnancy or birth.
[2] Epilepsy is a neurological disorder characterised by seizures.

12. This report discusses the care provided to Master A by Ms B and the pharmacy in relation to the dispensing of valaciclovir, and the pharmacy's response to the error. It also discusses the care provided by NDHB, after Master A's admission to the public hospital.

Pharmacist Ms B

13. At the time of events, Ms B was the Pharmacist in Charge (PIC) at the pharmacy. She had held this position since March 2017.

14. Ms B's role included, amongst other responsibilities, leading the pharmacy team and ensuring "compliance with ethical, professional and legal pharmacy standards to ensure that every customer receives a safe, accurate and efficient dispensing service". As PIC, Ms B was also responsible for maintaining an up-to-date version of the pharmacy's standard operating procedure (SOP) manual and ensuring compliance with it.

Pharmacy

15. At the time of events, the pharmacy was owned and operated by a pharmacy company, which also owned one other pharmacy.

Pharmacy relocation and shelving layout

16. The pharmacy relocated its premises a short time prior to 26 January 2018. The pharmacy told HDC that the relocation occurred over the weekend, and staff assisted with the move, but that all staff had one day off over that weekend.

17. The pharmacy stated that following the relocation, the shelving system changed, with the introduction of a new "Propharma" shelving system, where medicines categorised as "high use" are placed in the shelving at eye-level, and the remaining medicines are shelved alphabetically on the lower shelves.

Standard Operating Procedures

18. The pharmacy's SOP "Dispensing 4 — Accuracy Check", in place at the time, stated:

> "Check the label and dispensed medicine against the original prescription and the stock supply used to dispense the medicine …
>
> Self-checking is not recommended — wherever possible the check should be done by a second person.
>
> If self-checking can't be avoided, separate the 'physical' and 'mental' activities by another task eg by dispensing another prescription."

19. The pharmacy told HDC:

> "It has always been, and still is, our organisations procedure to have two people involved with the dispensing and checking of each medication dispensed. We believe this to be 'best practice' and our daily rostering of staffing in all three of our pharmacies reflect this. Even though it is legal for a Pharmacist to dispense and check a medication on his or her own, our practice is that an additional check is carried out

> by either a pharmacy technician or another Pharmacist. Our Standard Operating Procedures reflect this currently and also did so at the time of this dispensing error …"

Dispensing error — 26 January 2018

20. The pharmacy said that on 26 January 2018 there were two pharmacists on duty (including Ms B as PIC), a dispensary technician, an intern, and a retail staff member.

21. Ms B told HDC that Master A's prescription of vigabatrin 500mg was due to be collected in the afternoon by Mrs A. She recalled that at the time of preparing Master A's medication, the retail staff member had gone home, the technician was on a lunch break, the other pharmacist was assisting to put together Master A's medications, and the intern may have been working on an urgent blister pack.[3] Ms B stated:

> "I intended to have a technician look at the dispensing prior to my final check, or if my colleague became free, I would ask him to do the final check. I was anxious to have all medicines ready, as we were expecting [Mrs A] soon. I recall going back to the bench and doing the final check because of the time frames and pressures on other staff at the time."

22. Ms B self-checked the medication prior to dispensation, instead of having another staff member check its accuracy. Ms B stated that when doing the final check of medication before dispensing, her usual practice is to "do something else and return with fresh eyes between these two steps". However, Ms B was unable to recall accurately how much time she allowed between the final check and the dispensing of the medication on this occasion.

23. Ms B mistakenly dispensed valaciclovir to Mrs A instead of vigabatrin. Ms B told HDC that during the dispensing process, evidently she selected the incorrect medicine, which "had a similar name and the same strength" as the vigabatrin.

24. In response to my provisional opinion, the pharmacy stated that four weeks' worth of medication was dispensed (75 tablets), and because the previous dispensing was in mid-January 2018, there still would have been "approximately two weeks' worth of correct medication at home to finish off".

25. In relation to the medication error, Ms B said that as a result of the new Propharma shelving layout, "there were few medicines in the 'V'-section and the two medicines in question were side-by-side". Ms B stated:

> "This is further compounded by the lack of time for team reflection on possible dispensing errors and reviewing the placement of medicines, between the move date and the date of the error."

[3] Pre-packaged medication strip.

26. The pharmacy stated:

> "The medications involved in this dispensing error were still stored alphabetically on the shelf (as they had been in the previous premises) so we believe it is unlikely that the new shelving contributed to the dispensing error."

27. In response to my provisional opinion, Ms B told HDC:

> "[A]though the medicines were also organised alphabetically at the old premises, the new premises differed in that the remaining medicines (minus the high-use medicines) were left within the alphabetical section. This resulted in a small number of medicines within each alphabetically section. Both medicines involved in this error were within the alphabetical section, side-by-side. The impact of this in a small pharmacy (due to a smaller number of medicines, compared to a large pharmacy) was overlooked and as I have stated, not yet realised at the time of the error."

28. In contrast, in response to my provisional opinion, the pharmacy submitted that the Propharma shelving was not new to the team, and stated:

> "It had been implemented at [the] Pharmacy three months prior in November 2017 and there are members of the team who had worked in both pharmacies. … We believe that the impact of different shelving or premises had on this incident is minor (if at all)."

29. The pharmacy also said that there were several other staff members on duty that day who could have carried out a second check of the prescription before dispensation.

30. Subsequently, Master A was administered 60 out of the 75 valaciclovir tablets dispensed until the error was identified in the public hospital on 5 March 2018 (discussed below). In the NDHB Serious Event Analysis (SEA) report that was completed following Mrs A's complaint to this Office, it is noted that Mrs A reported that Master A's sleep pattern had changed over this period, but she was unsure about whether his seizure activity had increased.

Public hospital admission — 2 March 2018

31. At 12.42pm on 2 March 2018, Master A presented to the Emergency Department (ED) at the public hospital, and was triaged at 1.11pm. At 2.30pm, Master A was seen in ED by a senior house officer, Dr H, and a paediatric consultant, Dr I, who diagnosed suspected aspiration pneumonia and a mild infection of Master A's PEG[4] insertion site. At 2.50pm, Master A was admitted for ongoing management. Dr H charted, amongst other medications, vigabatrin 1.5g "mane" (in the morning) and vigabatrin 500mg "nocte" (at night).

[4] A PEG (percutaneous endoscopic gastrostomy) is a flexible feeding tube that is inserted directly into the stomach through the abdominal wall.

32. In the SEA report it is noted that vigabatrin 1.5g mane was prescribed in error, and that it was unclear where this incorrect information came from, "as the patient's clinic letters and the community pharmacy records clearly state 750mg". The medication chart in the clinical records shows that vigabatrin 1.5g mane was crossed off after one dose had been administered on 3 March 2018, and re-charted on 4 March as vigabatrin 750mg mane. There is no documentation regarding this error, including who identified it.

33. Dr H told HDC that she has no recollection of being directed to prescribe 1.5g of vigabatrin, and therefore concludes that the prescription was a "human error" on her part, for which she apologised.

34. At 6.15pm on 2 March 2018, Master A was transferred to the paediatric ward. RN D was assigned to Master A.

35. RN D told HDC that at the time of admission, Master A was due his charted medications, with the exception of the vigabatrin 1.5g mane. RN D said that upon arrival on the ward, she administered one of his due medications immediately — the antibiotic Augmentin — because this was a new medication. However, because the other medications were regular medications for Master A, RN D believes that she would have asked Mrs A when Master A normally received these so that he could be given them at the same time.

Sourcing of vigabatrin

36. The NDHB SEA report states that because "[v]igabatrin is a non-formulary item at NDHB (not normally stocked) and due to the day and time of admission this medication would have to be sourced via on call services".[5]

37. The NDHB "Medicines Administration" policy states:

> "In circumstances where the medication needed is not on a ward's imprest, fax the chart to the pharmacy or, if out of hours, the duty nurse manager must always be contacted to access the medication from the emergency medication cupboard. Medication should not be borrowed from other wards/units unless first approved by the on call pharmacist or duty nurse manager."

38. The "Emergency drug cupboard" policy states:

> "
> - The emergency drug cupboard will be accessed by the Duty Manager (or approved and trained medical or surgical resource nurse) when needed outside standard pharmacy hours of Monday to Friday 8am to 4.30pm.
> - The room will contain a current list of its contents.
> - If the required medication is not in the emergency drug cupboard, call the on call pharmacist for advice."

[5] In response to my provisional opinion, Mr J (NDHB senior pharmacist) stated: "[T]o clarify vigabatrin is not on 'imprest' of the paediatric ward — the 'non-formulary' phrase is a little misleading as it is held on site via the emergency cupboard."

39. RN D told HDC that all of Master A's regular medications, except for vigabatrin, were available on the ward. She stated:

> "I prepared the other medications and I called my duty manager to see if they had the Vigabatrin in stock in the emergency cupboard. Unfortunately they did not have it there either."

40. There is no record of either a pharmacist or the duty nurse manager being called at that time. Mr J, NDHB senior pharmacist, told HDC that at the time of this incident, vigabatrin 500mg was in stock in the emergency cupboard "and could have therefore been obtained if usual procedure was followed".

41. RN D told HDC that while she had the option of calling the courier delivery service to source the vigabatrin,[6] she decided to speak to Mrs A first. RN D stated:

> "I wanted to first explain the situation regarding medication to [Master A's] mother. I cannot recall if it was his mother that offered to call her partner to bring in the medication, or whether I asked [her] if she had the Vigabatrin at home. I knew that it was a regular medication for [Master A], so I wanted to know what the options were for sourcing it quickly. [Master A's] mother offered to call her partner at home who had a supply of (what she thought was) Vigabatrin that she had been giving to [Master A] for a couple of months. She said that her partner could bring the [Vigabatrin] to the hospital within 30 minutes. This seemed like it would be the quickest way to get the medication for [Master A]."

42. RN D stated: "My only concern was ensuring that [Master A] was administered his medications as charted in a timely way."

43. Master A's own medication was provided to NDHB nursing staff for administration and storage during his hospital admission.

44. The NDHB "Self-administration of medication and patients own medications" policy (May 2017) states:

> "Administration of patients' own medication may sometimes be necessary where the hospital pharmacy cannot provide stock as the item is either not on the Pharmac HML[7] or is not routinely stocked and will take time to obtain. A pharmacist or prescriber must check the product's appropriateness for use …"

45. There is no evidence that RN D contacted the on-call pharmacist, or the prescriber, to approve the use of Master A's own medication in the circumstances. NDHB told HDC: "Although no ward pharmacist was available over the weekend, there was on call prescriber services available."

