Pharmacist, Ms B

Pharmacist, Ms D

Pharmacy Technician, Ms C

Pharmacy

A Report by the

Deputy Health and Disability Commissioner

(Case 15HDC00183)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

Factual background

1. On 20 November 2014, Ms A visited a pharmacy (the Pharmacy) to have a prescription filled for her son, Master A, aged seven years. Master A has cerebral palsy and was prescribed baclofen (a muscle relaxant and antispastic agent).

2. Pharmacist Ms B processed the prescription, pharmacy technician Ms C compounded the baclofen, and pharmacist Ms D checked it. The Pharmacy dispensed 10mg/ml of baclofen for Master A instead of the prescribed 10mg/10ml, meaning that Master A was dispensed ten times the strength prescribed.

3. Following the dispensing error, Master A presented to the Emergency Department at a public hospital on three occasions with increased seizures, shortness of breath and deep breathing with salivation, and was assessed on each occasion by paediatric registrar Dr F.

4. On the third presentation, on 23 January 2015, the dispensing error was identified by a hospital pharmacist and reported to the Pharmacy. The Pharmacy apologised to Ms A and undertook an investigation.

Deputy Commissioner's findings

5. By failing to process the correct strength of baclofen and failing to check the appropriateness of the dose on 20 November 2014, pharmacist Ms B failed to provide Master A with services in accordance with professional standards and, as such, breached Right 4(2)[1] of the Code.

6. By failing to check accurately the strength of baclofen being dispensed, and failing to check the appropriateness of the dose on 20 November 2014, pharmacist Ms D failed to provide Master A with services in accordance with professional standards and, as such, breached Right 4(2) of the Code.

7. Non-compliance with the Pharmacy's Standard Operating Procedures by multiple staff played a significant part in Master A receiving the incorrect medication. Accordingly, the Pharmacy did not provide services to Master A with reasonable care and skill and breached Right 4(1)[2] of the Code.

8. Adverse comment is made about pharmacy technician Ms C's failure to check the strength of the medication against the prescription, and failure to identify that the strength of the baclofen she selected and compounded was different to the strength listed on the prescription.

9. Adverse comment is made about paediatric registrar Dr F's failure to perform further investigations on 23 January 2015, having been aware that Master A was receiving

[1] Right 4(2) states: "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards."
[2] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."

40mg of baclofen daily. This was especially concerning given that previously, on 19 December 2014, Dr F believed that Master A was having an adverse reaction to as little as 6mg baclofen daily.

Recommendations

10. It was recommended that Ms B and Ms D each undertake assessments through the New Zealand College of Pharmacists and apologise to Master A and Ms A for their breaches of the Code; the Pharmacy conduct an audit of staff compliance with dispensing SOPs and apologise for their breach of the Code; and both Ms C and Dr F review their practice in light of the comments in this report.

Complaint and investigation

11. The Commissioner received a complaint from Ms A about the services provided by the Pharmacy to her son, Master A. The following issues were identified for investigation:

- *Whether pharmacist Ms B provided Master A with an appropriate standard of care in November 2014.*
- *Whether pharmacy technician Ms C provided Master A with an appropriate standard of care in November 2014.*
- *Whether pharmacist Ms D provided Master A with an appropriate standard of care in November 2014.*
- *Whether the Pharmacy provided Master A with an appropriate standard of care in November 2014.*

12. An investigation was commenced on 6 August 2015. This report is the opinion of Meenal Duggal, Deputy Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

13. The parties directly involved in the investigation were:

Master A	Consumer
Ms A	Complainant, consumer's mother
Ms B	Pharmacist
Ms C	Pharmacy technician
Ms D	Pharmacist
Ms E	Pharmacy director
The Pharmacy	Provider
Dr F	Paediatric registrar
District Health Board	

Also mentioned in this report:

Dr G	Paediatrician

Ms H	Speech therapist

14. Independent pharmacy advice was obtained from pharmacist Mr Paul Vester **(Appendix A)**.

Information gathered during investigation

Background

15. Master A, aged seven years at the time of events, has cerebral palsy[3] and was prescribed baclofen.[4] Ms A is Master A's mother.

Prescription

16. On 20 November 2014, paediatrician Dr G prescribed Master A baclofen 10mg/10ml to be administered at 2ml three times daily for seven days (a total of 6mg daily), increasing by 2ml every seven days until a dosage of 8ml three times daily was reached (a total of 24mg daily).[5]

17. The New Zealand Medsafe data sheet for baclofen states that for children:

> "Treatment should usually be started with a very low dose, e.g. 0.3mg/kg a day, in divided doses. The dosage should be raised cautiously, at about 1 to 2 week intervals, until it becomes sufficient for the child's individual requirements. The usual daily dosage for maintenance therapy ranges between 0.75 and 2mg/kg body weight."

