Waitemata District Health Board

A Report by the

Health and Disability Commissioner

(Case 13HDC00756)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. On 25 January 2013, Miss A, aged two and half years, suffered four epileptic seizures and, at 4.10pm, was taken by her mother to the Emergency Department (ED) at a public hospital (Hospital 1). Miss A was assessed by registered nurse (RN) RN I and by paediatric emergency specialist Dr H. Dr H noted that Miss A had not responded to her usual anti-epileptic medication and recommended that, if she had further seizures, Miss A be given phenytoin, a different type of anti-epileptic medication. Miss A's care was then transferred to the paediatric team.

2. Miss A suffered further seizures, and paediatric registrar Dr E prescribed intravenous (IV) phenytoin. Dr E and RN I inserted an IV line in Miss A's left hand. They flushed the line and checked for patency, and then bandaged the IV site. The phenytoin infusion was commenced at 6.35pm and completed at 7.34pm. At 7pm RN I handed over care of Miss A to RN J.

3. Dr E did not give specific instructions about how Miss A should be monitored during the infusion. Miss A did not receive one-on-one monitoring, and there is no record that Miss A was monitored during the infusion or that the IV site was checked.

4. Following completion of the infusion, Miss A was transferred to the Paediatric Ward. She suffered a further seizure, and nursing staff on the ward checked the IV site, which was purplish with swelling in the arm. Nursing staff alerted the on-call registrar, who ordered a further half-dose of phenytoin to be given via an IV line in Miss A's right elbow. Miss A was monitored during the infusion and during the night. At 4.30am nursing staff noticed a blister on Miss A's hand, and, following assessment by the on-call registrar, Miss A was transferred to another hospital (Hospital 2) for treatment of an extravasation injury.

5. The Commissioner found that a combination of factors led to Miss A receiving inadequate monitoring during the phenytoin infusion in the ED. Dr E did not give specific instructions about monitoring, and Waitemata District Health Board's (Waitemata DHB) policies did not specify that children receiving IV phenytoin infusions should have cardiac and blood pressure monitoring and be observed for signs of respiratory depression. There were also staff failures to follow policies that were in place. In addition, the Commissioner found evidence that the care provided to Miss A suffered because of staffing issues. These factors demonstrated a systemic failure by Waitemata DHB to provide services to Miss A with reasonable care and skill and, accordingly, Waitemata DHB breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[1]

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

Complaint and investigation

6. The Commissioner received a complaint from Mrs A about the services provided to her daughter, Miss A, at Hospital 1. The following issue was identified for investigation:

   - *Whether Waitemata District Health Board provided an appropriate standard of care to Miss A in January 2013.*

7. The parties directly involved in the investigation were:

Mrs A	Consumer's mother
Waitemata District Health Board	Provider
RN B	Registered nurse/provider
RN C	Registered nurse/provider
RN D	Registered nurse/provider
Dr E	Paediatric registrar/provider
Dr F	Registrar/provider
Dr H	Paediatric emergency specialist/provider
Dr G	Paediatrician/provider
RN I	Registered nurse/provider
RN J	Registered nurse/provider
RN K	Registered nurse/provider
RN L	Registered nurse/provider
Ambulance service	Ambulance service/provider

Also mentioned in this report:

Dr M	Paediatric consultant
Hospital 1	
Hospital 2	

8. Independent expert advice was obtained from paediatrician Dr Roger Tuck (**Appendix A**) and registered nurse Wendy Sinclair (**Appendix B**).

Information gathered during investigation

Background

9. Miss A, aged 2 years and 6 months at the time of these events, has a history of generalised epilepsy[2] that had been resistant to medical therapy. She has had multiple admissions to hospital for management of her epilepsy, and was being treated with a number of medications for her prolonged seizures, including sodium valproate, clobazam, and buccal midazolam.[3] Miss A also had some developmental delay and progressive ataxia[4] exacerbated by her medication.

[2] A form of epilepsy characterised by generalised seizures with no apparent cause.
[3] Anticonvulsant medications. Miss A was also being treated with melatonin, a hormone naturally produced in the brain to help regulate a person's internal body clock. Patients who suffer from epilepsy

10. This report concerns an incident where Miss A suffered an injury to her hand, which was diagnosed as an extravasation injury, following intravenous (IV) administration of anticonvulsant medication.[5] Extravasation occurs where certain types of IV medication are administered incorrectly. Extravasation can occur where an IV line is not inserted correctly, or as a result of "tissuing", where the patient's vein ruptures and, as a result, blood leaks into the surrounding tissue. Extravasation can lead to oedema,[6] causing pain and tissue damage, and even necrosis,[7] depending on the medication.

Presentation at Emergency Department

11. On 25 January 2013, Miss A had four seizures, which were each witnessed by her mother, Mrs A, and each lasted approximately one minute. Mrs A noticed that Miss A went blue around the lips during the seizures. During the fourth seizure, Mrs A gave Miss A 1ml buccal midazolam and the seizure stopped.

12. Mrs A called the ambulance and, according to the ambulance service's records, Miss A arrived at Hospital 1's Emergency Department (ED) at 4.10pm. At 4.20pm, Miss A was assessed by registered nurse (RN) RN I, who recorded Miss A's weight (13.6kg) and vital signs, including her score on the Glasgow Coma Scale[8] (GCS), all of which were within normal limits.

13. Paediatric emergency specialist Dr H told HDC that she reviewed Miss A within five to ten minutes of RN I's assessment. Dr H recorded her assessment in the clinical notes. She noted that Miss A had had no further seizures since the midazolam had been given at 3.30pm. Dr H also recorded that recently Miss A had had a barking cough and a hoarse voice, but had otherwise been well. When Dr H examined Miss A she was drowsy but rousable, which Dr H told HDC was in keeping with the dose of

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have lower levels of naturally occurring melatonin. There is mixed evidence about whether melatonin is an effective or appropriate treatment for epilepsy. Melatonin is approved for use in New Zealand in the treatment of insomnia, under the name Circaden (Medsafe Data Sheet, 28 June 2011).

[4] A neurological sign consisting of a lack of voluntary coordination of muscle movements. Ataxia is a non-specific clinical manifestation implying dysfunction of the parts of the nervous system that coordinate movement.

[5] Miss A's clinical notes refer in numerous places to a diagnosis of extravasation. During the course of the investigation Waitemata DHB stated that it is unclear whether the injury Miss A suffered was caused by extravasation or by purple glove syndrome, a rare complication of IV phenytoin administration that causes swelling, discolouration and pain and may occur with or without concurrent extravasation. In response to the provisional decision Waitemata DHB stated that a number of factors suggest that Miss A's injury was more likely to have been a purple glove injury than extravasation.

[6] Swelling due to fluid accumulation.

[7] Damage to skin cells resulting in premature death of the cells.

[8] A neurological scale that aims to give a reliable, objective way of recording the conscious state of a person for initial as well as subsequent assessment. A patient is assessed against the criteria of the scale, and the resulting points give a patient score between 3 (indicating deep unconsciousness) and either 14 (original scale) or 15 (the more widely used modified or revised scale).

midazolam, as well as being in a postictal state.[9] Miss A was also mildly hypotonic,[10] but had no increased work breathing and her chest was clear.

14. Dr H recorded that she assessed Miss A as having a cluster of breakthrough seizures, which may have been secondary to croup.[11] Dr H told HDC that, as she felt that Miss A was at high risk of having further seizures, she referred her to the general paediatric team for ongoing observation and further management if required. Dr H documented her recommendation that if Miss A had further seizures she could be given a loading dose of an anti-epileptic medication such as phenytoin[12] or phenobarbitone,[13] but that phenobarbitone was not an ideal choice.[14] Dr H also recommended that a dose of steroid could be considered if Miss A demonstrated symptoms and signs of croup.

Assessment by paediatric team

15. RN I stated to HDC that Dr H told her that if Miss A had another seizure, to take a very calm approach and become concerned only if the seizure lasted longer than five minutes. RN I said that Dr H suggested that they put EMLA cream[15] on Miss A, in case they needed to insert an IV line.

16. RN I told HDC that, while she was applying the EMLA cream, Miss A had another seizure lasting around 10–20 seconds. RN I said that there was no frothing at the mouth, vomiting or change in colour during the seizure. Following the seizure, RN I asked paediatric registrar Dr E to assess Miss A.

17. RN I told HDC:

> "Whilst my back was turned briefly, [Miss A's] mother pressed the emergency bell. More staff arrived but I assured them the paediatric registrar and I were handling the situation. I put a heart rate monitor on [Miss A] whilst the Paediatric Doctor [Dr E] applied oxygen. Both (oxygen) saturations and pulse rate were within normal limits."