[6] In response to my provisional opinion, Mr J stated that nurses are not able to call a courier service themselves, and that they would have to go through the duty manager, who in turn would call the on-call pharmacist to arrange an emergency order.
[7] Hospital medicines list.

Administration of valaciclovir — 2–4 March 2018

46. For medicines not listed as requiring a second check on the ward, which includes vigabatrin,[8] the NDHB "Medication Administration" policy (July 2017) states that the responsibilities of the first checker include:

> "• Ensuring medication chart meets charting, prescribing and allergy/ADR [9] requirements
>
> • Ensuring appropriateness of medication, dose, route, weight and time for this patient"

47. RN D said that prior to administering vigabatrin she went through a process of checks, including checking the right patient, right medications, right dose, right route, right reason, and right documentation. She said that she was not familiar with the medication vigabatrin. RN D told HDC that she checked that the box was labelled correctly, and it is possible that she noted the writing "Valaciclovir" on the box but may have thought this was the trade name for vigabatrin. She noted that the box was labelled clearly with Master A's name and "vigabatrin". She said that the medication strip she used had only a few tablets left, and therefore it is possible that the writing on the strip may not have been read easily.

48. RN D prepared Master A's remaining medications, and a new graduate nurse, RN E, checked them. RN E said that at the time she was still in her orientation as a new graduate nurse, and has no recollection of signing off the medication, but believes she did so because she was accompanying her preceptor.[10] RN E stated:

> "It appears that the dose and name of the medication as shown on the label were correct but that we have not identified that the name of medication on the blister pack was different to the name on the label."

49. RN E further stated that the nursing environment at the public hospital was "particularly busy with almost constant pressure on staff", which she said affected her ability to focus on undertaking all checks in a "calm, uninterrupted manner".

50. At 8.30pm, RN D administered Master A valaciclovir 500mg, instead of the prescribed vigabatrin 500mg. This error was then repeated four more times by RN D and three other nurses over the following two days:

- At 8.30am on 3 March, RN C administered Master A valaciclovir 1.5g, instead of the prescribed vigabatrin 1.5g.
- At 8.30pm on 3 March, RN D administered Master A valaciclovir 500mg instead of the prescribed vigabatrin 500mg.

[8] NDHB stated, however, that as per its policy at the time of these events, a patient's own supply of medication must be checked by either a prescriber or a pharmacist prior to being supplied to the ward.
[9] Adverse drug reaction.
[10] An experienced practitioner who provides supervision during clinical practice.

- At 8.30am on 4 March, RN G administered Master A valaciclovir 750mg instead of the prescribed 750mg vigabatrin.
- At 8.40pm on 4 March, RN K administered Master A valaciclovir 500mg instead of the prescribed vigabatrin 500mg.

51. RN C told HDC that while she does not recall the incident, her usual process when administering medications is first to check the "five rights" — right patient, right drug, right dose, right route, and right time. In addition, she said that normally she would check the medication box, packaging, and medication strips against the medication chart, and check the dose against the weight of the patient when that patient is a child. RN C said that if there is any query about the dose, she will check it with a doctor.

52. In relation to the prescribed dose of vigabatrin 1.5g, RN C stated:

> "I expect that I would have checked with the doctor in [Master A's] case, and because I administered the medication, and I would not have done so if it was outside the expected range without confirmation from the doctor."

53. Further, RN C stated: "My administration of the 1.5g dose was in accordance with the prescription chart that I was working from, and likely would have been confirmed by the doctor." There is no documentation to show that RN C checked this dose with a doctor.

54. RN C stated:

> "In this instance, I must have missed the '[Valaciclovir]' writing on the packaging and the top of the medication strip, and relied on the label only which had the patient's name and the correct medication name."

55. RN G[11] told HDC that while she cannot remember what happened during her shift on 4 March 2018, the fact that she signed for having administered medication to Master A suggested to her that she would have given the medication adhering to the "six rights" of medication administration (as outlined above). RN G further stated:

> "I cannot recall at this stage whether there were any policies in place regarding administering patient's own medication. But I am sure there would have been one at the DHB, and I would have seen it at some stage."

56. RN K told HDC that the main focus of care was Master A's respiratory condition. While she does not recall administering Master A's medications, she said that her normal practice when administering a medication with which she is unfamiliar is to use the New Zealand Formulary to check that the dose is correct. RN K stated:

> "It is probable that I checked the prescribed dose of Vigabatrin in the NZ Formulary … I am really not sure and can't recall how I didn't pick up the error which is really

[11] As noted later in this report at paragraph 95, originally NDHB overlooked RN G's medication administration error, and NDHB made her aware of it only in March 2020.

> disappointing … I feel like maybe [I] missed something in concentrating more on the acuity of [Master A's] condition."

57. All the nurses involved in administering Master A the incorrect medication between 2 and 4 March 2018 told HDC that they were either not aware of the NDHB policy "Self-administration of medication and patient's own medications", or, in RN G's case, could not recall confidently whether they had seen it. Further to this, NDHB told HDC:

> "When staff were questioned following this event first being brought to our attention (November 2018), it became evident that there was poor awareness amongst nursing and medical staff of this policy."

Error identified

58. On the morning of 5 March 2018, the error was identified by RN F while she was preparing Master A's morning medications. RN F told HDC that when checking the medications, she identified that the box for Master A's vigabatrin medication contained the incorrect medication valaciclovir.

59. RN F said that after she identified that the box contained the incorrect medication, she asked the ward pharmacist to check the medications, and the ward pharmacist confirmed that the medication was incorrect. RN F said that she then asked Mrs A about the medication, and Mrs A said she thought that it was vigabatrin and had been administering it to Master A for several weeks before his admission. RN F then contacted the Ward Manager, who advised her to let the doctor and pharmacist know and to fill out an incident form, which she did.

60. RN F said that when she informed the doctor, a paediatric fellow, the paediatric fellow noted that the vigabatrin 1.5g dose had been charted incorrectly, and crossed this off the chart and re-charted the correct dose. RN F stated that she then ordered the correct medication from the hospital pharmacy and completed the incident form, but did not document the incident in the clinical records. RN F told HDC:

> "As I found this error, notified the correct people and completed an adverse event, I hold my hand responsible for not documenting this medication error in [Master A's] nursing notes at the time as I honestly thought I had done so."

61. Contrary to RN F's recollection that vigabatrin 1.5g was re-charted to 750mg on the morning of 5 March, the medication chart shows that the 1.5g dose had in fact been re-charted to 750mg on 4 March 2018.

62. At 8pm on 5 March 2018, the paediatric fellow documented in the clinical records:

> "*Note: [Master A] has been receiving Valaciclovir rather than Vigabatrin since last prescription collected (including on the ward this admission).
>
> This was provided by community pharmacy incorrectly.

This has now been rectified.

→ Parents need to be made aware of this tomorrow as mother not present this evening for me to have this discussion."

63. Subsequently, Mrs A was advised of the dispensing error by NDHB staff. However, the Clinical Nurse Manager, who was responsible for looking at adverse events, told HDC:

> "At the time of the incident I did not recognise this as an inpatient administration error but as a community pharmacy dispensing error and this is where the focus was placed."

64. Consequently, NDHB investigations into this adverse event were closed "prematurely".[12]

65. Dr I told HDC that after the incident was identified, the Ward Pharmacist contacted the National Poisons Centre on the afternoon of 5 March 2018 to seek clarification on the effects of valaciclovir on Master A. A serum biochemistry test was carried out to look at possible liver and kidney side effects, and Dr I stated that therefore he is certain that staff had considered the effects of valaciclovir on Master A, "hence the blood test and call to National Poison[s] Centre".

66. NDHB advised that vigabatrin was then re-introduced over a three-week period until Master A returned to his usual dose.

Pharmacy — notification of error and response

67. On 7 March 2018 at 8.58am, Mr J emailed the pharmacy advising of the error, noting that it "appears to have originated at [the pharmacy] on the 26th Jan 2018". The pharmacy told HDC that on receipt of this email,[13] it was immediately forwarded first to the General Manager and then to the Director and pharmacist Mr L.

Immediate response

68. The pharmacy told HDC that at the time of being notified of the error, Ms B was on leave, so Mr L took responsibility for managing the response to the incident.

69. Mr L commenced an incident form on 7 March 2018, recording all the information about the incident he had available to him at that time, and that he had attempted to contact Master A's parents the same day "but unfortunately the cellphone numbers [the pharmacy] had on file did not work". Mr L obtained an alternative number from Master A's GP practice, and on 8 March 2018 he telephoned Mrs A and apologised for the error. He also emailed Mr J on 7 March 2018, and they discussed the situation the next day.

[12] In its response to this complaint in November 2018, NDHB told HDC: "A formal NDHB Serious Event Analysis (SEA) has now been initiated so that learning can be shared across the organization."
[13] The pharmacy told HDC that initially the email was sent to an email address of the pharmacy's previous director.

70. The pharmacy told HDC that as Ms B was still on leave and due to return on 19 March 2018, it decided that "there was nothing to be gained from contacting her during her leave so a slight delay occurred … [T]he decision was made on the basis that [Mr L] was not a locum but a Director and Shareholder of the Company as well as the clinical lead Pharmacist for the Pharmacy. It seemed appropriate at the time for him to contact the parents and apologise, have contact with the hospital and commence the [Pharmacy Defence Association] Notification."

71. Mr L emailed Mr J again on 13 March 2018 to seek clarification on when the medication error was picked up at the hospital. Although the email did not specifically enquire after Master A's well-being, the pharmacy told HDC that this was part of the intention, and that it was staying apprised as to how Master A was doing. It said that Mr L did not contact the family again following 8 March 2018 because Master A was still in hospital, and they "did not want to cause extra stress on an already stressed whānau and believed he was being well taken care of".

Pharmacy Defence Association notification

72. The pharmacy did not notify the Pharmacy Defence Association (PDA) about the incident until 20 March 2018, when Mr L contacted it by telephone. The pharmacy told HDC that while it was aware of the requirement to notify PDA of the incident, "[Mr L] hadn't sent the Notification form earlier as he was under the impression that it needed to be completed before sending".[14] Further, Mr L's decision not to contact PDA earlier was based on "his experience and wisdom" and wanting to be clear about what had happened "so that he could report accurately and correctly to PDA". The pharmacy stated:

> "In [Mr L's] opinion nothing was to be gained as far as the patient was concerned by rushing the PDA process. [Mr L] wanted to understand exactly what happened so that we could address anything that needed to be done so that it didn't happen again."