Dispensing

18. On 20 November 2014, at approximately 12pm, Ms A arrived at the Pharmacy to have Master A's prescription dispensed.

19. At 12.11pm on 20 November 2014, pharmacist Ms B entered Master A's prescription into the Pharmacy computer system and generated the dispensing label. The Pharmacy's Standard Operating Procedure in place at the time of the incident, *B1.3 Entering a New Prescription*, required the pharmacist entering the prescription to check that the dose prescribed was within appropriate limits, and that the generated label was correct. The SOP also stated: "Dispensing is to be done in accordance with the Code of Ethics, Code of Good Manufacturing Practice and Pharmacy Legislation."

20. Ms B entered the prescription as 10mg/ml rather than the prescribed amount of 10mg/10ml.[6] This was ten times the dose that was prescribed to Master A. The dispensing SOP also required:

[3] A term used to describe a group of impairments that affect motor skills and posture.
[4] Prescribed to minimise episodes of spasticity and back thrusting.
[5] This was the first incidence of baclofen being prescribed to Master A.
[6] The ratio of 10mg/10ml baclofen is the same as the ratio of 1mg/1ml baclofen.

> "Before placing the label on the container … check the drug, strength and quantity of the medication against the prescription … the label also needs to be checked against the prescription — drug name, strength … ALWAYS CHECK LABEL AND MEDICATION AGAINST THE PRESCIPTION NOT EACH OTHER."[7]

21. Ms B told HDC:

> "Looking back at the prescription, I have clearly chosen the wrong strength baclofen mixture from the dropdown list of mixtures and this would have printed an incorrect label and job sheet … At this stage I did not undergo a clinical check[8] and I do not remember discussing with any staff member anything about the prescription and it would have been left aside to compound[9] at a later time."

22. Ms B said that she did not contact the prescribing doctor on 20 November 2015 as she "did not realise that the dosage was incorrect or to be questioned at the time of processing".

23. After Ms B generated the label, pharmacy technician Ms C did not identify the error on the label, and compounded the baclofen as 10mg/ml, as stated on the label, rather than 10mg/10ml, as stated on the prescription. The dispensing SOP in place at the time of events, *B1.4 Dispensing and Checking a Prescription*, required: "[W]hen selecting the medicine from the shelf, check the drug name and strength against the prescription. NEVER CHECK AGAINST THE LABEL."[10] The dispensing SOP also required that if the prescription was dispensed by a technician, "the prescription must be checked by a pharmacist".

24. Ms C told HDC that she compounded the baclofen using baclofen and Ora-blend[11] and had the final product checked by pharmacist Ms D.

25. Ms D performed the final check of the medication. The checking SOP in place at the time of events, *B1.5 Checking Prescriptions*, required Ms D to check that the label had the correct dose on it, and that the medication dispensed was the correct dose. It also required Ms D to consider the appropriateness of the dose. The Final Checking SOP, *B1.6 Final Checking of Dispensed Prescriptions*, required Ms D to check that the dispensed medication was the correct strength. It also required Ms D to check the appropriateness of the dose of the dispensed medication.

26. Ms D told HDC:

> "I performed the final check only on the compounded liquid. I checked the consistency of the mixture and checked the varying doses matched those on the prescription. I checked the strength prescribed was 10mg/ml, this was the strength

[7] Emphasis in the original.
[8] Determining the appropriateness of a prescription for an individual patient by assessing it against a number of factors such as age and weight.
[9] Where an individual combines, mixes or alters ingredients of a drug to create a medication.
[10] Emphasis in the original.
[11] Ora-blend® is a sweetened oral suspending vehicle used to simplify the process involved in the compounding of oral suspensions.

> on the batch sheet, but when I checked it against the prescription I failed to detect it was written as 10mg/10ml as 10mg/ml was the strength [another hospital] had recently requested we make all baclofen mixtures. However I misread the prescription and this was not the correct strength. I did not calculate the dose for weight which I should have done, and I am unsure whether I discussed the prescription with other staff."

27. The Pharmacy has a guide called *The Dispensing Procedures: A Guide to Eliminating Errors*, which provides checks and procedures that are considered necessary for the Pharmacy's staff to avoid dispensing errors, and requires that the dosage be checked at all stages of the dispensing process.

28. The baclofen was dispensed by the Pharmacy as 10mg/ml with two repeats to be dispensed by 18 February 2015.

29. After the medication was dispensed, Ms A began giving the baclofen to Master A, in accordance with the instructions on the prescription, and the dispensing label. Accordingly, over the following weeks Master A received ten times the amount of baclofen he had been prescribed.

Visit to Emergency Department — 10 December 2014

30. On 10 December 2014, Master A was taken to the Emergency Department because he had unusual breathing and a possible seizure. Paediatric registrar Dr F assessed Master A. Dr F documented that Master A's chest was clear and that he appeared "undistressed" and well on examination. Master A's weight was documented as 20.18kg.