18. At 5.15pm, Miss A's vital signs were recorded on the Observation Sheet in the nursing clinical notes as "P[ulse] 120,[16] R[espiration rate] 24,[17] O[xygen] saturations

[9] An altered state of consciousness after an epileptic seizure. It usually lasts between 5 and 30 minutes, but sometimes longer in the case of larger or more severe seizures, and is characterised by drowsiness, confusion, nausea, hypertension, headache or migraine, and other disorienting symptoms. Additionally, emergence from this period is often accompanied by amnesia or other memory defects. It is during this period that the brain recovers from the trauma of the seizure.
[10] Low muscle tone.
[11] A respiratory condition usually triggered by an acute viral infection, characterised by a loud barking cough.
[12] An anticonvulsant medication, discussed further below.
[13] A widely used anticonvulsant medication.
[14] Dr H did not note why.
[15] EMLA cream is a topical anaesthetic agent used for needle insertion and minor dermatological procedures.
[16] Normal rate for a child aged 1–3 years is 70–110 beats per minute.
[17] Normal rate for a child aged 1–3 years 22–34 breaths per minute.

98% O/A [on air]"[18] (ie, within normal limits). No other vital signs are recorded, and there are no further recordings of vital signs during Miss A's stay in the ED.

19. Dr E told HDC that she saw Miss A at 5.15pm and remained involved in Miss A's care until her shift ended at 7pm. Dr E stated that she reviewed Miss A's documented notes, observation recordings and laboratory investigations for this admission, as well as her previous electronic records. Dr E then re-elicited a patient history from Miss A's mother and examined Miss A. Dr E made a detailed record of her assessment at 5.28pm.

20. RN I stated that she was asked by the nurse from the Resuscitation area[19] to help with another patient shortly after Miss A's seizures and, as Dr E was reviewing Miss A and would be able to assess Miss A post seizure, RN I felt it was safe to leave her. RN I further stated that, after she had assisted in the Resuscitation area, she was advised by the Associate Clinical Charge Nurse that two further patients had arrived in ED, and that Miss A had had a further seizure. RN I told HDC: "We received further patients at 1730(hrs) and the paediatric area was full with nine patients to two nurses …"

Placement of first IV line

21. Dr E stated that during her initial examination of Miss A, she observed her to have two generalised tonic-clonic[20] seizures of short duration with postictal state. Dr E told HDC:

> "Whilst [Miss A] was postictal I placed an (24G)[21] intravenous line (IVL) to the left dorsum of her hand,[22] took bloods for a blood glucose level and assessed the IVL for patency.[23] As per my usual practice, I flushed the IVL[24] after it was placed to check patency, and again after initially taping; as the line can tissue during these times and if they do, then I take out the line and look to place another. However, the IV lines I placed in [Miss A] were all patent at the time I completed these procedures."

22. Dr E stated that the line was then taped with the assistance of RN I, using a back board to the volar[25] aspect of the hand/wrist/forearm and tape. Dr E stated that "this initial taping ensured that the insertion point of the IVL was [as] maximally visible as taping would allow".

[18] Concentration of oxygen in the blood. Normal levels are 95–100%.
[19] Most EDs have a resuscitation area where the most seriously ill or injured patients are treated.
[20] Tonic-clonic seizures (formerly known as grand mal seizures) are a type of generalised seizure that affects the entire brain. Tonic-clonic seizures are the seizure type most commonly associated with epilepsy.
[21] 24 gauge, which refers to the size of the cannula, with 14 being a large cannula and 24–26 the smallest.
[22] The back of the hand.
[23] Patency refers to the IV line being patent, ie open (not blocked) and correctly placed, allowing the treatment administered through the IV line to flow directly into the patient's vein.
[24] IV lines are flushed with saline solution when inserted in order to check for patency.
[25] Palm of the hand.

23. RN I also told HDC that, when Dr E flushed the IV line, there was no evidence of swelling or tissuing, so they splinted and bandaged the IV line.

Prescription of phenytoin

24. Dr E recorded that she discussed Miss A with the on-call neurologist and with paediatric consultant Dr M. Dr E told HDC that, following those discussions, she decided to give Miss A a loading dose of IV phenytoin (270mg, calculated based on 20mg/kg) because of her ongoing seizure activity. Dr E also prescribed dexamethasone (a steroid medication) to treat Miss A's croup, and recorded that Miss A would be admitted to the ward after completion of the phenytoin infusion. Dr E recorded no instructions regarding monitoring during the phenytoin infusion, but she stated to HDC that it was her expectation that monitoring and supervision of Miss A would occur "via the attending nurse as per the usual monitoring protocols".

Phenytoin

25. Phenytoin is an anticonvulsant drug used primarily in the management of complex partial seizures and generalised tonic-clonic seizures. Local side effects of peripheral IV phenytoin infusion can include oedema, discolouration, and pain in the distal limb (described as "purple glove syndrome"). This may or may not be associated with extravasation. Cardiovascular side effects can include low blood pressure, slow heart rate, other irregularities and, rarely, cardiac arrest. Phenytoin has been implicated as a possible cause of myocarditis[26] related to drug hypersensitivity. The Medsafe datasheet for phenytoin (6 June 2012) states that continuous monitoring of the electrocardiogram (ECG)[27] and blood pressure are essential for patients being administered phenytoin. It also states that patients should be observed for signs of respiratory depression, and cardiac resuscitative equipment should be available.

Administration of phenytoin

26. According to the clinical records, Miss A's phenytoin infusion was started at 6.35pm and finished at 7.34pm. Miss A's phenytoin infusion was administered via an infusion pump.[28]

Care provided by RN I

27. RN I told HDC that, prior to the infusion commencing, she and another nurse "read the protocol" (discussed further below), checked the medication, and ensured that they had the correct equipment for the infusion. RN I also stated that before the infusion commenced, the infusion pump alarmed twice while she was in the room, because she had not unclipped the tubing lock.[29] RN I further stated:

[26] Inflammation of the heart muscle.
[27] Monitoring of the electrical activity of the heart.
[28] A device that delivers fluid in controlled amounts, sometimes used to regulate the rate at which IV medication is administered.
[29] There is a tubing lock on the IV line, which is a plastic device used to "lock" and "unlock" the IV line in order to prevent/allow the IV medication to flow from the infusion pump through the IV line and into the patient. Infusion pumps alarm when there is an issue with the administration (for example, if the medication cannot flow through the IV line because the tubing lock is on).

> "Before starting the infusion the Paediatric Doctor decided to flush the line again. She flushed it … and asked me to flush it as well as we both knew it was patent. I flushed the IV line and felt no resistance and observed no swelling around the site that would alert me to the fact that the line was tissued."

28. Dr E told HDC that, when she provided Mrs A with an update regarding Miss A's management plan, Mrs A told her that the infusion pump had alarmed.[30] Dr E told HDC that she was reassured by the attending nurse (RN I) that the IV line was still patent without signs of tissuing or any other concerns.

29. RN I stated that the infusion itself ran smoothly and did not alarm "in the last 25 minutes [she] was with [Miss A]". At 7pm, RN I handed over Miss A's care to RN J (discussed further below).

Placement of second IV line

30. Dr E told HDC that between 6.35pm and 7pm she took the opportunity to place a second IV line in the right antecubital fossa[31] (ACF) while Miss A was drowsy. Dr E stated that she did so because Miss A had known difficult IV access on previous presentations to ED, and because it seemed prudent to provide additional vascular access in case it should become necessary later. Dr E stated that she verbally advised RN I that if the infusion alarmed again, to swap the infusion to the new IV line.

Care provided by RN J

31. At 7pm RN J began her shift and took over care of Miss A from RN I. RN J stated that during handover the emergency bell went off, and she and other staff went to Miss A's room. RN J said that it was unclear why Mrs A had pressed the bell, "but it was not an emergency; we left within minutes".

32. RN J told HDC that, later, Mrs A again pressed the emergency bell. The infusion pump was alarming because the phenytoin infusion had finished. RN J said that she asked Mrs A why she pressed the emergency bell, and that Mrs A said she had done so because she could not reach the nurse call bell. RN J said that she pressed the "hold" on the infusion pump[32] in order to move Miss A, and added: "I completely forgot I had pressed 'hold' because I was in the middle of [attending to another patient]; I went back to [attending to the other patient]."

33. RN J stated that subsequently the emergency bell went off again, and she and a bureau nurse went into the room and turned off the infusion pump. The bureau nurse said that she would flush the IV line while RN J continued attending to the other patient. RN J told HDC: "At no time did the machine show an occlusion. At no time did [Mrs A] mention that [Miss A] was upset/sore hand, etc."

34. Waitemata DHB was unable to provide a statement from the bureau nurse concerned.

[30] Dr E did not state what time this conversation occurred.
[31] The triangular area on the anterior view of the elbow.
[32] Pressing "hold" on an infusion pump temporarily suspends the functioning of the infusion pump.

Monitoring

35. RN I told HDC that she placed Miss A on cardiac monitoring in her room rather than moving her to another room, (a resus room), because the ED was short staffed and she felt that Miss A was "stable enough to remain on monitoring in [her room]".