73. In response to my provisional opinion, the pharmacy also said that this was not a straightforward notification as there were "a number of factors to investigate given [Master A's] health conditions, the fact that [he] was in hospital and that other health professionals were involved in the case. … Until such time as we could fully investigate and complete the form there was very little to say to PDA …"

74. It further stated:

> "What we also possibly should have done on that day [the day it was notified of the incident] is make a phone call to PDA advising them that there was a potential issue, that we were not aware of all circumstances yet and that we were investigating."

75. In response to my provisional opinion, the pharmacy stated that the PDA has since updated its incident form to say:

[14] The PDA notification form at the time of these events stated: "To enable PDA to obtain all necessary information of the incident please fill out ALL of the following boxes with as much detail as possible."

> "In the first instance please email the completed form and copy of prescriptions to PDA. We will assess the information received and contact you if we require anything further or have advice to provide about the situation. … Note: If you have already notified us about an incident by phone, you must also email us a copy of this completed form or we cannot assist you."

76. Ms B returned from leave on 19 March 2018, at which time she was first notified of the incident. Ms B noted that Mr L had commenced the PDA notification but had not sent it. She said that she followed up with Mr L on 20 March 2018 and was told that he had not received all of the information required. Ms B told HDC:

> "On [21 March 2018] I advised him that I needed to send the report to the PDA for advice and that he would need to add details and resend the report once he had received the information."

77. Ms B said that she spoke with PDA on 21 March 2018.

78. On 21 March 2018, the pharmacy sent a partially completed notification form to PDA. The pharmacy stated:

> "[W]e were not able to fully complete this document until after the meeting with [Master A's] mother so the fully completed notification form was not lodged with PDA until early April."

Contact with Mrs A and follow-up

79. On 21 March 2018, Ms B contacted Dr I to enquire into Master A's progress. On the incident form, Ms B documented that Dr I told her that Master A was "doing ok", and that he did not feel that the length of Master A's stay in hospital was due to the error.

80. On 21 and 22 March 2018, Ms B unsuccessfully attempted to contact Mrs A. On the afternoon of 22 March, Ms B contacted Mrs A successfully and apologised for the error and arranged a time to meet with her.

81. On 23 March 2018, Ms B and Mr L met with Mrs A. At that time, Ms B apologised both verbally and in writing on company letterhead, and outlined the changes the pharmacy had made to prevent a similar incident happening again.

82. The pharmacy told HDC that no separate letter of apology was given from the company because although the letter of apology was signed by Ms B, it was on company letterhead and had been approved by the General Manager, and therefore was considered to be from "all parties".

Changes made by the pharmacy

83. Ms B stated:

> "When I arrived back to work following annual leave, I learnt of the error. I initiated a meeting with all dispensary staff the following morning. We discussed how the error

> happened and actioned the separation of these medicines in the drawer. As a team, we also discussed other medicines that could pose a similar risk and relocated these."

84. The pharmacy told HDC that as a result of this error it made the following changes:

- Vigabatrin and valaciclovir have been separated in the Propharma shelving.
- Sundry/double-check labels have been attached to each of the medications that require dispensing of the medication to be circled and signed.
- It has reviewed "double-check" labels in each of its three pharmacies to ensure that all dispensaries were updated to include all currently used double-check labels.
- It has ensured that all team members are following the organisation's SOPs in relation to carrying out a second check of medications being dispensed.
- SOPs have been updated to reflect that staff should contact the PDA as soon as possible after a reportable incident occurs, even if all the information needed to complete the PDA notification report is not available.

85. The pharmacy has also provided team training in respect to:

- Recording near misses and why actions are taken to address them.
- Reviewing dispensing SOPs and the need for a second check of medication.
- Empowering staff to instigate change themselves when they identify potential issues.

Further information from Ms B

86. Ms B recalled that the dispensary was under pressure at the time she signed off Master A's medication "due to medicines requiring compounding and late blister packs in the afternoon". Ms B further stated:

> "The script count for this day was 142. This number does not reflect the additional services this pharmacy offers or the number of close control patients we serve. We were adjusting to a new workflow following the relocation of premises … Ultimately this doesn't excuse the error … I acknowledge that this error should not have occurred and that I failed in my final checking procedure."

87. In response to my provisional opinion, the pharmacy said that in addition to general dispensing, it has a small number of methadone patients and has a clozapine contract. It stated that while clozapine patients in particular can require additional time and work, on 26 January 2018, staffing levels were such that there would have been on average 4.18 scripts per hour per dispensary team member. The pharmacy said that it has measured "script numbers versus stress levels for many years" and has found that 10 scripts per hour per team member allows for accurate dispensing.

88. Ms B told HDC:

> "I am devastated that I made an error that resulted in hospitalisation and harm to a small vulnerable child. This has affected me deeply and one of my professional organisations has assisted me by providing counselling to enable me to cope with the situation. They also provided a mentor to assist me through the process. This pharmacist mentor has assisted me in analysing my role in what happened and guiding me to regain my confidence in dispensing safely again."

89. In relation to the pharmacy's response to the error, Ms B told HDC:

> "Following the decision by [the General Manager] and [Mr L] not to contact me while I was on annual leave, I would have expected [Mr L] to act on my behalf in a professional and timely manner. He did not."

90. In response to my provisional opinion, Ms B described the actions she took as soon as she became aware of the error. She stated:

> "Upon my return from leave, I contacted [Mrs A], [Dr I], and the PDA on the 23rd March. I wrote the only letter of apology to [Mrs A]. I asked [Mr L] to attend the meeting with [Mrs A], to give her the opportunity to have questions answered that I did not have the answer to (relating to the initial contact from the hospital). I initiated and held the meeting with the staff to review the error and identify other potential issues. I actioned the automatic checking label for both of the medicines involved in the error. I followed up with [Mrs A] to see how [Master A] was doing."

Changes made to practice

91. Ms B told HDC that as a result of this incident she now never carries out the dispensing and final check for the same script, and has undertaken the following:

- A review of medicine indications, appropriate dosing, and side-effects.
- Since June 2018, she has met with a peer group for advanced practice pharmacists to "review cases, do presentations and discuss new evidence".
- Training on "Meeting the Needs of Māori and reducing Health Outcome Inequity".
- Currently she is studying towards a Postgraduate Diploma in Clinical Pharmacy.

92. Ms B said that following discussions with her mentor, she now places a physical tick over all components of a medicine script, and finds that it positively reinforces each component of the checking process.

93. Ms B told HDC that she is now employed at another pharmacy "that has many pharmacists working in it for collegial support and a well-structured environment".

Further information from NDHB

94. In relation to the care provided to Master A at the public hospital and subsequent corrective actions taken by staff upon discovery of the medication errors, NDHB told HDC that it found the following:

- Insufficient investigation of the events at the time.
- Insufficient documentation about the event in the patient's notes.
- A lack of documentation of open disclosure and apology to Mrs A.
- Protocol about the use of a patient's own medication not adhered to or sufficiently socialised amongst staff.
- Nurses involved were not asked to complete a "mini" root cause analysis to reflect on their error, as is usual process following medication errors.
- Nurses involved were not made aware of medication errors at the time, but as of November 2018 are now all aware.

95. NDHB further stated that its initial review and subsequent SEA report had overlooked RN G's part in the medication administration error on 4 March 2018, but that she was made aware of her mistake in March 2020.

96. The NDHB Quality Facilitator told HDC that while speaking to Mrs A in November 2018, she acknowledged that the medication error should have been investigated fully when it occurred in March 2018, and apologised to Mrs A for this error.

97. The NDHB Quality Compliance and Feedback Manager told HDC that an audit was undertaken of all reported paediatric incidents entered into NDHB's Integrated Patient Reporting System from September 2017 to February 2018, to determine whether those events had all been investigated and responded to appropriately. She confirmed that all 54 adverse event reports completed for the paediatric ward, infant unit, and Child Health Centre had "appropriate progress notes, including a plan of action if required, and outcomes completed for each event".

98. In relation to the prescribing error that resulted in 1.5g vigabatrin being charted for Master A's morning medication instead of 750mg on the day he was admitted to the public hospital, NDHB's Clinical Director for Paediatrics, Dr M, stated that he suspects that the error was due to "human factors, and compounded by the complexity of Master A's medication list".[15] In particular, he noted that on the medication list, "clobazam 1.5 mg" may have been confused with the vigabatrin dose.

99. Dr M told HDC that Dr I attempted to discuss the error with Dr H at some point after the incident, but noted that she had left NDHB by that time, and "her recall was limited". Dr M stated that he is "not aware of [Dr H] having any more prescribing concerns than an

[15] The medication list included: vigabatrin 750mg mane, 500mg nocte; levetiracetam 400mg twice a day; clobazam 1.5mg twice a day; Scopoderm patch, a full patch every 72 hours; baclofen 7.3mg/kg daily; Cavilon dressings to PEG site.

average doctor". Dr H told HDC that Master A was on a "complex collection of specialist medication" of which she had "less awareness", and that she recognises the importance of checking the relevant formulary and seeking senior input as required. Dr H stated that she remembers having "extensive discussions around prescribing and dispensing of Master A's medication" following identification of the prescribing error, and said that she has since reflected extensively on how to minimise the risk of repeating such an error.

100. Dr M further stated that all resident medical officers (RMOs) at NDHB have access to education in relation to prescribing, and that NDHB has "excellent" clinical electronic records that reduce risk.

101. Dr H is no longer employed at NDHB. She is practising overseas and does not hold a current New Zealand practising certificate.

Changes made by NDHB

102. NDHB told HDC that it has made a number of changes since this incident, including:

- Communication of the "Self-administration of medication and patients own medications" policy (May 2017) to all paediatric ward nursing and medical staff.
- Medication safety is now also discussed regularly at paediatric ward and infant unit staff meetings.
- It is revising the paediatric admission-to-discharge planner to include a self-assessment filled in by the patient's caregiver/whānau, and usual medications.
- It is reviewing the paediatric ward and infant unit orientation manual to ensure that medication safety is addressed adequately.
- It is moving to a more open feedback system to share errors with the RMO team to heighten knowledge of clinical safety, and believes that it has established a culture of open disclosure.