31. It is documented that Ms A informed Dr F that Master A's baclofen dosage had been increased from 4ml three times daily, to 6ml three times daily, in the previous 24 hours. This increase was in accordance with the instructions on the prescription from Dr G. Dr F advised HDC: "A known side effect of baclofen is that it can lower the threshold for seizures."

32. Master A was discharged with a plan to reduce the baclofen to 4ml three times a day and to return to hospital if he had a seizure that lasted for more than five minutes. At this stage it was not identified that the dispensed medication was 10mg/ml rather than 10mg/10ml. Ms A continued to give Master A baclofen in accordance with the new dosage recommended by Dr F.

Consultation with speech therapist Ms H

33. On 18 December 2014, Master A saw speech therapist Ms H. Ms H identified that Master A was at a high risk of aspiration[12] and was coughing on his food and fluids. Ms H referred Master A to the Emergency Department for an urgent

[12] Inhalation of material (eg, food or fluid) into the air passages.

videofluoroscopy[13] and possible nasogastric feeding.[14] Ms H documented that Ms A would take Master A to the Emergency Department the following day.

Visit to Emergency Department — 19 December 2014

34. On 19 December 2014, Master A presented at the Emergency Department in accordance with Ms H's instructions. Dr F assessed Master A. It is documented that Ms A informed Dr F that she had reduced Master A's dosage of baclofen further to 2ml three times daily owing to a possible increase in seizure events and abnormal behaviours. Ms A informed Dr F that since the reduction in baclofen, Master A's symptoms had improved.

35. Dr F assessed Master A and documented that she discussed his presentation with a paediatric emergency care specialist and the decision was made for Master A to be discharged. Dr F advised Ms A to give Master A thickened fluids to minimise the risk of aspiration, and to give Master A the prescribed antibiotic (Augmentin) if he became chesty or short of breath. Dr F also advised Ms A to return to the hospital if Master A deteriorated or had ongoing difficulties breathing. Dr F discharged Master A from the Emergency Department. At this stage it was not identified that the dispensed medication was 10mg/ml rather than 10mg/10ml.

36. In this respect, Dr F told HDC:

> "I had no clinical reason to suspect that the dose strength dispensed initially was different from the dose strength prescribed by [Dr G]. The side effects reported by [Master A's] mother were certainly possible at the dose I believed he was getting, and therefore I had no reason to suspect that he was being (inadvertently) overdosed."

37. Ms A continued to give Master A baclofen.

Visit to Emergency Department — 23 January 2015

38. On 23 January 2015, Master A was referred to hospital by Dr G because of concerns regarding "chronic aspiration of thick/thin fluids, poor weight gain in the past year — for initiation of nasogastric feeds and review. Also concerns re: ? increased spasticity." Dr F assessed Master A. Master A's weight was documented as 18.28kg. Dr F told HDC: "Whilst he appeared well cared for, he was now thinner than previously, with reduced muscle bulk and fat stores and his tone seemed to be increased." Dr F also documented that Ms A informed her that Master A had a "long standing weak cough".

39. Dr F documented that Ms A told her that the family had reduced Master A's baclofen further to 2ml twice daily owing to an increase in symptoms including breath holding, eye rolling episodes and hypotonia.[15]

[13] A moving X-ray study that is useful in evaluating how food/liquid moves from the mouth to the oesophagus. This type of test is used to evaluate, diagnose, and treat specific swallowing problems.
[14] A nasogastric tube carries food and medicine to the stomach through the nose.
[15] A state of low muscle tone often involving reduced muscle strength.

40. Dr F also documented that Master A's medication currently included "baclofen 2ml [twice daily] (10mg/ml) — i.e. 20mg [twice daily] (approx. 1mg/kg/dose)". Dr F told HDC that she noticed for the first time that Master A had been dispensed baclofen at the strength of 10mg/ml. Dr F stated: "Whilst at the time I was aware that this was the upper limit for the recommended daily dosage of baclofen, I was aware that it was still within the recommended range."

41. Dr F's documented treatment plan for Master A included multidisciplinary team review, and blood tests to check his nutritional status and thyroid function.

42. Master A had a nasogastric tube inserted.

43. That afternoon a hospital pharmacist identified the dispensing error by the Pharmacy during her medication reconciliation of Master A's medication. Later that day, the hospital pharmacist informed the Pharmacy of the dispensing error.

44. Following the identification of the dispensing error, Master A's baclofen dosage was reduced to 1ml of 10mg/ml twice daily.

45. On 24 January 2015, Master A was discharged home by a registered medical officer with a referral for a home care nurse to visit him to support the family with the introduction of nasogastric feeding.