36. Waitemata DHB provided a statement from ED Associate Clinical Charge Nurse RN L, who said:

> "The [ED] was short staffed … [The paediatric area] was meant to have had three RNs but due to illness/roster shortfall this was reduced to two nurses between the hours of 1500–1900. Given the workload and number of children in this area, this was not ideal but within accepted guidelines. […]
>
> … [F]or the most part each patient [in a resus room] requires one on one care. Should [Miss A] have been put into [a resus room], a nurse would have to have been allocated to the resus room to care for her. The most likely RN to have been allocated would have been [RN I] as the other paediatric nurse was not yet orientated to resus and was relatively junior to the paediatric area. Conversely, to leave the relatively junior RN by himself in a busy paediatric area would have been equally unsafe.
>
> The safest solution at the time was to have [Miss A] remain in the bed space in the paediatric area. This bed space was immediately outside the nurse's station in full view of both nursing and medical staff. She was placed on a monitor in the best space for continuous monitoring of vital signs."

37. In response to the provisional decision, Waitemata DHB told HDC that, earlier in the shift, RN L contacted the hospital duty manager to inform her that the ED was short staffed. Waitemata DHB stated that the hospital duty manager "had no nursing resource in the hospital to help with ED staffing immediately but did provide a bureau nurse after [7pm]". It stated that, at 3pm, the paediatric bedspace area in ED was not full, but that there were eight new admissions to the paediatric area between 3.44pm and 5.40pm.

38. Waitemata DHB advised HDC that during the infusion Miss A was monitored via a cardiac monitor that measured her heart rate and oxygen saturations.[33] No record was made of Miss A's observations during the infusion. The records do not include a fluid chart, and there is no documentation of any check of the IV site while Miss A was in the ED. RN I told HDC:

> "I felt that because of the busyness of the department and the workload, that it made it harder to sit down and document notes. If we had had one more staff member, it would have been a lot easier … Even though the patient was being monitored and as nurses we visualise the monitor, the recordings should have been documented … [I] spent the majority of my shift tending to [Miss A]."

[33] Waitemata DHB stated that this particular monitor is capable of being centrally monitored but that the central monitor is located in the ED's "adult monitored area", and that paediatric nurses were therefore "unable to directly observe this".

39. RN J also told HDC that the ED was busy, stating: "We came onto an extremely busy shift with approximately nine patients in the (paediatric) cubicles, more arriving by the minute."

40. As stated above, after 5.15pm there is no record of Miss A's vital signs in the clinical notes while she was in ED. In addition, there is no record in the clinical note that the IV insertion site was checked in ED during or after the phenytoin infusion.

Transfer to Paediatric Ward

41. Miss A was transferred to the inpatient Paediatric Ward at approximately 7.50pm. Miss A was allocated to RN D's care, and RN D orientated Mrs A to the ward. The clinical notes record that RN D took Miss A's vital signs. Miss A's pulse was slightly elevated at 132,[34] but otherwise her vital signs were within normal limits.

42. The shift coordinator on the Paediatric Ward, RN B, told HDC that soon after Miss A's arrival to the ward Mrs A pressed the emergency bell, and RN B, RN D and the staff nurse responded to the emergency bell. Miss A was lying on the bed, semi awake, with tonic-clonic seizure activity. RN B said that a pulse oximetry monitor[35] was applied to Miss A's toe, showing oxygen saturations of less than 90%. RN B stated that the seizure lasted 30–40 seconds, and that the on-call paediatric registrar was informed of the seizure activity. Miss A was given oxygen via a mask, and her saturations increased to 98%. Miss A's saturations were then maintained off oxygen.

43. The nursing notes recorded by RN D after this seizure state: "Noticed that her [left] hand IV line is tissued and is completely swollen until anticubital fossa. A purplish discolouration was there in the insertion site. Informed the doctor." At 9.30pm, Dr M reviewed Miss A and recorded: "Loaded with IV Phenytoin. Unfortunately the IVL was tissued & Phenytoin was not given properly. So loaded with 1/2 dose."

44. RN B told HDC that Mrs A gave verbal consent to the administration of the phenytoin, and the infusion was commenced via the line in Miss A's right ACF, which was patent and flushing well with a satisfactory site. RN D told HDC:

> "[Miss A] was closely monitored throughout the infusion by use of a Dash monitor[36] and observations were recorded on the vital signs chart (the Dash monitor does not print out the result). The observations including blood pressure were satisfactory. The child slept during the infusion and did not have any seizure activity after that. I stayed in the child's room while the infusion was running, checking on the observations and on the administration site."

45. RN D stated that Miss A's vital signs continued to be monitored throughout the night. At around 4.30am, RN D noticed that Miss A had developed a blister on her left hand at the IV site. She informed the on-call paediatric registrar, Dr F.

[34] As stated above, the normal rate for a child aged 1–3 years is 70–110 beats per minute, and, on arrival in ED, Miss A's pulse was 120.
[35] Pulse oximetry is a non-invasive method for monitoring a patient's oxygen saturation, using a sensor placed on a thin part of the patient's body, usually a fingertip or earlobe.
[36] A wireless monitor used to monitor patients' vital signs.

46. Dr F told HDC that Dr M had verbally handed over Miss A's care to her at 10.30pm on 25 January 2013. Dr M informed Dr F that Miss A had most likely experienced extravasation of some of the infusion into her left hand earlier that evening. Dr M reported to Dr F that she had given Miss A a reduced dose infusion of phenytoin via the IV line in Miss A's right ACF.

47. Dr F stated:

> "On enquiry about the extravasation [Dr M] informed me that [Miss A] did not appear to have any visible signs of injury to the arm apart from some swelling and she did not feel any further action was required at that point. She explained that [Miss A's] family had been quite distressed by the events of the evening and requested that [Miss A] be left undisturbed for the night unless she had further seizures or the nursing staff on [the unit] had new concerns that needed review. [Dr M] informed me that she would review [Miss A] again after a handover and would tell me if there were any changes to this plan needed."

48. At around 5am, Dr F reviewed Miss A. At 5.45am, Dr F recorded in the clinical notes that Miss A's left arm was markedly swollen from her fingers through to her ACF, but it was not a tense swelling, and her peripheral perfusion[37] remained normal. Miss A had a restricted range of movement in her fingers, but did not appear to be experiencing any discomfort when she moved her fingers or was examined, and she had a good radial pulse.

49. Dr F noted an area of superficial necrosis[38] of approximately 3x4cm over the back of Miss A's left hand, with a blister in the centre of approximately 1cm diameter. Dr F's impression was that Miss A had experienced a phenytoin extravasation injury to her left hand and would need inpatient review by the plastic surgery service at Hospital 2 that morning. Consequently, Dr F requested that Miss A's arm be elevated in a tube-grip sling, and that a warm compress be applied for 20 minutes at the dorsum of her hand four hourly, and that neurovascular observations[39] of the limb be formally recorded every two hours until the plastic surgery review was conducted.

50. Dr F said that she explained to Mrs A her assessment findings, planned management, and the need for consultation and review by the plastic surgery services at Hospital 2, and obtained verbal consent for photos to be taken of Miss A's hand so that they could be emailed to the plastic surgery team at Hospital 2.

51. Following consultation with the plastic surgery team at Hospital 2, a plan was made to transfer Miss A to their care later that morning.

Transfer to Hospital 2

52. At 10.50am on 26 January 2013, Miss A left Hospital 1 for Hospital 2, where she was diagnosed with an extravasation injury and treated with antibiotics. Miss A remained

[37] Blood flow to the extremities.
[38] Necrosis that is confined to the upper layers of the skin.
[39] Assessment of nerve function and blood flow.

at Hospital 2 until 29 January 2013. On discharge, arrangements were made for the district nurse to dress her hand. A follow-up appointment was arranged for the following week, and when Miss A was reviewed there was evidence of a full thickness burn to the back of her left hand. On 26 February 2013, Miss A was admitted for debridement[40] and a skin graft, and was discharged home the following day.

Waitemata DHB policies at the time of events

53. At the time of these events, Waitemata DHB's "Intravenous Cannulation — Paediatrics"[41] policy stated: "Use minimal amount of tape possible to secure the IV … Leave the area where the catheter tip is situated and [the] insertion site visible."[42] With regard to monitoring, it stated: "Be aware of what drugs and infusions are more likely to cause infiltrations [eg extravasation] and monitor closely … Check for signs of inflammation."

54. When asked to provide "the protocol" referred to by RN I (above), Waitemata DHB provided HDC with its "Medication Management & Administration — Paediatric Inpatient" policy. That policy includes a "Monitoring" section, which states that staff must monitor a child's response to treatment prior to, during and after administration of medication; record vital signs appropriate to the medication being administered (and in this regard states: "refer to the relevant medication protocol"); and monitor the infusion and administration site for integrity of site, progress of infusion, and reaction to infusion.