103. Dr M told HDC that in future, NDHB hopes to be able to prescribe medications electronically. Further, he stated that enhanced staffing and more senior RMO presence would be key to reducing the chance of the kind of prescription error made by Dr H from happening again.

Responses to provisional opinion

104. Mrs A, Ms B, the pharmacy, and NDHB were given the opportunity to respond to relevant sections of my provisional opinion.

105. Mrs A received a copy of the "information gathered" section of my report. She had no further comments.

106. NDHB said that its Child Health Service had no further comments to make in response to the provisional report, and comments provided by Mr J have been incorporated into this opinion where relevant. RN C, RN D, and RN F all stated that they do not necessarily agree with the conclusions of the provisional report in relation to their care, but do not wish to

comment further. The Ward Pharmacist stated that nurses are routinely checking patients' own medications as required and "using our imprest drugs as much as possible".

107. Ms B accepted that not accurately checking Master A's prescription before dispensing was below the expected standard of care.

Pharmacy

108. In response to my provisional opinion, the pharmacy told HDC that it does not believe that the new premises, workflow, or staff numbers contributed to the dispensing error, and said that it acted promptly to minimise the impact of the medication error on Master A and his family. The pharmacy stated:

> "As [Master A] was in hospital the incorrect medications had already been retrieved by them and we contacted the family as soon as we could get hold of them to apologise. Those two things are paramount in our opinion."

109. In relation to the pharmacy's contact with Master A's family after NDHB had advised it of the error, the pharmacy stated that both Mr L and Ms B were representatives of the pharmacy at the time, and that together they made eight attempts to contact the family (including telephone calls and one meeting) between 7–23 March 2018. It further stated:

> "[T]here was only a one week period that no contact was made with the family. Given that [Master A] was in hospital during this time, we believe that the number of touch points with the family was appropriate in the circumstances."

110. In relation to the pharmacy's incident reporting to the PDA, the pharmacy submitted:

> "Neither the [PDA] form in use at the time or the current form says to telephone PDA immediately that an issue comes to light and in fact says in the 'first instance' email the 'completed' form. We believe it is reasonable for any Pharmacist to take from this: 1. That the PDA form needs to be completed; 2. That PDA cannot help you until it has a completed form. We note that The [PDA] is a non-profit, pharmacist support organization. Membership of PDA is designed specifically to provide assistance to pharmacists in the event of professional indemnity, public liability and statutory liability claims. It is an organisation of Pharmacist for Pharmacists (not patients). … We believe that any perceived delay in notifying PDA had no adverse impact on [Master A] or his family."

Relevant standards

111. The Pharmacy Council Code of Ethics (2011) states:

> "7.6 Ensure that you are able to comply with your legal and professional obligations and that your workload or working conditions do not compromise patient care or public safety."

112. The Pharmacy Council Competence Standards for the Pharmacy Profession (2015) states:

> "O1.4 Deliver Quality and Safe Services. … [E]nsures patients access and receive quality services and care commensurate with their health needs."

Opinion: Ms B — breach

Dispensing error

113. There is no dispute that Ms B selected and dispensed the incorrect medication to Master A on 26 January 2018 — dispensing the anti-viral medication valaciclovir, instead of the anti-seizure medication vigabatrin.

Medication selection

114. The initial error occurred when Ms B selected the wrong medication from the shelf.

115. Ms B told HDC that the medication shelving system had changed following the relocation of the pharmacy the previous weekend and, as a result, the two medications were stored next to each other, in alphabetical order.

116. I note that the pharmacy told HDC that the storage of the two medications in question were not affected by the pharmacy relocation in that they were still shelved alphabetically. In contrast, Ms B advised that as a result of the new shelving system, there were fewer medications in the "V" section, with the two medications now located next to each other. Further, she said that there had been no time for "team reflection on possible dispensing errors and reviewing the placement of medicines, between the move date and the date of the error".

117. In my view, even if the change in the position of the two medications was minor, the change in premises, and the adjustment to a new system, may have added to the pressures on the day.

Checking

118. Nevertheless, regardless of the initial selection error, the error should have been picked up during the checking procedure. The relevant SOP in place at the time required the medicine being dispensed to be checked against the original prescription, and stated:

"Self-checking is not recommended — wherever possible the check should be done by a second person."

119. The pharmacy told HDC:

> "It has always been, and still is, our organisations procedure to have two people involved with the dispensing and checking of each medication dispensed. We believe this is 'best practice' and our daily rostering of staffing in all three of our pharmacies reflect this."

120. Despite the pharmacy's SOP recommending that all medications are checked for accuracy by a second person, Ms B made the decision to self-check the medication. She explained that she made the decision because all other staff were busy and she was anxious to have the prescription ready when Mrs A arrived to collect it.

121. The pharmacy's SOP states that if self-checking cannot be avoided, staff should "separate the 'physical' and 'mental' activities by another task eg by dispensing another prescription".

122. Ms B told HDC that when carrying out a self-check for dispensing medication, her usual practice is to "do something else and return with fresh eyes between these two steps". However, she said that she was unable to recall accurately how much time she allowed between dispensing the medication and the final check.

Conclusion

123. Ms B has referred to a number of factors that she believes contributed to this error occurring and going undetected. However, at the time of this error, Ms B was the PIC at the pharmacy. Her role included leading the pharmacy team and ensuring "compliance with ethical, professional and legal pharmacy standards to ensure that every customer receives a safe, accurate and efficient dispensing service". Further, I note that the Pharmacy Council's Code of Ethics requires that a pharmacist's workload or working conditions do not compromise patient care or public safety.

124. Accordingly, Ms B still had a professional responsibility to take appropriate steps to ensure the provision of safe and accurate services, particularly given her senior role at the pharmacy. This is a fundamental part of professional pharmacy practice.

125. My expert advisor, pharmacist Ms Sharynne Fordyce, considered Ms B's error in dispensing the incorrect medication to be a severe departure from accepted standards, particularly considering that "[b]oth medications have the potential for harm if not taken, or taken incorrectly", and Master A was vulnerable owing to his medical conditions.

126. Ms B has accepted this. She stated: "I acknowledge that this error should not have occurred and that I failed in my final checking procedure."

127. While I acknowledge the steps that Ms B took to mitigate harm from this error soon after she became aware of it on 19 March 2018, which included contacting NDHB Paediatrics

and the PDA, as well as meeting with Master A's family and pharmacy staff to discuss the error, I conclude that by failing to take sufficient steps to check that she was dispensing the correct medication, which placed Master A at increased risk of harm, Ms B failed to provide services in accordance with professional standards as set by the Pharmacy Council, and breached Right 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code).[16]

128. I note that Ms B has undertaken considerable reflection on how this error occurred, and has stated that she will not self-check medications again.

Opinion: Pharmacy — adverse comment

Introduction

129. The pharmacy had a duty to ensure that it provided services to Master A with reasonable care and skill. This included ensuring that its staff provided safe, accurate, and efficient dispensing services.

130. While it is clear that Ms B made an error by selecting the wrong medication and then failing to identify the error before the medication was dispensed, this opinion considers whether there were any systemic factors that contributed to the error occurring. Further, I have also considered the adequacy of the pharmacy's response once it was notified of the error.

The pharmacy's SOPs

131. SOPs provide important guidance to staff to support them to comply with professional standards.

132. In this case, the relevant SOPs in place at the time of the incident outlined the pharmacist's responsibility to "[c]heck the label and dispensed medicine against the original prescription", and recommended that staff not carry out self-checking. The SOP stated that in situations where this cannot be avoided, staff should ensure a "fresh eyes" check by separating the dispensing and checking procedures.

133. Ms Fordyce advised that the SOPs in place at the time were "current and complete". I accept this advice.

Pharmacy environment

134. The environment in which the pharmacist is working is relevant when considering whether there were any systemic factors that influenced staff actions, including staffing, culture, and the physical layout of the pharmacy.

[16] Right 4(2) states: "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards."

135. In the week prior to this incident, the pharmacy had relocated its premises. The pharmacy told HDC that following the relocation, while the shelving systems for high-use medications had changed, this had not affected how the medications in question had been stored, which was alphabetical. However, Ms B advised that as a result of the change in shelving system for high-use medications, there was a small number of medications in the "V" area, and the two medications in question were relocated side by side. Furthermore, Ms B said that following the relocation, staff had not had the opportunity for reflection on possible dispensing errors and reviewing the placement of medicines. Ms B said that staff were also getting used to the new workflow. I note that the pharmacy believes that the different shelving or premises had little or no impact on this incident and did not contribute to the dispensing error.

136. While I note Ms B's submission that staff had not had an opportunity to reflect on potential risks as a result of the environmental and workflow changes, I consider that it would be reasonable to expect Ms B, as the PIC, to have been cognisant of the potential for errors while staff got used to the new systems and physical environment.

137. I note that the pharmacy has since separated vigabatrin and valaciclovir in its shelving, and "double-check" labels have been attached to each medication, requiring the dispensed medication to be circled and signed, which I consider to be appropriate actions.

Response to incident

Contact with family

138. The pharmacy said that immediately after being notified of the error by NDHB on 7 March 2018, it attempted to contact Mrs A but had the incorrect telephone number on file. The following day, it obtained the correct contact number, and Mr L contacted Mrs A to apologise for the error. On 7 March 2018, Mr L also contacted Mr J at NDHB and spoke to him the following day. Mr L emailed Mr J again on 13 March 2018 to seek clarification on when the hospital identified the medication error, and said that although the email did not specifically ask after Master A's well-being, that was part of the intention. The pharmacy said that as Master A was in hospital, it did not consider it appropriate to contact Mrs A again because they "did not want to cause extra stress on an already stressed whānau and believed he was being well taken care of".

139. Ms B said that following her return from leave, initially she tried to contact Mrs A by telephone on 21 March 2018, and spoke with her the following day when she apologised for the error and arranged for a meeting with Mrs A. Ms B said that she also contacted the paediatrician at the hospital on 21 March 2018 to enquire after Master A.

140. On 23 March 2018, Ms B and Mr L met with Mrs A, at which time Ms B also provided a written apology to Mrs A. Ms B said that at that time she apologised for the delay in contact.