Consultation with Dr G — 27 January 2015

46. On 27 January 2015, Dr G reviewed Master A. Dr G documented:

> "[Master A's] recent video fluoroscopy on 20.1.15 reveals silent aspiration associated with all phases of dysphasia.[16] Hence a nasogastric tube was inserted in [ED] on 23.1.15 and made nil by mouth. It is possible that some of the abnormalities on video fluoroscopy may have been related to complications from high doses of baclofen."

Further contact with the Pharmacy

47. On 27 January 2015, Ms A returned to the Pharmacy to make a complaint. Charge pharmacist Ms E told Ms A that she was able to make a formal complaint to HDC, and instructed her how to submit a complaint online. Ms E informed HDC that during the conversation, she apologised to Ms A for the error. Ms E also completed an internal investigation to determine how the error occurred.

48. On 28 January 2015, after the internal investigation was completed, Ms E wrote a letter of apology to Ms A on behalf of the Pharmacy (signed by Ms D, Ms C and Ms B). Ms E outlined how she considered the error occurred, and informed Ms A of procedural changes the Pharmacy had made to avoid such an error in the future. (These changes are outlined below.)

[16] One in a group of speech disorders in which there is impairment of the power of expression by speech, writing, or signs, or impairment of the power of comprehension of spoken or written language.

49. Ms E also told HDC that on the day Master A's prescription was dispensed there were no staff away.

Action taken by the Pharmacy

50. On 28 January 2015, Ms E completed an incident form for the dispensing error on 20 November 2014. Ms E told HDC:

> "I, along with the other pharmacists, believe that the error occurred because the prescription was written as Baclofen 10mg/10ml rather than the standard formation of 10mg/ml. … To further compound this, the pharmacy had received a phone call from [another hospital] Pharmacy on 14 November 2014 asking us to change the strength we make for another child from 2mg/ml to 10mg/ml as this was the standard formulation."

51. Ms E told HDC that the Pharmacy has made changes to its dispensing procedures to ensure a similar mistake does not occur in the future. The Pharmacy introduced a new dispensing policy, *B6.6a Policy For Dispensing New Extemporaneous Suspensions*, which includes:

> "1. When receiving the prescription tell the patient or caregiver that the suspension will take 2 hours to be prepared.
>
> 2. When processing a new prescription of an extemporaneous suspension for a patient stamp the prescription with the stamp 'DOSE APPROPRIATE CHECK CHECK'.
>
> 3. Dispense 1 week only initially then monthly dispensings — this is especially important if there is an increasing dose regime for this suspension.
>
> 4. 2 pharmacists are to check the calculation (on prescription — stamp).
>
> …
>
> 6. 2 pharmacists are to check the final product and label and sign the job sheet and prescription beside the third part label, except on Saturday where a pharmacist and intern will do the final sign off."[17]

52. Ms B, Ms C and Ms D have all confirmed that they have changed their practice to ensure compliance with the new SOP.

Master A's current condition

53. Ms A has informed this Office that Master A enjoyed food, and that his quality of life decreased because of the nasogastric feeding. Master A is now unable to be fed orally and receives food via a percutaneous endoscopic gastrostomy tube.[18]

[17] The words "except on Saturday where a pharmacist and intern will do the final sign off" have been handwritten on the document.
[18] A tube that is inserted into the stomach through the abdomen. The tube is used to supply nutrition when a person has trouble eating.

Relevant professional standards

54. The Pharmacy Council of New Zealand's Competence Standards for the Pharmacy Profession (2011) states:

> "2.3.2 For each medicine, checks the dosages and methods of administration are optimal
>
> Examples of Evidence:
>
> Assesses efficacy & safety of medicine recognising pharmacokinetic factors, e.g. age, weight …
>
> 6.2.2 Follows workplace dispensing criteria when dispensing a prescription item.
>
> …
>
> 6.4.4 Identifies patient factors likely to affect the efficacy or safety of specified medicines
>
> Examples of Evidence:
>
> e.g. age, weight, pregnancy, breast-feeding, disabilities, allergies, risk factors, other medicines
>
> …
>
> 6.6.2 Maintains a logical, safe and disciplined dispensing procedure
>
> Examples of Evidence:
>
> Selects correct product, dose form and quantity for each prescribed medicine. Dispenses off prescription, not label."

55. The Pharmacy Council of New Zealand publication *Safe Effective Pharmacy Practice* (2011) states:

> "1.2 Take appropriate steps to prevent harm to the patient and public.
>
> …
>
> 5.1 Be accountable for practicing safely and maintain and demonstrate professional competence relative to your sphere of activity and scope of practice."

Responses to provisional opinion

56. Ms A received the "information gathered" section of the provisional opinion and had no further information to add.

57. Ms B, Ms D, Ms C and the Pharmacy were provided with an opportunity to respond to the provisional opinion. They accepted the findings of the provisional opinion and had no further information to add.