55. Waitemata DHB provided HDC with an ED flowchart titled "Convulsive Status Epilepticus" in place at the time of these events, which stated that ECG monitoring was required during phenytoin infusion, but did not state that other monitoring was required. Waitemata DHB had a "Phenytoin (Intravenous) — Adults Only" policy at the time of these events which, on the first page, refers the readers to "WDHB Policy — Phenytoin IV — Paediatrics". However, Waitemata DHB told HDC that, while there was a paediatric phenytoin policy "in draft" at the time of these events, it did not have a specific paediatric phenytoin policy in place. Waitemata DHB also stated that, at the time of these events, it had an online "Paediatric Emergency Treatment Drug Calculator tool" accessible to all staff. It stated:

> "This online tool was considered detailed, precise and a reliable consultative tool at the time, with the aim of providing staff with quick access emergency drug treatment calculations and drug information, thus reducing policy document search times and potential drug and drug dosage errors."

[40] The surgical removal of dead or damaged tissue.
[41] Cannulation refers to inserting an IV line.
[42] Waitemata DHB also had a "Cannulation — Intravenous" policy at the time of these events, which outlined "the accepted practice of cannulation for adults". That policy referred the reader to "WDHB Policy — Administration and Medication management — 3 Procedures". When asked to provide the "WDHB Policy — Administration and Medication management — 3 Procedures", WDHB advised HDC that this refers to five separate policy documents rather than a single specific policy.

Incident Investigation Report

56. Waitemata DHB carried out a review into the care provided to Miss A, and found that:

- Miss A's first IV site was covered with a crêpe bandage, and so the IV site was not visible.
- At the time Miss A was admitted, RN I felt she would be able to monitor her adequately in the monitoring area in the ED (where the nursing ratio is generally one nurse to three patients). However, Miss A should have been moved from the monitoring area in the ED into a Resuscitation room, where she could receive one-on-one nursing for the phenytoin infusion.
- Given the potential side effects of phenytoin, Miss A should have had ECG and blood pressure monitoring. However, there is no documentation that Miss A was monitored at the commencement of, or during, the infusion. The fluid balance chart was not completed, there was no documentation of Miss A's observations or that the IV site was checked, and the exact time of the doctor's review was unspecified.
- The ED was very busy. At the time Miss A's phenytoin infusion was completed, there were nine children being treated in the ED.
- While the infusion pump alarm caused additional anxiety for Mrs A, it was not a contributory factor in Miss A's injury.

57. The recommendations from Waitemata DHB's Incident Investigation Report included that:

- IV sites are covered by Surgifix (netting sock). Crêpe bandages have been removed from IV trolleys, and staff education sessions have been held.
- Staff are made aware of monitoring and documentation requirements when administering phenytoin, and that all appropriate staff in ED/Child Health are advised of the most appropriate administration route for phenytoin.

58. The adverse reaction was notified to the NZ Pharmacovigilance Centre via the Centre for Adverse Reactions Monitoring, and the Health Quality and Safety Commission was notified of the injury as part of the National Serious and Sentinel Event reporting process.

New policy introduced

59. In April 2013, Waitemata DHB introduced a new policy relating to the administration of phenytoin to children: "Phenytoin (Intravenous) — Paediatrics" (the new policy).

60. With regard to observation and monitoring, the policy requires:

- Resuscitation equipment is available.
- ECG monitoring during administration.

- Monitoring and documentation of blood pressure, pulse, and respiratory rate before commencing infusion then every 5–10 minutes during infusion (depending on patient's general condition), and for 10 minutes after the infusion has stopped.
- Reducing the rate of administration if the heart rate decreases more than 10 beats per minute or hypertension occurs.
- Measuring urea[43] and electrolytes.
- Two hours after end of infusion, measuring blood serum and phenytoin levels to obtain therapeutic range.
- Monitoring the peripheral injection sites every 10 minutes for signs of extravasation.

61. The new policy lists the following possible side effects of phenytoin administration:

- Respiratory depression and respiratory arrest.
- Extravasation, which may result in local tissue damage with subsequent necrosis.
- Skin rash (most often measles-like rash).
- Purple glove syndrome, which may present with pain, oedema and discolouration of the involved limb.

62. In June 2013, Waitemata DHB introduced a further policy titled "Extravasation — paediatric", which outlines the risk factors, prevention strategies, assessment and documentation standards, and treatment for extravasation injuries in children.

Response to provisional decision

Mrs A

63. Mrs A was given the opportunity to comment on the "Information gathered during investigation" section of the provisional decision and her comments have been considered during the course of the investigation.

Waitemata DHB

64. Waitemata DHB was given the opportunity to comment on the proposed findings and courses of action. Its comments have been considered during the course of the investigation and included where appropriate.

65. In addition, Waitemata DHB submitted that it took reasonable steps, in accordance with Clause 3 of the Code,[44] to give effect to Miss A's rights under the Code, by rostering ED nursing staff in numbers that would ordinarily be sufficient to meet demand and providing additional staff as soon as they were available.

[43] A chemical compound found in urine.

[44] Clause 3(1) of the Code states: "A provider is not in breach of this Code if the provider has taken reasonable actions in the circumstances to give effect to the rights, and comply with the duties, in this Code."

Opinion: Waitemata District Health Board

Introduction

66. In January 2013, Miss A attended Hospital 1, where she was administered phenytoin and later suffered an injury to her hand which was diagnosed as an extravasation injury. Waitemata DHB and the staff involved in Miss A's care had a responsibility to take all reasonable steps to ensure that services were provided to her with reasonable care and skill. District health boards are responsible for the operation of clinical services within hospitals, and can be held responsible for any service-level failures. The individuals who provided care to Miss A bear some responsibility for the deficiencies in the care provided to Miss A, but I am of the view that, overall, those deficiencies were a result of systemic issues at Hospital 1.

67. My consideration below concerns the standard of care that Miss A received based on information available to the hospital staff treating her at the time. It is not my role to make findings of causation and my report should not be interpreted as drawing any conclusions about the cause of Miss A's injury. However, I note Dr Tuck's comment:

> "[I]nserting and maintaining IV lines in small children can be notoriously difficult, and extravasation or 'tissuing' is a common occurrence in paediatric wards even with the best of nursing care."

Initial treatment provided — No breach

68. On 25 January 2013, Miss A had four seizures, following which she was transported to Hospital 1 ED. Paediatric emergency specialist Dr H assessed Miss A and referred her to the general paediatric team, where her care was taken over by registrar Dr E. Shortly thereafter, Miss A had a further seizure lasting 10–20 seconds. Dr E reviewed Miss A at 5.15pm and observed her to have two generalised tonic-clonic seizures of short duration with postictal state. Dr E decided to commence IV phenytoin and prescribed 270mg (calculated based on 20mg/kg). Dr E and RN I placed an IV line into the back of Miss A's left hand, and checked that the line was patent.

69. My expert advisor, consultant paediatrician Dr Roger Tuck, advised that it appears that Miss A was triaged and initially managed in a timely and appropriate manner. He stated that IV phenytoin is a standard treatment for continuing seizure activity, and advised that the dosage for Miss A was calculated appropriately. Similarly, my expert nursing advisor, RN Wendy Sinclair, considered that, based on the available information, the IV line was patent and correctly sited when it was checked prior to the commencement of the infusion. I accept that advice, and consider that the care Miss A received prior to the phenytoin infusion was appropriate.

Care provided during first phenytoin infusion — Breach

70. Miss A's phenytoin infusion started at 6.35pm and finished at 7.34pm. Dr E recorded no instructions regarding monitoring, but she said that it was her expectation that monitoring and supervision of Miss A would occur "via the attending nurse as per the usual monitoring protocols". RN I told HDC that she placed Miss A on cardiac monitoring (which Waitemata DHB advised included monitoring of her heart rate and oxygen saturations). However, there is no record in Miss A's notes of her observations being taken. In addition, there is no record that the IV site was checked

during or after the infusion (until Miss A's transfer to the Paediatric Ward), and there has been no evidence presented by any of the parties involved in this investigation to suggest that it was.

71. RN I was responsible for Miss A until 7pm, when her care was handed over to RN J. RN I told HDC that the ED was very busy, which she felt made it harder to document in the notes. She said that, prior to Miss A's phenytoin infusion, she was called away a number of times to attend to other patients, but she spent the majority of her shift tending to Miss A. RN I told HDC: "Even though the patient was being monitored and as nurses we visualise the monitor, the recordings should have been documented." She said that the infusion pump alarmed while she was in Miss A's room because she had not unclipped the tubing lock, but that the infusion ran smoothly in the last 25 minutes she was with Miss A.

72. RN J started her shift at 7pm. She also stated that it was an extremely busy shift. RN J told HDC that the emergency bell rang a number of times during the infusion, and that she was attending to another patient at the time. RN J said that it was unclear why Mrs A pressed the emergency bell on the first occasion, and on the second and third occasions the infusion pump was alarming because the infusion had finished. RN J stated that the infusion pump did not show an occlusion, and Mrs A did not mention that Miss A was upset or had a sore hand.