141. Ms Fordyce advised that following an incident such as this, the accepted practice would be to make contact with the consumer or whānau as soon as possible to ascertain personally any harm done, to offer a verbal apology, and to retrieve and isolate the incorrect

medication. Ms Fordyce also considered that given the delay in Ms B's return, in this case it would have been appropriate for the pharmacy to provide a written apology earlier than the meeting on 23 March 2018, and to make regular telephone calls to the hospital to check on Master A's progress.

142. Ms Fordyce considered that the lack of contact with the family from when they were originally contacted on 8 March until 21 March 2018, after Ms B's return, was inappropriate. In relation to the pharmacy's email to NDHB on 13 March 2018, Ms Fordyce advised:

> "[It] makes no enquiry as to the patient's health, only about details the pharmacist needed to complete his report. There was, therefore, a gap of two weeks between enquiries …"

143. Ms Fordyce advised that this was a moderate departure from accepted standards.

144. I accept Ms Fordyce's advice and am critical that the pharmacy did not make more enquiries about Master A's health at the time, although I also acknowledge that it was reasonable for the pharmacy to expect that Master A was being cared for adequately in the public hospital during the time in question. I also note that the pharmacy's level of contact with the family appears to have been a well-considered decision, as it felt that its contact, together with Ms B's contact, was sufficient to ensure Master A's needs were being met, but not risk causing Master A's family additional stress.

Incident reporting

145. After notification of the error on 7 March 2018, Mr L recorded all the information about the incident he had available to him on an incident/PDA notification form; however, the PDA was not notified of the error until 20 March 2018, after Ms B had returned to work.

146. The pharmacy told HDC that while it was aware of the requirement to notify the PDA, this was not a straightforward notification and, based on "his experience and wisdom", Mr L made the decision not to notify the PDA until he had all of the facts available to him. The pharmacy stated:

> "In [Mr L's] opinion nothing was to be gained as far as the patient was concerned by rushing the PDA process. [Mr L] wanted to understand exactly what happened so that we could address anything that needed to be done so that it didn't happen again."

147. Ms Fordyce advised that following an incident such as this, the accepted practice would be to complete an incident report as soon as the pharmacy had been notified of the incident, preferably by the pharmacist who was involved in the incident, and for the PDA to be notified promptly.

148. Ms Fordyce advised:

> "In [Ms B's] absence it would have been appropriate for [Mr L], a Director of the company, and a clinical lead pharmacist for the Pharmacy, to notify PDA immediately

of the incident, and provide them with as much information as was available on an incident form."

149. Ms Fordyce considered that Mr L's failure to do so was a moderate departure from accepted standards.

150. I accept Ms Fordyce's advice that it would have been better in these circumstances for Mr L to notify the PDA immediately in order to provide the information that was available on 7 March 2018, and I note that the pharmacy has acknowledged that possibly it should have done so. However, I acknowledge Mr L's submission that he did not notify PDA immediately because, as an experienced pharmacist, he did not require guidance from PDA in how to investigate the medication incident. I accept that the pharmacy promptly recorded the information it had available in the incident form on the day it was informed about the error. While PDA may have been able to provide useful advice in how best to manage the incident, I note that primarily PDA's purpose is to provide assistance to its pharmacist members in the event of incidents such as this. Therefore, I consider that it is not unreasonable to delay contacting PDA if no such assistance is required at a given time.

Conclusion

151. As discussed above, the systems in place at the pharmacy relating to dispensing medications were reasonable. However, I am critical about the insufficient enquiries made to the hospital and the family about Master A's health after 8 March 2018.

152. I note that the pharmacy has since updated its SOPs to reflect that pharmacy staff should contact PDA as soon as there is awareness of an incident, even if full details are not known at the time.

Opinion: Northland District Health Board — breach

153. NDHB was responsible for ensuring that Master A was provided with services that complied with the Code, and for having in place adequate systems to ensure that the care delivered to Master A was safe and appropriate. In my view, there were a number of deficiencies in the care provided to Master A that arose from systemic issues at the public hospital.

Use of own medications

154. Master A arrived in the ED at 12.42pm and was admitted to the paediatric ward at 6.15pm. At that time, RN D, the nurse caring for him, identified that one of Master A's prescribed medications, vigabatrin, was not available from the ward stock medicines, and made the decision to use Master A's own supply of vigabatrin.

155. When a prescribed medication is not available on the ward and it is after hours, the NDHB "Medicines Administration" policy requires that the duty nurse manager is contacted to access the medication from the emergency medication cupboard.

156. RN D told HDC that she contacted her duty manager to see whether vigabatrin was available from the emergency cupboard stock, but was told it was not. However, there is no record of the duty nurse manager or on-call pharmacist being contacted at that time. Furthermore, NDHB senior pharmacist, Mr J, told HDC that vigabatrin 500mg was in fact available in the emergency cupboard at that time, and that had the correct process been followed, it would have been available for Master A. Accordingly, I do not accept that RN D contacted the duty nurse manager at that time.

157. RN D said that she had the option of ordering the medication through the courier delivery service, but decided to speak to Mrs A to explain the situation in the first instance. RN D said that during the conversation, it was agreed that Mrs A would arrange for Master A's own supply of vigabatrin to be brought into the hospital.

158. The NDHB "Self Administration of medication and patients own medications" policy requires that when a decision is made to use a patient's own supply of medication, the medication must be checked by a pharmacist or prescriber before use. There is no evidence that this occurred, either by RN D, or subsequently by any of the other nurses involved in administering medications to Master A between 2 and 4 March 2018.

159. All the nurses involved told HDC that they were not aware of the "Self Administration of medication and patients own medications" policy, or could not recall whether such a policy existed. Further to this, NDHB told HDC that when questioning staff after this event, "it became evident that there was poor awareness amongst nursing and medication staff of this policy".

160. My expert advisor, RN Becky Conway, advised that it is "doubtful" that staff did not know how to access medications after hours, as this is a relatively common occurrence for nursing staff working afternoon, night, and weekend shifts. RN Conway noted that there were factors that may have influenced the decision to use Master A's own medications on the evening of 2 March 2018, including pressure in administering the medication on time. RN Conway stated: "Although this is not acceptable practice, it is perhaps understandable."

161. However, RN Conway advised that when no one questioned the use of Master A's own stock of vigabatrin over the following days, this was "less acceptable" and a moderate departure from accepted standards. I accept RN Conway's advice. Regardless of the policy and whether staff were aware of it, I find it concerning that not one staff member thought to question the continued use of Master A's own stock of medicine.

Failure to identify incorrect medication

162. Nursing guidelines emphasise the five rights of medication administration,[17] which include checking the right patient, right dose, right time, and right route. As noted by RN Conway, this is "routinely taught to nursing students at an undergraduate level and again during graduate nursing orientation".

[17] NZNO 10.2 Guidelines for Nurses on the Administration of Medicines.

163. The nursing staff involved in this incident said that it is their usual process to follow these well-established rules, and they are unsure how they missed the fact that they were dispensing the wrong medication. RN D said that she may have mistaken the wording "Valaciclovir" as being the trade name, and that it is possible the medication strip may not have been easy to read. RN C said that she must have missed the "Valaciclovir" writing on the packaging and on the medication strip. RN K said that she is unclear how she missed the error, and RN G could not recall the incident.

164. I am not convinced that staff checked the medication as they said they did, and, if they did, the check was certainly not done to an adequate standard. Had they carried out adequate checks, they should have identified that they were administering the wrong medication.

165. RN Conway advised:

> "It is unfortunate that the medication box was incorrectly labelled as vigabatrin by the community pharmacy when the medication was in fact valaciclovir. Nevertheless, it is expected nursing practice that the dose and strength of a medication is checked from the printed manufacturer's marking on the blister card as well as the box. In this case, inadequate checking provided an opportunity to continue the original dispensing error."

166. RN Conway noted:

> "Safe medication checking is an everyday part of nursing practice in an acute paediatric ward. Medication checking procedure is a well-known, often talked about aspect of patient care that is covered in Domain One of the competencies for Registered nurses[18]."

167. Further to this, RN Conway advised:

> "The failure to check the medication blister card for the name and the strength of the dose is a significant departure from medication checking practice that should occur at every administration of every medication. Unfortunately, in this case this failure led to a continuation of the dispensing error. This same omission error occurred in the ward for four consecutive drug administrations, which suggests that at the time, the medication safety culture was poor."

168. I accept RN Conway's advice and agree that the fact that these errors were repeated by multiple staff on more than one occasion, points towards deficiencies in the system.

Failure to identify incorrect prescription

169. The incorrect morning dose, which was prescribed by Dr H (1.5g instead of 750mg), was administered on one occasion, on 3 March 2018. While I note that RN F said that this

[18] Domain One of the Nursing Council of New Zealand Competencies for registered nurses states: "Accepts responsibility for ensuring that his/her nursing practice and conduct meet the standards of the professional, ethical and relevant legislated requirements." Indicator: "Demonstrates knowledge of, and accesses, policies and procedural guidelines that have implications for practice."

prescribing error was identified on 5 March, I also note that the medication chart was changed after only one incorrect dose was given, such that the correct 750mg dose was administered on 4 March. As such, I conclude that RN F's recollection is incorrect.

170. RN C, who administered Master A 1.5g valaciclovir (believing it was vigabatrin) on 3 March 2018, said that while she cannot recall the details, she believes she would have identified that vigabatrin 1.5g was high for Master A's weight. She stated:

> "I expect that I would have checked with the doctor in [Master A's] case, and because I administered the medication, and I would not have done so if it was outside the expected range without confirmation from the doctor."

171. However, there is no evidence of this in the clinical records.

172. RN Conway advised:

> "[When administering a medication to a child,] [o]n each occasion that medication is administered, I would expect an administering nurse(s) to check a drug reference such as the New Zealand Formulary for Children … against the prescribed dose. If a prescribed dose falls outside the usual dose range, I would expect the nurse to check with the prescriber before administering the drug."

173. RN Conway noted that there is no indication in the clinical notes that "the nurse(s) went back to a prescriber to check the reason for prescribing a dose that was outside the expected range given in the New Zealand Formulary".

174. Accordingly, and given that RN C also failed to identify that she was administering the wrong medication, I consider it unlikely that she checked with the doctor about the vigabatrin dose.

Other comment

175. Dr H's initial prescribing error is very concerning, and she accepts that this appears to have been an individual error on her part. It is of equal or greater concern that this error was not identified quickly by the checking procedures in place at the DHB, which contributes to the overall picture of poor care provided at NDHB.