58. Dr F provided a response and reiterated that Master A was admitted for review of his feeding and nutrition. Dr F said that she did not consider that there was "any indication for acute investigations in the ED setting".

59. Dr F stated:

> "In such circumstances investigations tend to be guided by multi-disciplinary team (MDT) input, which include review by speech and language therapist, physiotherapist, occupational therapist and a dietitian. I requested this input."

60. Dr F also stated:

> "It is common in paediatric practice to round doses up or down for ease of administration. I now accept that, although this practice may be applicable to other medications, given the toxicity of baclofen and the risk for dosing error that I should have been more diligent in prescribing the dose as exactly 1mg/kg/dose."

61. Dr F has reviewed her practice in light of the findings of the provisional report. Dr F said she has made the following changes:

> "(a) I now routinely cross check clinic letter medication doses with those from community pharmacy records and with the patients medications if available when I prescribe.
>
> (b) I have familiarised myself with the Medsafe data sheet on baclofen and its side effects.
>
> (c) I have since worked in an outpatient rotation in both developmental paediatrics and paediatric rehabilitation where I was supervised in the prescribing of baclofen. This included initially starting this medication and reviewing the dosage regime with the patient's family, with the premise that the dose is started at a low dose, and increased slowly, until the clinical effect is achieved or until the development of any side effects.
>
> (d) I provided advice on what side effects to monitor and arranged for telephone and clinic follow up to ensure the medication was tolerated.
>
> (e) I have also now been made aware that in some centres, baclofen is mainly prescribed using tablet form in 2.5mg increments to avoid errors such as the one that occurred in this case. The oral tablets remove the need for a pharmacy to mix up a formulation, and the risk for error with this, but also remove the issues of using a suspension that needs to be dispensed every 2

> weeks as the solution can be unstable, and the risk of dosing error when drawing up the liquid medication."

62. Dr F stated: "I would again like to express my sincerest apologises to [Master A] and his family for the upset and distress caused by the delay in identifying the baclofen medication dispensing error"

Opinion: Introduction

63. On 20 November 2014, Master A was dispensed the incorrect strength of medication — baclofen 10mg/ml rather than baclofen 10mg/10ml. Because of this dispensing error, Master A received ten times the prescribed strength of baclofen in every dose he was given. For the avoidance of doubt, I note that during my investigation no concerns were raised regarding the standard of care provided to Master A by Dr G. For this reason, this report relates only to the care provided to Master A by the Pharmacy, Ms B, Ms D, Ms C and Dr F.

Opinion: Ms B — Breach

64. The error occurred when Ms B entered the medication into the Pharmacy's computer system. Ms B selected the incorrect strength of baclofen 10mg/ml from the dropdown list on the computer instead of the prescribed strength of baclofen 10mg/10ml. This generated a label that listed the incorrect strength.

65. As a registered pharmacist, Ms B is responsible for ensuring her adherence to professional standards. The Pharmacy Council of New Zealand (PCNZ) competence standards, outlined above, require that registered pharmacists ensure that they "maintain … a logical, safe and disciplined dispensing procedure" and assess the efficacy & safety of medicine having regard to pharmacokinetic factors such as the age or weight of the consumer. The PCNZ code of ethics requires registered pharmacists to be accountable for practising safely and for "maintaining and demonstrating professional competence". I also note that the SOPs in place at the time of the incident required Ms B to enter the prescription into the computer system correctly, and to check that the dosage prescribed was appropriate for the individual patient and within appropriate limits.

66. My expert advisor, pharmacist Paul Vester, advised:

> "By choosing to dispense the 10mg/ml formulation, then the starting dose of 2ml is a dose of 20mg, repeated three times a day in a 7 year old child! This should have immediately raised a concern to be clarified with the prescriber."

67. Ms B failed to identify the correct strength of baclofen in accordance with the prescription and consequently entered the incorrect strength into the Pharmacy computer system. In addition, Ms B failed to identify that the entered strength of 10mg/ml at the prescribed dose would not be appropriate considering Master A's age, which was listed on the prescription. Maintaining a logical, safe and disciplined dispensing procedure, including assessing the efficacy and safety of medicine, are fundamental aspects of pharmacy practice, and are requirements of both the Pharmacy Council of New Zealand professional standards and the Pharmacy SOPs.

68. By failing to identify the correct strength of baclofen listed on the prescription, and by failing to check the appropriateness of the strength of the medication for Master A, Ms B failed to provide Master A with services in accordance with professional standards and, as such, breached Right 4(2) of the Code.

69. I note that Ms B has accepted her error, and that she now undertakes a clinical check on new prescriptions, which includes checking the efficacy and safety of the medicine for the consumer.

Opinion: Ms D — Breach

70. Ms D checked the dispensed medication and failed to notice that the prescription had been entered incorrectly and, subsequently, that the medication had been compounded at the incorrect strength. Ms D accepts that she failed to identify the error during the checking procedure.