73. Both my independent advisors considered that Miss A should have been better monitored during the infusion.

74. Dr Tuck stated that there is a risk of severe injury associated with the IV administration of phenytoin, and "extreme care" needed to be exercised. Dr Tuck advised that Miss A should have been observed in a high dependency area with one-on-one nursing care, which would have provided the best opportunity to observe Miss A for early signs of complications, both local (at the IV site) and systemic (eg, cardiac rhythm disturbance). He said that it is only with close observation that early signs of complications can be identified and mitigated.

75. RN Sinclair advised that, as the well documented side effects of phenytoin are significant and include low blood pressure, slow heart beat and other irregularities, adequate monitoring would include blood pressure recordings as well as heart rate, respiratory rate, and cardiac rhythm. RN Sinclair advised:

> "Not only is the recording of these parameters required, a staff member must be available to respond to any clinical situation that arises. The available evidence fails to reassure me that this occurred throughout the administration of the Phenytoin infusion to [Miss A] in the Emergency Department. There is also no evidence that the cannula insertion site was checked during or after the infusion. Checking the site is an important component of the flushing procedure following the administration of a medication. This is even more vital when the infusion fluid is a tissue irritant."

76. I accept my experts' advice and consider that Miss A should have been better monitored during the infusion. In particular, she should have received one-on-one

nursing care, the IV site should have been checked, and her blood pressure, respiratory rate and cardiac rhythm should have been monitored. All her observations (including her heart rate and oxygen saturations which, according to RN I and Waitemata DHB, were being monitored) should have been documented.

77. In my view, a number of factors contributed to the failures in the care provided to Miss A during the infusion. First, Dr E did not give specific instructions about monitoring because she thought that monitoring would occur "as per the usual monitoring protocols". In my view, Dr E should have given nursing staff instructions for adequate monitoring when she prescribed the phenytoin. If that level of monitoring was not practicable in a busy ward, Dr E should have transferred Miss A to the Paediatric Ward before commencing the infusion. Furthermore, Waitemata DHB's policies were inadequate. Although there was reference in its "Phenytoin (Intravenous) — Adults Only" policy to a "WDHB Policy — Phenytoin IV — Paediatrics", Waitemata DHB advised that in fact it did not have a specific policy regarding the administration of phenytoin to children.[45] Its policy relating to the administration of phenytoin to adults specified only that ECG monitoring was required whereas, as stated in the Medsafe datasheet for phenytoin and acknowledged in Waitemata DHB's investigation, continuous ECG and blood pressure monitoring was needed. The Medsafe data sheet also states that patients should be observed for signs of respiratory depression, and cardiac resuscitative equipment should be available. In addition, there were policies that Waitemata DHB did have in place that were not followed. For example, its "Medication Management & Administration — Paediatric Inpatient" policy required staff to record vital signs appropriate to the medication being administered, and to monitor the infusion and administration site, and neither of these things occurred.

78. There is also evidence that the care provided to Miss A suffered because of staffing issues. ED Associate Clinical Charge Nurse RN L told HDC that the ED was short-staffed on the evening these events occurred. She stated that, before 7pm, there were two registered nurses allocated to the paediatric ED area rather than three and that, of those two registered nurses, one had insufficient experience either to provide care to Miss A in the Resuscitation area, or to be the only registered nurse providing care in the paediatric area. In response to my provisional decision, Waitemata DHB submitted that it took reasonable steps, in accordance with Clause 3 of the Code, by rostering ED nursing staff in numbers that would ordinarily be sufficient to meet demand and providing additional staff as soon as they were available. However, the fact remains that, at the time Miss A's phenytoin infusion commenced, there were insufficient nursing staff for Miss A to receive one-on-one nursing care. I accept that the staff at the time concerned considered that "the safest solution at the time" was for Miss A to remain in the paediatric area, although it was full. However, in light of advice from both my experts that Miss A should have received one-on-one nursing care during the phenytoin infusion, I remain of the view that this was unacceptable.

[45] Waitemata DHB stated that it had an online "Paediatric Emergency Treatment Drug Calculator tool" accessible to staff at the time of these events. However, as the dosage of phenytoin Miss A was given is not at issue in this case, I consider a tool used to calculate medication dosages of limited relevance.

79. RN I also told HDC that she felt that the busyness of the ED had an impact on her ability to document notes, which I consider was especially important given that Miss A's care was handed over to another nurse during the infusion. I agree with Dr Tuck's observation that "a busy department should not result in a decline in the standard of care".

80. I note RN Sinclair's advice that the nurses' responses to the infusion pump alarming were appropriate, and I accept that advice. Notwithstanding that, I agree with my experts that, given the risks of severe injury associated with IV administration of phenytoin, overall Miss A should have been better monitored during the infusion, and her observations should have been documented. I consider that a number of factors contributed to the failures in this case, as outlined above, including Dr E's failure to give monitoring instructions, the inadequacy of Waitemata DHB's policies, staff failures to follow policies, and the staffing issues on the day. While the individuals involved must accept responsibility for their shortcomings in the care provided to Miss A, overall, and for the reasons set out above, in my view there was a systemic failure by Waitemata DHB to provide Miss A services with reasonable care and skill. Accordingly, Waitemata DHB breached Right 4(1) of the Code.

Care provided on the Paediatric Ward — No breach

81. Miss A was transferred to the Paediatric Ward at approximately 7.50pm. On arrival she suffered a further seizure, and nursing staff checked the IV site on Miss A's left hand, which was noted to be purplish with swelling in the arm. Nursing staff informed Dr M, who reviewed Miss A and ordered a further phenytoin infusion via the IV site in Miss A's right ACF. RN D monitored Miss A during the infusion and for the rest of the night. At 4.30am on 26 January 2012, she noticed a blister at the IV site on Miss A's left hand, and alerted Dr F. Dr F examined Miss A and noted her impression that Miss A had an extravasation injury. Dr F then consulted with the plastic surgery service and Hospital 2, and arranged transport for Miss A.

82. Dr Tuck advised me that he does not have concerns about the paediatric care provided to Miss A following her transfer to the ward, and RN Sinclair advised me that Miss A was monitored appropriately on the ward. I accept that advice, and do not consider the care provided to Miss A after the initial phenytoin infusion, administered in ED, to be a breach of the Code.

Standard of policies generally — Adverse comment

83. As stated above, Waitemata DHB's policy relating to the IV administration of phenytoin for adults made reference to a "WDHB Policy — Phenytoin IV — Paediatrics", but Waitemata DHB advised that in fact, at that time, it did not have a specific policy regarding the administration of phenytoin to children. During the course of my investigation I have also noted other instances where Waitemata DHB's policies make erroneous or confusing references to other policies,[46] which I consider limits the utility of those policies in guiding staff to provide safe care. In addition, RN

[46] For example, the reference in the "Cannulation — Intravenous" to "WDHB Policy — Administration and Medication management — 3 Procedures" which, as advised by Waitemata DHB, is a reference to five separate policy documents rather than one policy.

Sinclair has made some criticisms regarding policies reviewed during the course of my investigation that are not directly related to the care Miss A received.

84. As such, I have recommended that Waitemata DHB review a number of its policies in light of RN Sinclair's comments and with a view to ensuring that references made to other policies are clear and accurate.

Recommendations

85. I recommend that Waitemata DHB provide an apology to Miss A and Mrs A for its breach of the Code. The apology should be sent to HDC within three weeks of the date of this report, for forwarding to Mrs A.

86. I recommend that, within three months of the date of this report, Waitemata DHB:

a) Review its "Cannulation — Intravenous", "Phenytoin Intravenous — Adults Only" and "Handover" policies in light of RN Sinclair's advice, to ensure that those policies are adequate to guide safe and effective care and the transfer of care between nurses, and report to HDC on the outcome of its review.

b) Review all its current policies relating to phenytoin and IV medication administration/cannulation for adults and children to ensure that references to other policies are clear and accurate, and report to HDC on the outcome of its review.

c) Review the systems it has in place for ensuring safe staffing in the Hospital 1 ED, and report to HDC on the outcome of its review.

d) Use an anonymised version of this report as a basis for staff training at Hospital 1, focussing particularly on the deficiencies in care identified in this case, and provide evidence of that training to HDC.