176. I note that Dr H is no longer practising in New Zealand, and that it appears she has reflected extensively on this incident to avoid a repetition of the error. I further note that NDHB has stated that all RMOs have access to education in relation to prescribing, that the electronic clinical records in use at NDHB reduce the risk of a similar prescribing error happening again, and that it appears that Dr H did not have a history of mis-prescribing and, as such, this was likely an isolated incident. In light of the above, I consider that it is not in the public interest of New Zealanders to take further action regarding Dr H in respect of her prescription error.

Incident reporting

177. The incorrect medication error was eventually identified by RN F on the morning on 5 March 2018. RN F identified that the medication contained in the box was not vigabatrin. Initially, she double checked this with the Ward Pharmacist, who confirmed that the medication was incorrect. RN F said that she then contacted the Ward Manager, informed the pharmacist and Master A's doctor, and commenced an incident form. However, RN F did not document the error in the clinical records. RN F stated that when she found the error, she notified the appropriate personnel and completed an incident form, but acknowledged that she did not document the error in Master A's clinical records.

178. RN Conway considered that although the incident reporting process was initiated as soon as the error was detected, the standard of clinical documentation in relation to the incident appears to have been inadequate. There is also limited documentation about what information was discussed with Master A's whānau. RN Conway advised that following an incident, it is good practice to document the details of the error and steps taken to address it, including disclosure to whānau, in the clinical records "at a time as close as possible to when an event has actually occurred". RN Conway further stated that it would be expected practice for the nurse in charge or the nurse who discovered the error to contact all the staff concerned as soon as possible to inform them of the error.

179. RN Conway advised that the standard of documentation relating to this error represents a moderate departure from accepted standards, and that the failure to inform relevant nursing staff of the error in a timely way was a severe departure from accepted standards. I accept RN Conway's advice.

Conclusion

180. When providing care to Master A, on a number of occasions NDHB staff could have identified that the wrong medication had been supplied, but did not, and Master A did not receive his prescribed medication for several days. I conclude that there were a number of failings in the care provided to Master A, including:

- The failure of multiple staff to comply with NDHB policy relating to the use of a patient's own medications, and obtaining medications after hours, which RN Conway advised was a moderate departure from accepted standards.
- The failure of multiple staff to check adequately that the medication and dose were correct, in accordance with accepted nursing practice. RN Conway advised that this was a severe departure from accepted standards.
- The failure to document the incident in the clinical records adequately, which RN Conway considered was a moderate departure from accepted standards.
- The failure to notify staff involved in the error, which RN Conway considered was a severe departure from accepted standards.

181. The number of errors by staff in the administration of Master A's medications is very concerning. In my opinion, the individuals involved in the errors hold some responsibility for failing to comply with appropriate standards and follow the relevant policies. However,

the failure of multiple staff to follow policies and procedures indicates a culture of tolerance where poor practice and non-compliance becomes normal. I note RN Conway's view:

> "The repetition of the same mistake over four consecutive doses, could suggest that the practices for checking medication in the ward at that time were of a poor standard, because four different nurses failed to notice the printing on the sheets of tablets that would have indicated that the medication was valaciclovir and not vigabatrin."

182. I also note that staff did not appear to have been aware of the policy for "Self Administration of medication and patients own medications", which I consider reflects a failing on the part of NDHB to ensure that its staff were fully familiar with its policies and procedures.

183. These failures meant that Master A received the wrong medication for several days, and was put at risk of harm. Accordingly, I find that NDHB failed to ensure that services were provided to Master A with reasonable care and skill, and breached Right 4(1) of the Code.[19]

Other comment

184. It is of some concern that the seriousness of the errors and omissions in this case were not recognised by NDHB at the time they happened, such that a review and serious event analysis were undertaken into the events immediately. It appears that Mrs A's complaint to this Office, several months after these events, was the instigator of NDHB's review and SEA report. Furthermore, NDHB noted that its SEA report failed to identify RN G as one of the nurses involved in the medication error, which meant that she was unaware of her error for a considerably longer time than the other nurses involved in this incident, and therefore unable to take appropriate remedial action. NDHB must do better and ensure that all adverse events involving its staff are reported and investigated in a timely, thorough, and appropriate manner.

Recommendations

185. I recommend that Ms B provide a written apology to Master A's family for her breach of the Code. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Master A's family.

186. I recommend that the pharmacy:

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

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

b) Consider amending its SOP for incident management to include a requirement for staff involved to be notified of incidents within a reasonable time frame. Evidence of this consideration and any changes should be forwarded to HDC within three months of the date of this report.

187. I recommend that NDHB:

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

b) Conduct an audit to check staff compliance with the "Self Administration of medication and patients own medications" policy. The audit should include Paediatrics and a representative cross-sample of other inpatient wards. Audit results and any actions that will be taken to address issues arising from the audit should be reported to HDC within three months of the date of this report.

c) Provide evidence, within three months of the date of this report, of the changes that have been made to the paediatric admission-to-discharge planner as a result of the review of that document.

d) Consider all the recommendations made by my expert advisor, RN Conway, in respect of its services (see Appendix A), and, within three months of the date of this report, advise HDC of the outcome of its consideration and the steps it has taken to improve its services in line with those recommendations.

Follow-up actions

188. A copy of this report with details identifying the parties removed, except the experts who advised on this case and NDHB, will be sent to the Pharmacy Council of New Zealand, and it will be advised of Ms B's name.

189. A copy of this report with details identifying the parties removed, except the experts who advised on this case and NDHB, will be sent to the Health Quality & Safety Commission, the Pharmaceutical Society of New Zealand, the Pharmacy Defence Association, and the New Zealand Pharmacovigilance Centre, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent advice to the Commissioner

The following expert advice was obtained from RN Rebecca Conway:

"**Statement of agreement to adhere to the guidelines**

I have been asked to provide an opinion in the case of [Master A] reference C18HDC01272. I have read the Guidelines for Independent Advisors and I agree to adhere to these for the purpose of this report.

Relevant training and experience

I am a Registered Nurse from a District Health Board where I have worked in a Child Health Department for 26 years. In that time have been a staff nurse on an acute children's surgical ward, a Child Health Nurse Educator, and am currently a Charge Nurse Manager of an acute children's medical unit and high dependency unit.

As an educator I developed an online medication safety module for clinical staff, and taught at a number of workshops and training days on medication safety.

As a nurse manager, I respond to reported medication incidents within my team by

- Taking measures to reduce the risk of medication error within my unit
- Interviewing staff who have been involved in medication errors
- Feeding back action points and practice issues to my team on a range of incidents
- Monitoring standards of everyday medication practice such as
    - Helping to reduce distractions during the medication process
    - Circulating information on changes in medication practice
    - Monitoring the supply and registers for controlled and recorded drugs
    - Monitoring the safe storage of vaccinations

Instructions from the Commissioner

The brief for this opinion is to review the documentation and advise whether it is considered that the care provided to [Master A] by Northland DHB was reasonable in the circumstances, and why. The documentation comprises of:

- A summary of the complaint
- A response from Northland District Health Board
- Statements of apology from three of the RNs
- Clinical documentation from [Master A's] file including
    - Emergency admission
    - Paediatric admission

- Clinical notes
- Patient transfer notes
- ECG/oximetry/
- Medication charts
- Fluid balance charts
- Enteral feeding charts
- Respiratory assessment charts
- Child observation early warning charts
- Laboratory and radiology results

The Commissioner has requested for particular comment on

1. The adequacy and appropriateness of the steps taken by the nurses when checking and administering medication
2. The adequacy of the relevant procedures in place at Northland DHB for checking and administering patients' own medication
3. Adequacy of incident reporting
4. Actions taken in the light of this incident, and any further changes that I consider may be appropriate
5. Any other matters that amount to a departure from accepted practice

For each question, the following advice is sought:

a) What is the standard of care/accepted practice?

b) If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be?

c) How would it be viewed by my peers?

d) Recommendations for improvement that may help prevent a similar occurrence in the future.

Facts and assumptions on which this opinion is based

The consumer, a five year old boy with Cerebral Palsy had been taking valaciclovir (an antiviral medication) instead of the prescribed vigabatrin (an antiepileptic medication) for a month following a dispensing error at a pharmacy.

The consumer was admitted to hospital on 2 March 2018. Three days after his admission it was found by hospital staff that his own (incorrect) medication was being used while on the ward.

Concerns are raised that four nurses at Northland DHB administered the incorrect medication for the first three days of his admission.

Expert opinion

1. The adequacy and appropriateness of the steps taken by the nurses when checking and administering medication

a) What is the standard of care/accepted practice?

Normal checking procedure for nurses who are administering a medication to a child should include:

- A check of the prescription that it:
  - Is legible and complete
  - Is appropriate for the age and weight of the child
  - Accounts for any known adverse reactions
  - Is for the right reason, patient, route, time and interval
- A check of the medication itself should include an inspection of the labelled box or container and of the foil and plastic printed blister packs where these are used. This check is for:
  - The drug name
  - Drug expiry date
  - Dose and strength

The checking procedure is routinely taught to nursing students at an undergraduate level and again during graduate nurse orientation. It is commonplace to hear nurses talking about the 'rights' of medication checking. These 'rights' refer to the right patient, drug, dose, route, time, reason, expiration and possibly other items such as drug levels and documentation (Clifton-Koeppel, 2008, p. 78).

Prescription Checking

There is increased complexity in paediatric medication management because prescribed doses are usually weight based, meaning that an extra calculation is required to check that the prescribed dose is appropriate for the weight of the child (Clifton-Koeppel, 2008, p. 73). In addition, most medications are designed for adults, which mean that paediatric medications require additional manipulation to achieve the prescribed dose (ibid. p. 73).

On each occasion that a medication is administered, I would expect an administering nurse(s) to check a drug reference such as the New Zealand Formulary for Children (NZFC, 2019) against the prescribed dose. If a prescribed dose falls outside the usual dose range, I would expect the nurse to check with the prescriber before administering the drug.

[Master A's] prescription

The prescription chart in this case has a field for dose calculation, but I note this was inconsistently completed both for the vigabatrin and for some other prescribed medications.

I am not able to tell if every nurse checked the vigabatrin prescription sufficiently every time, as this is not a task that is usually recorded. However, the medication record shows that a 1.5 g dose of vigabatrin was prescribed on March 2nd and was administered on the morning of March 3rd. This dose was double the intended dose of vigabatrin. There is no indication in the clinical note that the nurse(s) went back to a prescriber to check the reason for prescribing a dose that was outside of the expected range given in the New Zealand Formulary. This 1.5 g dose was subsequently discontinued and re-charted as a smaller dose.