71. As a registered pharmacist, Ms D is responsible for ensuring her adherence to professional standards. The Pharmacy Council of New Zealand (PCNZ) competence standards, outlined above, require that registered pharmacists ensure that they "maintain … a logical, safe and disciplined dispensing procedure" and assess the efficacy and safety of medicine having regard to pharmacokinetic factors such as the age or weight of the consumer. The PCNZ code of ethics requires registered pharmacists to be accountable for practising safely and for "maintaining and demonstrating professional competence".

72. I note that the Pharmacy also had a number of SOPs of relevance at the time of the incident. The SOPs required Ms D to check the accuracy of the dosage listed on the label, and the dosage of the dispensed medication against the prescription. The SOPs also required her to consider whether the dosage was appropriate.

73. My expert advisor, pharmacist Paul Vester, advised:

> "By choosing to dispense the 10mg/ml formulation, then the starting dose of 2ml is a dose of 20mg, repeated three times a day in a 7 year old child! This should have immediately raised a concern to be clarified with the prescriber."

74. Ms D failed to identify that there was a discrepancy in strength between the baclofen compounded by the pharmacy technician and the strength listed on the label, compared with the strength of the baclofen listed on the prescription. In addition, Ms D failed to identify that the dispensed strength of 10mg/ml would not be appropriate considering Master A's age, which was listed on the prescription. Checking that the correct medication is being dispensed and assessing the efficacy and safety of medicine are fundamental aspects of pharmacy practice, and are requirements of both the Pharmacy Council of New Zealand professional standards and the Pharmacy's SOPs.

75. By failing to identify the discrepancy between the baclofen strength compounded and the baclofen strength listed on the prescription, and by failing to check the appropriateness of the strength of medication dispensed, Ms D failed to provide Master A with services in accordance with professional standards and, as such, breached Right 4(2) of the Code.

Opinion: Ms C — Adverse comment

76. Ms C was the pharmacy technician who compounded the solution of baclofen.

77. Ms C compounded the baclofen at the strength listed on the incorrect label, instead of the strength listed on the prescription. Ms C did not check the label against the prescription as per the Pharmacy's SOPs.

78. I note that the SOPs in place at the time of the incident state that during the selection and dispensing of a medication, the strength of the drug must be checked against the prescription, never the label.

79. Ms C failed to identify that the strength of the baclofen she selected and compounded was different to the strength listed on the prescription. Ms C accepts that she compounded the baclofen at an incorrect strength. I am critical that Ms C did not check the strength of the baclofen that she compounded, against the prescription.

80. I do, however, acknowledge that, as recognised by the relevant professional standards and the pharmacy SOPs, it is the pharmacists in charge of the dispensing who are ultimately responsible for the safe dispensing of medication.

81. Ms E told HDC that at the time SOP *B.6 One-off Compounding* was implemented, there were no pharmacy technicians employed at the Pharmacy. Ms E said that the SOP has now been amended to reflect Ms C's employment. The revised SOP requires that if a pharmacy technician is performing the calculations during the dispensing process, a pharmacist will double check the calculations.

Opinion: The Pharmacy — Breach

82. The Pharmacy was responsible for ensuring that services were provided to Master A with reasonable care and skill. This includes the need to ensure staff compliance with its policies and procedures. Pharmacies are responsible for the operation of services provided by their staff and can be held responsible for any individual failures by staff. While the individual pharmacists and pharmacy technician also bear responsibility for the deficiencies in the care provided, I am of the view that the deficiencies were also a result of issues at the Pharmacy.

83. It is very concerning that both pharmacists and the pharmacy technician failed to adhere to the SOPs. The SOPs for dispensing and checking prescriptions provided a number of opportunities to check the medication against the prescription. If each step of the SOP had been adhered to, it is likely that the error would have been identified and corrected before Ms A left the Pharmacy with the medication.

84. Consumer safety is of the utmost importance, and I consider that it is the responsibility of the Pharmacy to ensure that every staff member complies with the SOPs in order to prevent harm to patients. The PCNZ, in its document "Writing Standard Operating Procedures", has stated that procedures are the cornerstone of a strong quality system, and support meeting the overall goal of providing the public with safe and effective medical products.

85. I acknowledge that, for the most part, the Pharmacy's SOPs appear to be satisfactory. However, I am concerned that more than one staff member failed to follow the SOPs. Staff members failed to identify the correct strength of the medication listed on the prescription, failed to consider the appropriateness of the strength of medication dispensed, and failed to check the dispensed medication against the prescription adequately. Without staff compliance, policies become meaningless. Ultimately, the Pharmacy had a responsibility to ensure that all staff complied with the SOPs and provided services of an appropriate standard.

86. In my opinion, non-compliance with the SOPs by multiple staff played a significant part in Master A receiving the incorrect medication. Accordingly, I consider that the Pharmacy did not provide services to Master A with reasonable care and skill and breached Right 4(1) of the Code.