Follow-up actions

87.
- A copy of this report with details identifying the parties removed, except Waitemata DHB and the experts who provided advice on this case, will be sent to the New Zealand Faculty of the Australasian College for Emergency Medicine, and the Paediatrics & Child Health Division of the Royal Australasian College of Physicians, for educational purposes.
- A copy of this report with details identifying the parties removed, except Waitemata DHB and the experts who provided advice on this case, will be sent to the Health Quality & Safety Commission and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A — Independent paediatric advice to the Commissioner

The following expert advice was obtained from Roger Tuck:

> "My name is Roger Tuck and I am currently practising as a Consultant Paediatrician for the Northland District Health Board. I graduated MBBS in 1972 from the University of London. Post graduate studies led to Membership of the Royal College of Physicians of the United Kingdom (MRCP UK), Fellowship of the Royal College of Physicians of Edinburgh (FRCP Ed) and Fellowship of the Royal Australasian College of Physicians (FRACP). I have practised as a general paediatrician for NDHB since 1983. Of relevance to this case, I have considerable experience in the acute and long term management of children with epilepsy.
>
> I have no involvement or clinical interest in this case.
>
> I have read all of the material provided by your office concerning [Miss A] who was admitted to hospital at 1612hrs on the 25 of January 2013, following several seizures at home. Your enquiry relates to the use of phenytoin intravenously in the management of [Miss A's] seizures and the subsequent complication of extravasation injury or purple glove syndrome. In particular, you enquire as to whether any aspect of her management contributed to this complication and, if so, whether there has been an appropriate remedial response by the health care provider.
>
> [Miss A] is a child known to the general paediatric service at the hospital where she was admitted for this episode, and also to [a specialised paediatric service at another hospital]. She has developmental delay and epilepsy. Her mother has a management plan for seizures occurring in the home and had responded appropriately with buccal midazolam prior to [Miss A's] arrival in the emergency department. From the documentation it would appear that [Miss A] was triaged and managed initially in a timely and appropriate manner in a department that at the time of admission was not particularly busy. When further seizures occurred in the ED, a decision to commence intravenous phenytoin was made. This is a standard treatment for continuing seizure activity not responsive to prn ('as indicated' in the context of individual seizures) doses of agents such as midazolam, diazepam or lorazepam. A dose of 20mg/kg was appropriately calculated for [Miss A]. (The recommended IV dose is 15–20mg/kg.) It would appear that the staff were aware of the requirements with regard to the rate of the infusion, the need to use the largest vein accessible and the need for close observation including cardiac monitoring for the duration of the infusion. The infusion commenced at 1835hrs through a cannula inserted in the dorsum of the left hand which was said to be patent and appropriately taped and splinted. Shortly after commencement there were one or two pump alarms which concerned the mother but were explained by nursing staff as caused by failure to release tubing lock. A second intravenous line was then inserted by the paediatric registrar in a larger vein in the opposite (right) antecubital fossa with the instruction to change the infusion to this line if there were further alarms or concerns about how well the infusion was running. The infusion finished at 1934hrs and there is reference in the nurse report that the cannula flushed normally at this time. There were

further pump alarms at this time due to the pump being placed 'on hold' as the department had become busy. This caused concern to the parent. The reported normal flushing of the cannula at the end of the infusion would suggest that there was no obvious evidence at that time that the IV had 'tissued' or extravasated. This is in the context of no IV site check documentation that I can find. There is an assumption therefore, but inadequate supporting documentary evidence that this infusion went without any adverse incident. At this stage I would point out that there are conflicting statements about when this IV was removed and what the IV site actually looked like at the time of line removal. One statement suggested that there was no swelling, just a 'small purple spot', suggesting that the IV was removed in ED, and others by the staff on the paediatric ward that at 2000hrs when the child had a further seizure, it was apparent that there was significant swelling up to the antecubital fossa with discolouration when an occluding crêpe bandage was removed to inspect the IV site on the dorsum of the left hand with the line still in situ. The statements from the ward describe that the IV was removed at that time. It would appear that this was the most likely scenario and reference to prior removal of the line in ED was incorrect. The consultant paediatrician who reviewed the child subsequent to the 2000hr seizure felt that due to the significant swelling of the left arm an undetermined portion of the phenytoin infusion had gone into the tissues and not into the circulation. Consequently a further 10mg/kg of phenytoin was infused through the line in the opposite antecubital fossa. This was despite the nursing indication that the initial infusion went without incident, the IV flushed normally at the end and no obvious extravasation was commented on in ED prior to transfer to the ward. Had [Miss A] received the appropriate one on one nursing care during the infusion in ED regular observation and documentation might have both potentially mitigated the subsequent site complication and potentially enabled the paediatrician to choose a different anticonvulsant strategy at 2130 hrs when she was called to see the child.

Q. Was the child appropriately monitored during the initial phenytoin infusion?

The child did not receive the recommended level of monitoring and observation. There has been an admission by the clinical team that the child should have been observed in a high dependency area with one on one nursing care. This would have provided the best opportunity to observe for the early signs of complications both local at the IV site, and systemic such as cardiac rhythm disturbance. A busy department should not result in a decline in the standard of care.

Q. Was the phenytoin dose appropriate?

The initial dose of phenytoin was an appropriate dose for this child based on her weight and international best practice guidelines.

Q. Was this an extravasation injury or a 'purple glove'?

The literature on the purple glove adverse response to phenytoin is sparse and based on case reports. Its relationship to extravasation is unclear. This may have been both extravasation and purple glove. If the nurse observation that the IV flushed normally at the end of the infusion with the inference that there was no

clear evidence of extravasation, then this may be a pure 'purple glove'. In a sense, whether it was or was not is irrelevant. What is relevant is that the child was probably not observed adequately during the infusion, and it is only with close observation that early signs of complications can be identified and mitigated.

Q. Were changes made by WDHB following the incident likely to appropriately address concerns with her care?

I think it very likely that the clinicians involved in [Miss A's] care will have learned valuable lessons. Guidelines for the management of phenytoin infusions are clear and if adhered to should significantly reduce the risk of this happening again. Purple glove syndrome may continue to be a rare complication even in the context of optimal observation and absence of obvious signs of extravasation. As has been stated, inserting and maintaining IV lines in small children can be notoriously difficult, and extravasation or 'tissuing' a common occurrence in paediatric wards with the best of nursing care. There are certain drugs and agents used that can cause severe injury in association with IV administration and extravasation, phenytoin being one. Extreme care needs to be exercised. I think that there has been an appropriate organisational response to this unfortunate incident. Lastly I would like to express my sympathy to [Miss A] and her family for what has clearly been a traumatic event.

Dr Roger Tuck FRACP. FRCP(Edin)
Paediatrician"

Further advice provided by Dr Tuck

When asked to comment further on whether Miss A was appropriately monitored during the initial phenytoin infusion, Dr Tuck advised that he considers the responsibility for the deficiencies in Miss A's monitoring lies with the team, including the prescribing doctor to ensure safe dispensation of the prescribed drug.

When asked to comment on the paediatric care provided to Miss A in the Paediatric Ward, Dr Tuck advised that he does not think there were any issues.

Appendix B — Independent nursing advice to the Commissioner

The following expert advice was obtained from Wendy Sinclair:

"Thank you for your request to provide clinical advice in relation to the complaint Ref 13/00756 from [Mrs A] about the care provided to her daughter [Miss A] on 25 January 2013. In preparing the advice on this case, to the best of my knowledge I have no personal or professional conflict of interest. I have read and agree to follow the Commissioner's Guidelines for Independent Advisors.

I registered as a General and Obstetric Nurse from Waikato Hospital in 1979. I hold a MN(Clin) degree from Victoria University of Wellington. I have worked in the Tertiary Emergency Service since 1988 in roles that have included Staff Nurse, Charge Nurse, Nurse Educator and Unit Manager. I am currently employed in a Tertiary Emergency Department as a Clinical Nurse Specialist.

As a RN peer, I have been asked to consider whether the nursing care provided to [Miss A] at [Hospital 1] was reasonable in the circumstances, and why. In particular:

- The adequacy of the nursing care provided by specific providers to [Miss A] including but not limited to:
  - Whether [Miss A] was appropriately monitored by nursing staff during her admission and particularly when she was administered phenytoin; and
  - Whether nursing staff's responses to the IV pump alarms and/or [Mrs A's] concerns were appropriate and why.
- Whether nursing staff were adequately supported in providing care to [Miss A] in all of the circumstances.
- The adequacy of the relevant policies and procedures in place at [Hospital 1] at the time of the events complained of, as well as new/updated policies.

I have read and reviewed the documentation provided to me:

1. Copy of complaint from [Mrs A] dated 12 June 2013
2. Copy of Waitemata DHB's letter to HDC dated 18 July 2013
3. Copy of relevant parts of Waitemata DHB's letter dated 7 March 2014 including the following enclosures:
   a. Relevant extracts of the cover letter;
   b. Clinical records from [Miss A's] admission on 25–26 January 2013;
   c. Statement from paediatric emergency specialist [Dr H];
   d. Statement from [senior medical officer];
   e. Statement from paediatric registrar [Dr F];
   f. Statement from paediatric registrar [Dr E];
   g. Statement from ED [RN J];
   h. Statement from ED RN/Charge Nurse [RN K];
   i. Statement from ED [RN I];
   j. Waitemata DHB's policy 'Handover of Patients — Emergency Medicine' (issued May 2010);

k. Waitemata DHB's policy 'Handover' (issued December 2012);
l. Waitemata DHB's policy 'Cannulation — Intravenous' (issued December 2012);
m. Waitemata DHB's policy 'Intravenous Cannulation — Paediatrics' (issued November 2012);
n. Waitemata DHB's policy 'Convulsive Status Epilepticus' (review date November 2015);
o. Waitemata DHB's policy 'Phenytoin (Intravenous) — Adults only' (reviewed December 2010);
p. Letter from Centre for Adverse Reactions Monitoring to [Waitemata DHB] dated 27 March 2013;
q. Waitemata DHB's policy 'Extravasation — Paediatric' (issued June 2013);
r. Waitemata DHB's policy 'Paediatric IV Infusions — Dose Reference Chart' (issued January 2012); and
s. Waitemata DHB's policy 'Phenytoin (Intravenous) — Paediatric' (issued April 2013.