Medication checking

It is unfortunate that the medication box was incorrectly labelled as vigabatrin by the community pharmacy when the medication was in fact valaciclovir. Nevertheless, it is expected nursing practice that the dose and strength of a medication is checked from the printed manufacturer's marking on the blister card as well as the box. In this case, inadequate checking provided an opportunity to continue the original dispensing error.

There are risks to using patient's own medication. Patients sometimes store their medications at home in a way that would not meet hospital standards. For example, I have known patients to place a variety of medication blister cards inside one medication box.

Whether one or two nurses should check

I note that the vigabatrin administration records for [Master A] have one signature in the area for administration indicating that only one nurse at each administration time checked the medication. There is variation across New Zealand in-patient paediatric care units on single- or double-checking policy for non-high risk medications for children and infants. Some units take the approach that all medications should be double-checked where others differentiate between medications that require single and double checks. Double checking of medications (where two nurses, rather than one) does not necessarily entirely avoid error (Clifton-Koeppel, 2008, p. 77; Dickinson, McCall, Twomey, & James, 2010, p. 731; Gill et al., 2012, p. 144). Given the vulnerability of the paediatric population double checking is sometimes thought to be a safer approach for all medications that are administered to children and infants. Children and infants are especially vulnerable to medication error because of their immature organs, because they cannot speak up for themselves and because of the extra calculations that are required (Clifton-Koeppel, 2008, p. 73).

The repetition of the same mistake over four consecutive doses, could suggest that the practices for checking medication in the ward at that time were of a poor standard, because four different nurses failed to notice the printing on the sheets of

tablets that would have indicated that the medication was valaciclovir and not vigabatrin.

Using a patient's own medication

The following two factors might have contributed to the failure to obtain hospital stock of medication for [Master A].

Firstly, the timing of [Master A's] arrival on the paediatric ward at 1815 hrs on a Friday evening may have contributed to the decision to use his own rather than dispensed medication. There was perhaps a missed opportunity in the Emergency Department where [Master A] was assessed between 1242 and 1815 to consider ordering medications from the hospital pharmacy when it was established that he was for admission. There was another missed opportunity to use hospital protocol for after-hours medication. It is not clear whether nurses knew about this protocol and decided not to use it, or whether the protocol had been poorly communicated by the pharmacy service.

Secondly, the nursing *Paediatric Admission to Discharge Planner* form lacks an area for nursing staff to list medications that a child is currently taking. It is helpful during initial nursing history taking for care-givers and paediatric nurses to discuss and review the medications that a child is currently taking. Such conversations can also include how they are best administered and stored and the child's preferences. In addition, although this form contains a multidisciplinary referral log, listing 18 specific specialist health services (including dietician, social work, and physiotherapist), it does not name a pharmacist service. If this form had contained fields for current medications and pharmacist referral, this might have triggered the process for obtaining the medication out of hours.

b) If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be?

The failure to check the medication blister card for the name and the strength of the dose is a significant departure from medication checking practice that should occur at every administration of every medication. Unfortunately, in this case this failure led to a continuation of the dispensing error. This same omission error occurred in the ward for four consecutive drug administrations, which suggests that at the time, the medication safety culture was poor.

c) How would it be viewed by my peers?

Safe medication practice is a team responsibility which should include the pharmacy, prescriber, administering nurse and the care-giver to make sure that the right dose of the right medication reaches the right child at the right time and interval, and for the right reason.

Safe medication checking is an everyday part of nursing practice in an acute paediatric ward. Medication checking procedure is a well-known, often talked about aspect of patient care that is covered in Domain One of the competencies for Registered nurses:

'Accepts responsibility for ensuring that his/her nursing practice and conduct meet the standards of the professional, ethical and relevant legislated requirements Indicator: Demonstrates knowledge of, and accesses, policies and procedural guidelines that have implications for practice.' (Nursing Council of New Zealand, 2016, p. 9)

For the reasons outlined above, this would be a serious departure from accepted practice.

I have reviewed this decision and have discussed it in general terms with a senior nurse colleague, who agrees that the failure to sufficiently check the medication *prescription and packaging* is a serious departure from accepted practice.

Safe medication checking is understood by student nurses and nurses upon graduation from training. I note that the NDHB policy (2019) includes a clear flowchart and detail about the responsibilities of the checker(s).

I note the policy document for medications that require a second independent check in paediatrics at NDHB. It might be worth considering the addition of 'any medication about which a nurse feels unsure'.

Recommendations for improvement that may help prevent a similar occurrence in the future.

- Processes for medication checking are reviewed
  - Consider the advantages and disadvantages of single versus double-checking medications that are currently single checked
  - Undertake a review of ward medication safety culture including
    - The use of drug references to check prescribed doses against the recommended dose range
    - The expected course of action for administering nurses to take when prescribed doses are outside of the recommended dose range
- Processes for recognising that medications need to be ordered are improved
  - Consider adding a prompt in the emergency department documentation
  - Consider adding a medication field in the *Paediatric Admission to Discharge Planner* form
- Information about obtaining medications after hours is reviewed to make sure that it is
  - Easy to find
  - Communicated to nurses who are new to the service

- Communicated regularly through hospital updates to help staff remember

It is good to see that the Admission to Discharge planner form is being reviewed including medication history.

2. The adequacy of the relevant procedures in place at Northland DHB for checking and administering patients' own medication

a) What is the standard of care/accepted practice?

I note from the review written by [Mr J], senior pharmacist for [NDHB] that at the time of [Master A's] admission, the staff had available:

- An on call pharmacist
- A courier delivery service for medicines
- A protocol for using a patient's own medication

It appears that none of these was used, thereby increasing the risk for error.

The summary of findings from [NDHB Quality Facilitator] lists that the protocol for using a patient's own medication was not sufficiently socialized amongst staff. It is unclear what the barriers to accessing the on call pharmacist or the after-hours courier service might have been.

b) If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be?

It is doubtful that staff did not know how to obtain medications after hours. This would be a relatively common occurrence for nursing staff working afternoon, night and weekend shifts in an acute care ward. It is more likely that because the patient's own medication was available that this was used.

It is possible that nursing staff believed that using the on call pharmacist and courier service would be costly for the DHB.

It is also possible that the timing of [Master A's] admission (early evening) and a perception that his medications had to be given on time might have added pressure to the nursing staff to administer the first dose from the patient's own medication for that first dose on March 2nd. Although this is not acceptable practice, it is perhaps understandable. What is less acceptable is that the error was repeated a further three times: subsequent nurses assuming that the medication given by the first nurse was correct, and not questioning why the patient's own medication was still being used. Failure to use the standard procedures for obtaining after hours dispensed medication in my opinion represents a moderate departure from accepted practice.

I have reviewed and stand by this decision that the failure to obtain medicines after hours according to policy was a moderate departure from accepted practice.

c) How would it be viewed by my peers?

Again, by failing to recognise a potential risk, NDHB nurses have failed to meet competency 1.4 in Domain One of the Competencies for Registered Nurses:

'Promotes an environment that enables health consumer safety, independence, quality of life, and health.' Indicator 'Identifies and reports situations that affect health consumers or staff members' health or safety … Recognises and manages risks to provide care that best meets the needs and interests of health consumers and the public.' (Nursing Council of New Zealand, 2016, p. 12)

d) Recommendations for improvement that may help prevent a similar occurrence in the future

- Ensure that information about accessing medication after hours is easy for staff to find
- Ensure that after-hours leadership, for example, a Duty Manager is easy to access and can advise staff on obtaining medicines
- Determine what barriers exist that prevent staff from following the correct procedures
- Annotate in patient medication chart where patient's own medications are being used to alert other staff (Canterbury District Health Board, 2015)

It is good to note that staff have been reminded to become familiar with the patient own medication policy. It is important that this policy is also included in orientation activities for new staff. It would be useful to find a mechanism for forcing a policy alert when patient own medications are being used, as staff who are new to practice since this incident may not have the same level of vigilance as staff who are familiar with this case. I acknowledge that it can be difficult for staff to remember the detail of policies when they are working in a busy clinical environment, juggling multiple complex tasks, thus a policy trigger could be very useful.

3. Adequacy of incident reporting

a) What is the standard of care/accepted practice?

Although the incident reporting process was initiated as soon as the error was detected, the clinical documentation appears to be of an inadequate standard.

It is likely that the initial discovery of the dispensing error was made at around 0800 hrs when the morning dose of vigabatrin was due. The documentation of the incident report occurred at 1030 hrs on March 5th, but the first entry in the patient clinical notes about the incident occurred at 2000 hrs that evening, and was made by a doctor. The nurse who discovered the error did not document this in the patient clinical notes.

A significant feature of the clinical notes is that there is no evidence that clinical staff considered the effects of valaciclovir on [Master A]. The New Zealand Formulary for

Children (NZFC, 2019) only lists valaciclovir for children from 12–18 years of age. There is no information for younger children. Given that [Master A] had received this medication for over one month it is possible he could have suffered adverse effects other than increased seizure activity from not having his correct vigabatrin dose.

b) If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be?

It is considered good practice to document in clinical notes at a time as close as possible to when an event has actually occurred (Kay, 2016). In this case the Registered Nurse [RN F], who discovered the error, did not document it in the patient's clinical notes, though her statement dated November 28 2018 does indicate the correctly initiated processes including

- Ordering the correct medication
- Informing the pharmacist
- Informing the medical staff
- Informing [Master A's] mother

However, [RN F's] clinical notes for that shift were all written at 1300 hrs. No information is written about the error and nor is any subsequent discussion with [Master A's] parents noted.

It would be expected practice to inform the family about the error as soon as possible during the same shift that it was discovered. It would be expected practice to document the discovery of the error in the clinical notes along with a description of immediate actions including:

- Filing an incident report
- Informing the medical staff, community pharmacist, the hospital pharmacist and nurse in charge
- Removing the mis-labelled medication from the medication room
- Ordering the correct medication
- Critical thinking about the effects of valaciclovir on the patient
- Consideration about the re-loading with vigabatrin

It would also be expected practice for the nurse in charge or the nurse discovering the error to get in touch with all the staff concerned as soon as possible to inform them of the error.

In my opinion, the standard of documentation represents a moderate to severe departure from the expected standard of care.