Opinion: Dr F — Adverse comment

87. I have concerns about paediatric registrar Dr F's failure on 23 January 2015 to identify that there were issues with Master A's dosage of 20mg twice daily.

88. On 23 January 2015, Dr F documented: "[B]aclofen 2ml [twice daily] (10mg/ml) — i.e. 20mg [twice daily] (approx. 1mg/kg/dose)." Dr F told HDC:

> "Whilst at the time I was aware that this was the upper limit for the recommended daily dosage of baclofen, I was aware that it was still within the recommended range."

89. The dosage of 20mg twice daily amounted to a total of 40mg daily. The Medsafe datasheet for baclofen states that, for children under the age of 10, "The usual daily dosage for maintenance therapy ranges between 0.75 and 2mg/kg body weight."

90. On 23 January 2015, Master A's weight was recorded as 18.28kg. Accordingly, the upper limit for Master A on 23 January in accordance with the Medsafe data sheet was 36.5mg daily.

91. Dr F told HDC:

> "I had no clinical reason to suspect that the dose strength dispensed initially was different from the dose strength prescribed by [Dr G]. The side effects reported by [Master A's] mother were certainly possible at the dose I believed he was getting, and therefore I had no reason to suspect that he was being (inadvertently) overdosed."

92. I am critical that Dr F was aware that Master A was receiving 40mg daily on 23 January 2015, yet failed to perform any further investigations regarding dosage, especially given that previously, on 19 December 2014, she believed that [Master A] was having adverse reactions to as little as 6mg baclofen daily."

Recommendations

93. I recommend that Ms B:

a) Arrange for an assessment through the New Zealand College of Pharmacists regarding the processing of prescriptions and processes for dispensing and checking medications, and provide evidence to this Office within three months of the date of this report, confirming the outcome of this assessment.

b) Provide a written apology to Master A and Ms A 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 Ms A.

94. I recommend that Ms D:

a) Arrange for an assessment through the New Zealand College of Pharmacists regarding the processing of prescriptions and processes for dispensing, and provide evidence to this Office within three months of the date of this report, confirming the outcome of this assessment.

b) Provide a written apology to Master A and Ms A 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 Ms A.

95. I recommend that Ms C review her practice in light of my comments in this report and report back to this Office on her learning, within three weeks of the date of the this report.

96. I recommend that the Pharmacy:

a) Conduct an audit of three months' compliance with the SOPs for dispensing, and report the results of the audit to HDC within four months of the date of this report.

b) Apologise to Ms A 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 Ms A.

97. I recommend that Dr F review her practice in light of my comments in this report and report back to this Office on her learning, within three weeks of the date of this report.

Follow-up actions

98. a) A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Pharmacy Council of New Zealand and the District Health Board, and they will be advised of Ms B's and Ms D's names.

b) A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Pharmaceutical Society of New Zealand (College Education and Training Branch), the Health Quality and Safety Commission, and the NZ Pharmacovigilance Centre.

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

Appendix A: Independent advice to the Commissioner

The following expert advice was obtained from pharmacist Mr Paul Vester on 7 November 2015:

"I have been asked to provide an independent opinion on case number 15/00183 (Master A). I have read and agreed to follow the Commissioner's Guidelines for Independent Advisors.

I am a current practising pharmacist and co-owner of two pharmacies. I qualified as a pharmacist with a Diploma in Pharmacy becoming registered as a pharmacist in 1981. I have worked as a pharmacist since qualifying, first as pharmacist for 2 other Pharmacies before buying my own business in 1989, then forming a partnership in 1999 for our current business. I have qualified as a preceptor trainer and had 6 interns over the last 10 years. We currently employ 20 staff (including 6 fulltime pharmacists). I was a founding member, and one time chairman of the Midland Community Pharmacy group, which developed many new pharmacy services for not only The Midland area but also New Zealand. This included helping set standards, developing reporting templates, and developing Standard operating procedures and policies. I am currently also engaged by the New Zealand Pharmacy Council as one of the pharmacists developing and critiquing the scenarios for the final assessment day for Pharmacy Interns, and as an assessor on those days.

1. The adequacy of the care provided to [Master A] by [the Pharmacy] and, if appropriate, please include specific comment on the care provided by individual pharmacists.

The source of this whole error would seem to be not recognising the dose. This has 2 components which contributed to this failure:

a. The technician and two checking pharmacists not recognising that the dose was written as 10mg/10ml (which is a much less common dose form) and not the more common 10mg/ml dispensed.

b. The two checking pharmacists not recognising that the dose being dispensed was very likely to be incorrect due to its very high dose of baclofen in mg per dose.

As a pharmacist myself I recognise this is one of those errors that 'make your blood run cold' and you are left wondering how this could ever happen, but mistakes like this do, and probably will always occur (hopefully very, very, rarely).