4. Statement from [RN B] ([Paediatric Ward] RN) dated 9 May 2014.
5. Statement from [RN C] ([Paediatric Ward] RN) dated 17 December 2013.
6. Statement from [RN D] ([Paediatric Ward] RN) dated 10 May 2014.

Background — brief summary

On January 2013 [Miss A] aged 2 1/2years, was brought to the Emergency Department (ED) at [Hospital 1] by ambulance at 1612 hours after suffering several seizures. She was accompanied by her mother, [Mrs A].

On her arrival in ED she was triaged as an Australasian Triage Score 3. The initial nursing assessment notes her history and a record of her vital signs.

It is recorded that she suffered a further self limiting seizure at 1715 hours. The clinical notes document a clinical assessment by the ED Consultant (no time noted) and referral to the Paediatric service who record a medical assessment by the Paediatric Registrar at 1728 hrs. An Intravenous line was inserted into [Miss A's] L hand and this was checked for patency and dressed and bandaged. A second IV line was placed in the right arm.

She was prescribed intravenous phenytoin infusion as a loading dose at 1745 hours and this was commenced as an infusion via the IV line in the left hand at 1835 hours.

The nursing note records completion of the infusion l934 hours, flushing of the line and hand over to the [paediatric] ward.

Nursing notes written at 0400 hours document that [Miss A] arrived in the ward at 1950 hours. They record another seizure 'shortly after' arrival in the ward at 2001 hours. At this time the hand and arm was noted to be swollen 'to the antecubital fossae' with a purplish discolouration at the insertion site. This was reported to the doctor and the IV line was removed.

Clinical notes record the assessment of the Paediatric SHO [Senior House Officer] at 2130 where it is noted that the IV had tissued but does not record an assessment of the injury to the hand or arm. It states that the phenytoin 'was not given properly' and therefore further phenytoin was prescribed and administered.

The next medical review occurred at 0545 in response to the nursing staff request. The hand and arm were noted to be grossly swollen with an area of discolouration over the dorsum of the left hand.

Later that morning [Miss A] was referred to [the Hospital 2] Plastic Surgery team and [Miss A] was transferred into their care.

Clinical Advice

- The adequacy of the nursing care provided by specific providers to [Miss A] including but not limited to:
  - Whether [Miss A] was appropriately monitored by nursing staff during her admission and particularly when she was administered phenytoin; and
  - Whether nursing staff's responses to the IV pump alarms and/or [Mrs A's] concerns were appropriate and why.

The clinical notes record that [Miss A] arrived in the Emergency Department by ambulance at 1612 hours on 25.01.2013 where she was assessed by the Triage Nurse and allocated as Australasian Triage Score (ATS) of 3. The Australasian College of Emergency Medicine (ACEM) Policy states that triage score allocation is in response to the question: 'This patient should wait for medical assessment and treatment no longer than …'. In relation to this case, the triage nurse clinically assessed [Miss A] as requiring further assessment/treatment within 30 minutes. This is in accordance with the indicative clinical descriptor provided in the 'Guidelines for the Implementation of the Australasian Triage Scale' policy guideline for seizure — now alert GCS >13'. I consider the triage assessment as undertaken by the triage nurse to be appropriate and to meet the expected standard described by ACEM.

On transfer into the paediatric area within the Emergency Department the clinical notes record an initial nursing assessment at 1620 hours. This includes a history and an assessment of [Miss A's] clinical condition which is described 'Airway patent, good colour, GCS 13/15 post-ictal, Cap refill <2'. Vital signs within normal limits are documented.

Based on my clinical experience I consider that this assessment by [RN I] and its documentation meets an appropriate standard and was carried out within an acceptable time frame.

Whilst completing the initial interaction with [Miss A], she is reported to have had another seizure. [RN I] escalated to the paediatric registrar and together they managed the seizure by supporting [Miss A's] safety until it self-resolved after 15–20 seconds. A set of vital signs are recorded at 1715 hours on the Observation sheet in the nursing clinical notes 'P 120, R 24, O_2 saturations 98% O/A' There is no documentation of the Glasgow Coma Scale or the level of consciousness noted. There are no other recordings of vital signs on the observation sheet throughout [Miss A's] stay in the Emergency Department.

An intravenous line (IVL) was inserted by the doctor into the left hand and it was flushed 'well' with Normal Saline and found to be patent. The line was then 'splinted and bandaged'. The statement from [Dr E] states that the splint was placed under the wrist and hand, taped in place 'that ensured that the insertion point of the IVL was maximally visible as taping would allow.' It is not clear from the information reviewed whether the 'bandaging' was performed after this initial taping and whether the cannula insertion site was left visible.

An infusion of phenytoin was prescribed at 1745 hours. The statement from [RN I] describes printing off the protocol to guide the preparation and administration of the Infusion, the use of a filter and an infusion pump. Her statement documents that the process of flushing the cannula that was performed prior to the initiation of the infusion by both [RN I] and [Dr E]. An assessment of the site at that time was made and they were reassured that the line was in place and patent. The process of flushing the cannula on insertion and after taping is also reported in [Dr E's] statement.

'Notes on injectable drugs 6th Edition' provides protocols for the preparation and administration of injectable medicines. It clearly describes the issues around the administration of a phenytoin infusion and strongly suggests the use of an in-line filter (0.22–0.5micron) to protect against the infusion of a precipitated solution as the diluted medication lacks stability. I am satisfied that the preparation of the infusion by [RN I] followed the guidelines to ensure that the Infusion was delivered in a safe manner.

I am satisfied that the IV line was checked prior to the commencement of the infusion by [RN I] and [Dr E], and that it was patent and correctly sited at that time.

The statement from [RN I] indicates that she put [Miss A] onto 'cardiac monitoring' in the room. Although there is no supporting documentation in the clinical notes to support the fact that [Miss A] was monitored throughout the infusion, I have no reason to question [RN I's] statement. I am unclear whether this monitoring was centralized that allowed the monitor to be viewed from outside the room, or whether it was on a bedside monitor only.

I am unable to determine what other vital signs were monitored. As the well documented side effects of phenytoin are significant and include hypotension, bradycardia and cardiac arrhythmias, adequate monitoring would need to include blood pressure recordings as well as heart rate, respiratory rate and cardiac rhythm. There are no recordings of any type documented on the Observation sheet or elsewhere in the clinical notes that would indicate that these parameters were monitored during the infusion.

I have made an assumption that [RN I] was also caring for other patients due to her comment regarding the admission of a further two new admissions during the period of the infusion and was therefore away from the bedside and depending on alarms from the monitor to alert her to any untoward effect of the infusion. This is supported by the original complaint from [Mrs A] who states that she rang the bell three times to call the staff when the machine 'beeped'. It is unclear whether she means the infusion pump bleeped or the monitor bleeped.

Information in the Notes on Injectable Drugs 6th edition is clear that phenytoin infusion carries significant risk and careful monitoring of cardiac rhythm, blood pressure, respiratory rate and heart rate is required to promote safe administration. Not only is the recording of these parameters required, a staff member must be available to respond to any clinical situation that arises. The available evidence fails to reassure me that this occurred throughout the administration of the phenytoin infusion to [Miss A] in the Emergency Department. There is also no evidence that the cannula insertion site was checked during or after the infusion. Checking the site is an important component of the flushing procedure following the administration of a medication. This is even more vital when the Infusion fluid is tissue irritant.

Therefore, I find that [Miss A] was not appropriately monitored by [RN I] when she was being administered phenytoin and the standard of documentation around the monitoring is inadequate. In my view this failure to meet an appropriate standard of care represents a severe departure from an acceptable standard.

[Mrs A's] complaint states that she rang the bell three times when 'the machine is bleeping'. It is not clear from this whether it was the infusion pump or the monitor that was alarming. She also states that [Miss A] started to cry at this time.

[RN I] reports in her statement that the infusion pump alarmed twice while she was in the room as she started the infusion as she had failed to unclip the tubing lock. Once this was remedied, the infusion ran smoothly for the remaining 25 minutes.

[RN J's] statement states that the emergency bell was rung by [Mrs A] while oncoming staff were receiving a handover at the start of their shift. She states that they responded to the bell, but quickly left the room as it was clear that there was no emergency. It is not stated why the emergency bell had been activated.

The second time the emergency bell was activated by [Mrs A] [was] when the infusion had finished. [RN J] states that she put the infusion pump on 'hold' and inadvertently left the pump on 'hold' and left to complete another task.