The failure to alert and counsel the other nurses who had also made this error represents a severe departure from accepted practice: these nurses had no opportunity to consider or improve their practice, thereby potentially exposing other patients to risk.

I note the statement from [RN F] outlining the sequence of events surrounding the discovery of mis-labelled medication. It is to her credit that she discovered the error and took prompt action. I understand the difficulty of not having access to the patient clinical record to document actions in a timely way. However, [RN F] could have obtained separate clinical note paper and documented her actions, then added this to the clinical record before the end of the shift. [RN F] should not have accepted the direction from the paediatric fellow to leave the documentation to her (the paediatric fellow), and should have taken professional responsibility for documenting her own record of the incident and ensuing actions.

I also note the statement from [the Clinical Nurse Manager], and the description of a range of actions that she has taken since the incident to provide education and policy awareness amongst the nursing staff.

I have reviewed my decision in this case and consider the adequacy of incident reporting to reflect a moderate departure from accepted standards.

c) How would it be viewed by my peers?

The standard of documentation regarding this incident and the standard for informing the four nurses who had made the medication errors falls below the expected standard of care that would be expected from Registered Nurses.

The Nursing Competencies that relate to this incident that were not met are listed as follows:

- Competency 2.3 describes standards for documentation; an indicator for this competency is that the nurse maintains clear, concise and timely records (Nursing Council of New Zealand, 2016, p. 16)
- Competency 2.4 is about the health consumer having adequate explanations about the effects of treatment (Nursing Council of New Zealand, 2016, p. 17)
- Competency 3.3 sets out the importance of communication between patients, families and the health care team; an indicator for this competency is that the nurse 'communicates effectively with health consumers and members of the health care team'. (Nursing Council of New Zealand, 2016, p. 27)

d) Recommendations for improvement that may help prevent a similar occurrence in the future

It is recommended that clinical staff take a more structured approach for incident reporting that includes

- Thorough documentation in the clinical notes

- Informing the family about the incident in a timely way, and letting them know the complaints process and the steps that are taken to reduce future risk (and documenting this)
- Informing the staff involved in a timely way
- Raising awareness of all relevant staff about incidents and outcomes of incidents as a learning activity

4. Actions taken in the light of this incident, and any further changes that I consider may be appropriate

a) What is the standard of care/accepted practice?

The initial incident reporting appears to have focussed on the dispensing error from the community pharmacy and not the checking errors that occurred in the hospital.

The dispensing error may have distracted hospital staff from the parts of the incident concerned with the medication checking errors that occurred in hospital.

It appears that it was not until [Master A's] mother, [Mrs A], made a formal complaint that an investigation into the medication checking errors and the process of informing the staff who made the error occurred.

b) If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be?

The standard of documentation and follow up with staff members who made the errors is of concern. This would be a moderate departure from the expected standard.

In the statements of apology from the staff who administered the doses in error, nowhere is it noted any details about the correct checking procedures and what the standards for checking should be.

I have reviewed and stand by my decision about the actions taken in the light of this incident.

I am aware of the multiple and competing demands placed on managers and clinicians in acute paediatrics wards, and understand that all of us can learn something from this case about the importance of fully investigating and following up medication incidents as soon as possible following the actual event.

I note that staff, in their statements are cognisant of the medication checking procedures and the policies for both using a patient's own medication and for obtaining medication after hours.

c) How would it be viewed by my peers?

This is covered in section 3(c)

d) Recommendations for improvement that may help prevent a similar occurrence in the future

The thorough and timely follow-up of incidents is critical to protecting patients from the risk of future harm.

5. Any other matters that amount to a departure from accepted practice

No

Rebecca Conway

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Appendix B: Independent advice to the Commissioner

The following expert advice was obtained from pharmacist Ms Sharynne Fordyce:

"I, Sharynne Fordyce, have been asked to provide an opinion to the Commissioner on Case number C18HDC01272 and have read and agreed to follow the Commissioner's Guidelines for Independent Advisers.

My qualifications include a Diploma of Pharmacy, and a Masters of Clinical Pharmacy. I have worked in Retail Pharmacy for over 30 years, both in New Zealand and in England, and also work for the Wairarapa DHB.

Background

The complaint involves a dispensing error at [the pharmacy].

The consumer, [Master A], a five year old boy with Cerebral Palsy, had been taking valaciclovir (an antiviral medication) instead of the prescribed vigabatrin (an antiepileptic medication) for a month following a dispensing error. The consumer's seizures had increased during this time.

The error was discovered while the consumer was admitted to hospital (Northland District Health Board).

Expert advice was requested on whether the care provided to [Master A] by [the pharmacy] was reasonable in the circumstances, and why.

1. The adequacy and appropriateness of the steps taken by [Ms B], the dispensing pharmacist, when dispensing and checking the prescription.

a. The standard of care, accepted practice includes the Code of Health and Disability Services Consumer's Rights 4 (1) to provide services with reasonable skill and care and 4 (2) to act in accordance with professional standards, and Competence Standard O1.4 to deliver quality and safe services. If only one pharmacist is responsible for dispensing and checking a prescription, accepted practice is to take a break in between the steps, to ensure 'fresh eyes' when carrying out the final check.

b) There has been a significant/severe departure from the standard of care due to the wrong drug being dispensed and consumed for a considerable period of time. Both the drugs involved have a high potential for harm if not taken, or taken incorrectly, valaciclovir being an antiviral medication, and vigabatrin an antiepileptic medication. The consumer is also a very vulnerable young boy due to his medical conditions.

c) This would be viewed as a significant/severe departure from accepted practice by my peers.

d) Recommendations for improvement would include physically separating these two drugs to reduce a picking error, and to ensure a time break between dispensing and

checking the same prescription, to allow for a fresh look at the final product. It is always preferable to have more than one person involved in the dispensing/checking process.

2. The appropriateness of [the pharmacy's] Standard Operating Procedures.

a) The accepted practice would be to have up to date Standard Operating Procedures (SOPs) that cover all aspects of dispensing, from accepting the prescription through to final check, including all legalities.

b) There has been no departure from accepted practice. The SOPs from [the pharmacy] were current and complete.

c) My peers would be impressed by this.

d) No further recommendations needed.

3. The adequacy of the incident reporting.

a) The accepted practice would be to complete an incident report as soon as [the pharmacy] had been notified of an incident. This preferably would be completed by the pharmacist involved in the incident, and the Pharmacy Defence Association (PDA) notified promptly.

b) There would appear to be a moderate departure from accepted practice in the reporting of the incident. [Mr L] was notified of the event on 7/3/18, but did not contact the PDA until 20/03/18 and did not submit the form until 21/03/18. This time lapse seems lax, given the severity of the incident. It would be unusual if [Mr L] was unaware of the incident notification process, or, if so, did not phone PDA to clarify matters earlier. It would appear that it was [Ms B's] repeated requests that prompted [Mr L] to finally notify the PDA and submit a report. In [Ms B's] absence it would have been appropriate for [Mr L], a Director of the company, and the clinical lead pharmacist for [the pharmacy], to notify PDA immediately of the incident, and provide them with as much information as was available on an incident form.

c) This would be viewed as a moderate departure from accepted practice by my peers.

d) Recommendations for improvement would include an SOP on Incident Reporting that emphasised the need for prompt reporting to the PDA and the prompt submission of a report that contained as much information as was available.

4. [The pharmacy's] management of this incident and the follow-up actions taken.

a) The accepted practice in such an incident would be to make contact with the consumer/family as soon as possible to personally ascertain any harm done, to offer a verbal apology, and to retrieve and isolate the incorrect medication. All staff involved would be informed and the incident discussed, preferably at a staff meeting, and plans put in place to avoid a repetition, with staff education planned. A written apology would be sent/personally delivered to the consumer/family. In this instance regular

phone calls to the hospital to check on [Master A's] progress would be appropriate. A meeting with the consumer/family to discuss changes in dispensing practice would be arranged, if family was agreeable.

b) There has been moderate departure from accepted practice with the initial delay in contacting [Master A's] family, particularly given the health impacts of the incident. There has been no mention of a written apology from [the pharmacy] which, given the delay in [Ms B's] return, would have been appropriate and timely. There also had been no communication with the hospital, or [Master A's] family from the initial contact on the 8/3/18 until the 21/3/18, a long delay.

c) These would be regarded as moderate departures from accepted practice by my peers.

d) Recommendations for improvement would include ensuring patient details are updated, and ensuring the need for a prompt written apology is included in [the pharmacy's] Complaints SOP.

5. Whether the changes undertaken by [the pharmacy] since the events in question are appropriate, and any further changes that may be considered to be appropriate.

a) The accepted practice would be to discuss the incident at a staff meeting with all the staff, and to put in place new procedures to prevent the incident happening again. Also to ensure all SOPs were current, appropriate and read by all the staff. That the pharmacist involved reviewed their personal dispensing practice, and received mentoring if appropriate.

b) There has been no significant departure from accepted practice.

c) This would be approved by my peers.

d) Recommendations would include separate storage for the two medications involved, preferably in physically separate areas, with appropriate signage.

6. No other matters."

Ms Fordyce provided the following further expert advice on 15 July 2020:

"Despite the new information provided by yourself and [the pharmacy] about case18HDC01272 I do not wish to change my advice as given in the document you hold in your records. The email dated 13/3 from the pharmacist to the hospital makes no enquiry as to the patient's health, only about details the pharmacist needed to complete his report. There was, therefore, a gap of two weeks between enquiries as stated in my original report. I hope this reply helps.

Kind regards

Sharynne Fordyce"

Ms Fordyce provided the following further expert advice on 9 August 2020:

> "On paper the staffing levels would appear to be sufficient for the number of prescriptions done that day, and fit well within [the General Manager's] figures, which would appear to have been extensively researched. Prescriptions and customers, however, vary widely in complexity and time consumption, and very rarely come into [the pharmacy] in a well regulated flow. Always ensuring adequate staffing levels for all situations is notoriously difficult in retail pharmacy. It is this unpredictability that causes stress with dispensing staff, as can new surroundings. Not having a dedicated retail staff member present at the time of the error would have also added pressure to the dispensing staff and increased the potential for distractions — I am not sure how busy the shop was during the time the error was made. Ultimately, however, whilst mentioning the issue, [Ms B] does not blame staffing levels for the error, and accepts full responsibility.
>
> Kind regards
>
> Sharynne"