As to the adequacy of care, the pharmacists did not follow the part of the SOPs regarding 'checking if dose is appropriate', but this was not due to the SOPs not being an adequate standard as a whole. [The Pharmacy] is a busy pharmacy (70 prescription items dispensed in the hour 12 to 1pm on that day when the script was presented). In my assessment, with only 1 Pharmacist and 1 Technician, to compound a mixture as well in that time was not a wise choice, however not

outside normal parameters of pharmacy practice (as timeliness of presentation of prescription to pick up is often a major patient concern).

As for the after care and response to [Ms A], Pharmacist [Ms E] gave accurate information, directed her as to next steps in pursuing a complaint, and obviously apologised. Requests for information from the Hospital and HDC have been responded to promptly, are very complete in their scope and at no time sought to deny blame or delay progress in the resolution of the error.

2. Whether or not the prescriber should have been contacted by the Pharmacist/individual pharmacists and if so, when and why.

Had the error in dosage been identified, I believe the prescriber would have been contacted, as the dose the Pharmacists and Technician have interpreted it, is very high. This should have been recognised in the check on 'dose appropriateness' in the Standard Operating Procedures. By choosing to dispense the 10mg/ml formulation, then the starting dose of 2ml is a dose of 20mg, repeated three times a day in a 7 year old child! This should have immediately raised a concern to be clarified with the prescriber. As the starting dose for adults is 5mg three times daily and children 0.3mg/Kg ([Master A's] weight could have been asked of his Mother), and a review of the Data sheet from Mylan (available in the dispensing computer) for baclofen states that in respect of higher doses: 'doses of 100mg to 120mg may be given to supervised (adult) patients in hospital'.

3. The appropriateness of [the Pharmacy's] relevant Standard Operating Procedures (included in [the Pharmacy's] response to the complaint dated 9 February 2015).

I believe the Standard Operating Procedures and Policies in place at the time of the error (One-Off-Compounding B6.6 revised 15/04/11), would be of a standard that I think would currently pass audit for New Zealand Pharmacy.

These documents contain all the steps to dispense the presented prescription correctly, and whilst the changes made subsequently should make an error less likely, if the Technician and 2 checking Pharmacists (as on the day of the error) just do not see the error then no policy or procedure will stop that.

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

Repeating what I have also stated above, in my assessment of the information presented I believe Pharmacist [Ms E] gave accurate information, directed her as to next steps in pursuing a complaint, and obviously apologised. The Pharmacy owner and staff have responded to requests for information from the Hospital and HDC promptly, are very complete in their scope and at no time sought to deny blame or delay progress in the resolution of the error.

The Pharmacy has also made changes to their Standard Operating Procedures and Policies regarding 'One-off Compounding' and introduced 'B6.6a Policy for Dispensing New Extemporaneous Suspensions' to make their chances of having

another error as small as they are able, which addresses the 'Expected results' detailed by [Ms A] in her HDC website complaint submission.

5. Whether changes undertaken by the Pharmacy, [Ms B] and [Ms D] since the events are appropriate.

The change made to the Standard Operating Procedures and Policies regarding 'B6.6 One-off Compounding' now includes 'check pharminfotech.co.nz for standardised Formulations of oral liquids and use wherever possible' is a good idea as it should introduce a further re-appraisal of the formulation and strength (even more important if only One pharmacist and technician entering the mixture).

The introduction of 'B6.6a Policy for Dispensing New Extemporaneous Suspensions' is a very good idea as it addresses the issues of time pressure and also introduces a further check on the 'Dose appropriate?' with two Pharmacists being charged with responsibility to do that.

6. Any other aspects of the care provided to [Master A] by the Pharmacy that you wish to comment on.

In regards to the Pharmacy and its staff, this error has obviously and appropriately caused much anguish, and not been denied or trivialised. It is the type of error a Pharmacist would never envisage themselves making, resulting in a thorough reappraisal of their processes and responsibilities, which as the error cannot be reversed, is an appropriate response to prevent a reoccurrence. Had this been done in their procedures before the error, it may have been prevented, but hindsight they say is 20:20.

Pharmacy dispensaries have become increasingly busy environments, and in my experience over the last 30 years or so, there are less Extemporaneous Suspensions to make, but they have become, in large, potentially more life threatening. To this end my thoughts on reducing errors in their compounding would be that the prescribing of extemporaneous mixtures become done to standard formulae (as was the directive of [another Hospital's] protocol) and especially that the dose in mg of the medication be the only allowed dose form written. So in this error situation, even if the 10mg/10ml was missed the writing of a dose of 2mg three times daily (not the quantity as 2ml) would have prevented the error. This does not however remove the Pharmacists' responsibility to check 'dose appropriateness' in all situations.

Paul Vester 7/11/15"