The 'buzzer' again activated and [RN J] and a colleague from the nursing bureau again went into the room, and this time turned the pump off. The bureau nurse offered to 'finish and flush' while [RN J] completed the other task with another patient.

[RN J] is clear in her statement that 'at no time did the machine show an occlusion. At no time did the mum mention that the baby was upset or sore'.

From the prepared statements it appears that the staff responded to the emergency bells activated by [Mrs A] in a timely manner. Each time, the pump was checked and a reason for the alarm was established. In my experience the causes of the alarms as stated in the nurses' statements are all reasonable and are common causes of the activation of the alarm on an infusion pump. If the cannula had become dislodged and extravasation had occurred, it is reasonable to expect the pump alarm to activate and the display would indicate that an occlusion had occurred. It is unlikely that the pump would run when restarted without the alarms re-activating if the problem had not been rectified.

None of the staff members who provided statements reported that [Miss A] showed signs of upset and agitation although [Mrs A] states in her complaint that [Miss A] started to cry at some point when she rang the buzzer.

None of the nurses involved stated that they checked the IV site at any time during or after the completion of the infusion. If the pump had alarmed and the display indicated that an occlusion was the cause of the alarm, the site should be checked to ensure that extravasation had not occurred. However in this case, the cause of the pump alarm activation was not occlusion, the fault was quickly resolved and the pump continued to function and so it is not unreasonable to assume that the IV cannula was not at fault.

I therefore find that the nursing staff's response to the IV pumps alarms were appropriate. The information provided does not identify [Mrs A's] specific concerns and I therefore cannot comment on this aspect.

The nursing notes record 'handed over to the ward' at 1934 and [Miss A] was transferred to the [Paediatric ward] at 1950 hours. The information provided does not record the transfer of care process and it is not stated whether [Miss A] was escorted by a nurse. [RN D] was assigned to [Miss A's] care in the ward. She states that [Miss A] arrived at 1950 hours and that she suffered a further seizure at 2001 hours. The seizure was managed appropriately with the assistance of [RN B] who was the shift co-ordinator. It was at this time that the bandaged hand was noted, the bandage removed and it was discovered that the IV had tissued and that the hand and arm were swollen to the antecubital fossae with a purplish discolouration at the insertion site. The situation was appropriately escalated to the doctor and appropriate first aid measures were instigated.

[Miss A] was seen by the Paediatric SHO and her findings are noted in the clinical notes at 2130 hours when a further dose of Phenytoin was prescribed.

This was administered under the direct observation of [RN D] whilst electronic monitoring of the vital signs and direct observation of the insertion site. This is supported by the documentation of these findings.

During the night [Miss A's] arm was checked and at 0430 hours [RN D] noted a blister forming at the insertion site. This change in condition was escalated to the medical team and further treatment measures were instigated.

Based on my clinical knowledge and experience, I believe that the nursing care provided by [RN D] was of an appropriate standard. Her assessments and care were provided in a timely manner, she escalated changes in [Miss A's] condition appropriately to the shift co-ordinator and to the medical staff.

The second phenytoin infusion was delivered with an appropriate level of monitoring and the documentation supports this.

- Whether nursing staff were adequately supported in providing care to [Miss A] in all of the circumstances.

The statements of both [RN I] and [RN J] both indicate that the paediatric area experienced a surge of patient presentations at the time of [Miss A's] admission and treatment and that the nursing staff were stretched to manage with the

multiple demands of new patients presenting and care that need to be provided. [RN I] reports that she was interrupted in her assessment and care for [Miss A] when she was asked to assist with a patient in Resus. Her statement records that she was later being assisted by the Charge Nurse to prepare the infusion who 'became busy' and so she had to find another nurse to assist her. She also states that she didn't feel she could transfer [Miss A] to Resus for the infusion as Resus was busy and they were short staffed.

[RN J's] statement also records the pressures of multiple demands and being distracted and forgetting to take the infusion pump off 'hold' when she answered the alarm because she was 'sorting out a Gentamycin Infusion' for another child.

The statement of the Charge Nurse [RN K] makes no comment about the level of workload or the level of support he was able or unable to provide the staff on duty that shift. It is unclear whether he was aware of the workload and acuity of patients in the paediatric area and how this was impacted in the context of the nursing needs in the whole department at that time.

All statements from the nurses indicate that they received medical support in a timely manner whenever they escalated and requested support.

There is no record or statement from any of the nurses that suggests they requested assistance due to workload pressures, or for senior nursing or medical support. I therefore find that although it is obvious from the nurses' comments that they were stretched with a workload of high demand, there is no evidence that suggests that requests for assistance or support were denied. Without further information regarding the patient census and acuity in the emergency department at that time, I am unable to comment further.

- The adequacy of the relevant policies and procedures in place at [Hospital 1] at the time of the events complained of, as well as new/updated policies.

I have reviewed policies and procedures provided to me that supported practice at the time of this incident. Aspects that apply to the context of this case are discussed individually.

Cannulation — Intravenous — Issued December 2012.

This is a generalised policy that discusses the procedures of IV cannulation in some detail. It is clear and follows a logical sequence and is clearly based on the adult patient although it does not specifically exclude paediatrics. Under the heading of 'Apply Dressing' it is recommended that 'an external cover i.e. Tubifast' is applied for long term cannula to prevent cannula movement. I found no recommendation that the site is left visible to allow for monitoring of the site. There are also no recommendations or guidelines for ongoing monitoring of the IV site in this policy.

Based on a review of policies and procedures from another tertiary service, Lippincott Nursing Procedures and Skills and my clinical experience I find that this policy is largely adequate but fails to describe guidance for monitoring of the IV site and cannula patency.

Intravenous Cannulation — Paediatrics, Issued Nov 2012

This document discusses the procedures of IV cannulation specifically for paediatric patients in some detail. It is clear and follows a logical sequence. It suggests that the IV cannula should be placed in a distal vein in the non-dominant hand in preference. No reference is made for the preference of a larger vein when siting a cannula to be used for infusions/injections of tissue irritant substances. Under the heading 'Taping the IV' it clearly advises that 'the area where the catheter tip is situated and the insertion site is visible'. Clear guidelines are provided to ensure adequate monitoring of the cannula insertion site.

Based on a review of policies and procedures from another tertiary service, Lippincott Nursing Procedures and Skills and my clinical experience I find that this policy is adequate to guide safe and effective patient management for intravenous cannulation of the paediatric patient.

Phenytoin Intravenous — Adults only, Reviewed Dec 2010

This is the only policy provided in regard to the administration of phenytoin at the time this incident occurred.

It outlines the specific requirements around the prescription, preparation, administration, observation and monitoring, mechanism of action, contraindications and precautions, possible adverse effects, special considerations and drug interactions. The specific issues of the drugs instability when mixing are discussed and it clearly describes the monitoring requirements to detect systemic adverse reaction at the earliest opportunity. It does not state a requirement for IV site inspection during or after the infusion or suggest that the use of a large vein is preferable.

Based on a review of policies and procedures from another tertiary service and Notes on Injectable Drugs 6 Edition, I find that this policy fails to adequately provide guidance to practitioners to avoid the consequences of the known adverse effects of tissue irritation when administering phenytoin.

Handover of patients — Emergency Medicine, Issued May 2010

This document relates to the handover responsibility for patients to another doctor within the Department of Emergency Medicine. It provides no specific guide to nursing handover.

As this document clearly states that it relates to doctor to doctor handover, it provides inadequate guidance to nurses in the Emergency Department setting for safe and effective patient handover within the ED setting and when transferring patient nursing care to another area.

Handover, Issued Dec 2012

This document defines handover and its importance in clinical care and outlines practice expectations. It is non-specific to the Emergency Department context. The document states that handover from 'Nurse to Nurse across services' requires a verbal telephone conversation between the nurse caring for the patient and the nurse expecting the patient in the new area and requires the receiving nurse to

document details on a prescribed form. A face to face handover should be made when the patient is bought to the new area. It is not stated whether all or which patients should have a nurse escort when transferring between areas.

The type of information that is required to be delivered during the handover is not described.

Based on a review of policies and procedures from another tertiary service, a review of current literature and my clinical experience I find that this policy is inadequate to guide safe and effective transfer of care between nursing practitioners. Although it provides a general overview of the principles of handover, the lack of specific detail in describing the handover content and process significantly reduces its effectiveness.

Extravasation — Paediatric Issued June 2013

Paediatric IV Infusions — Dose Reference Chart Issued January 2012

Phenytoin (Intravenous) — Paediatrics issued April 2013

It is my opinion that these policies provide a full, clear, logical and detailed guidance to practitioners caring for children receiving phenytoin and other infusions/medications.

Conclusion

Thank you for the opportunity to contribute to quality care in New Zealand by acting as a peer reviewer in the HDC case 13/00756. I wish [Miss A] and her family well and trust that the HDC process will support a satisfactory outcome for them and result in an improved safety service for the public of New Zealand.

Wendy Sinclair RN, MN(Clin).

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