A District Health Board

ICU Registrar, Dr B

ICU Consultant, Dr C

ICU Registrar, Dr D

Registered Nurse, Ms E

Registered Nurse, Ms F

Registered Nurse, Ms G

Registered Nurse, Ms H

A Report by the

Health and Disability Commissioner

(Case 02HDC08949)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Master A	Consumer
Mr and Mrs A	Consumer's parents
Dr B	Provider, ICU consultant
Dr C	Provider, ICU consultant
Dr D	Provider, ICU registrar
Ms E	Provider, Registered nurse
Ms F	Provider, Registered nurse
Ms G	Provider, Registered nurse
Ms H	Provider, Registered nurse
Dr I	ICU Consultant
Dr J	Paediatrician
Mr K	Burns surgeon
Dr L	ICU registrar
Dr M	ICU consultant
Dr N	A Clinical Director at the public hospital
Dr O	ICU House Officer
The public hospital	Provider, public hospital
A District Health Board	Provider, public Hospital

Complaint

On 20 June 2002 the Health and Disability Commissioner (the Commissioner) received a complaint from Mr and Mrs A about the treatment provided to their late son, Master A, by a public hospital. Mr and Mrs A's complaint was summarised as follows:

Complaint against a District Health Board
The District Health Board did not provide services of an appropriate standard to Master A. In particular:

- *while Master A was in a public hospital from 17 to 26 March 2002, medical and nursing staff failed to monitor Master A's medications properly*
- *Master A suffered a paracetamol overdose*
- *medical and nursing staff failed to detect the paracetamol overdose and the decline in Master A's health in a timely manner*
- *medical and nursing staff failed to respond to the paracetamol overdose and the decline in Master A's health and did not treat it in a timely and effective manner*
- *although the public hospital knew that Mr and Mrs A were dissatisfied with Master A's treatment, they did not advise Mr and Mrs A of the existence of the Health and Disability Commissioner's Office or of the independent advocates provided under the Health and Disability Commissioner Act 1994.*

Complaint against Dr C, Dr B and Dr D
Over the weekend of Saturday 23 and Sunday 24 March 2002, intensive care consultants Dr C and Dr B and ICU Registrar Dr D did not provide services of an appropriate standard to Master A. In particular, they:

- *failed to detect the paracetamol overdose and the decline in Master A's health in a timely manner*
- *failed to respond to the paracetamol overdose and the decline in Master A's health and did not treat it in a timely and effective manner.*

Complaint against Ms E
The District Health Board did not provide services of an appropriate standard to Master A. In particular, at 11am, 3pm and 7pm on 23 March 2002, registered nurse Ms E administered to Master A 1gm doses of paracetamol, instead of the prescribed 250mg doses.

Complaint against Ms F
The District Health Board did not provide services of an appropriate standard to Master A. In particular:

- *at 11pm on Saturday 23 March 2002 and at 3am on Sunday 24 March 2002, registered nurse Ms F administered to Master A 1gm doses of paracetamol, instead of the prescribed 250mg doses*
- *Ms F subsequently altered the records to state that at 11pm on Saturday 23 March 2002 and at 3am on Sunday 24 March 2002, she had administered to Master A the prescribed 250mg doses of paracetamol*
- *having altered the records, Ms F failed to notify anyone that she and the preceding nurse (at 11am, 3pm and 7pm on Saturday 23 March 2002) had administered 1gm doses of paracetamol to Master A instead of the prescribed 250mg doses.*

Complaint against Ms G
The District Health Board did not provide services of an appropriate standard to Master A. In particular, from 7am to 7pm on Sunday 24 March 2002, registered nurse Ms G did not provide services of an appropriate standard to Master A. Ms G:

- *failed to detect the paracetamol overdose and the decline in Master A's health in a timely manner*
- *failed to respond to the paracetamol overdose and the decline in Master A's health and did not treat it in a timely and effective manner.*

Complaint against Ms H
The District Health Board did not provide services of an appropriate standard to Master A. In particular, from 7pm on Sunday 24 March 2002 to 7am on Monday 25 March 2002, registered nurse Ms H did not provide services of an appropriate standard to Master A. Ms H:

Names have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

- *failed to detect the paracetamol overdose and the decline in Master A's health in a timely manner*
- *failed to respond to the paracetamol overdose and the decline in Master A's health and did not treat it in a timely and effective manner.*

An investigation was commenced on 18 March 2002.

Information reviewed

- Master A's patient records from the public hospital
- Master A's patient records from the children's hospital
- File compiled by Mr A containing the complaint and information about Master A's care and treatment and events following his death
- Responses to complaint from Dr C, Dr D, Dr B, Ms E, Ms F, Ms G and Ms H
- Notes of interviews with Dr D, Dr B, Ms E, Ms F, Ms G and Ms H
- Report by Dr N for the family of Master A dated September 2002
- Letter dated 7 May 2003 from Dr N, Department of Intensive Care Medicine, the public hospital
- Advice provided by Professor Laurie Prescott to Ms E's barrister, dated 10 August, 10 November and 24 December 2002
- Report by Professor Begg dated 28 November 2003
- Pathologist's post-mortem report
- Letter dated 24 February 2004 from Dr I
- Letter dated 24 February 2004 from Dr M
- Letter dated 23 February 2004 from Dr L
- Response to provisional opinion from the District Health Board, Ms E, Ms F, Ms H and Mr A

Independent expert advice was obtained from:

- Dr John Fountain, toxicologist, on 14 December 2002 and 12 April 2003
- Dr Ross Freebairn, intensivist, on 8 June and 10 December 2004
- Ms Janet Hewson, registered nurse, on 31 May and 13 December 2004.

Information gathered during investigation

Background
Master A was a three-year-old boy who lived overseas. On 15 March 2002 local time (16 March 2002 New Zealand time) Master A suffered burns over 60–70% of his body from boiling water. He was resuscitated and treated initially in his home country and then transferred to a public hospital (part of the District Health Board).

Before the accident, Master A had been in generally good health although there is some debate as to whether he had had diarrhoea for several days prior to his injury. Irrespective of this dispute it is clear that he was suffering from diarrhoea during his admission to the public hospital.

17–22 March 2002
When he arrived at the public hospital on 17 March 2002, Master A was sedated but had fairly normal breathing and circulation. He was burnt on his neck, back, chest, right arm, right leg, left arm and left leg. He was taken to theatre to have his burn wounds debrided and dressings applied and was then admitted to the Intensive Care Unit (ICU) where he was intubated and ventilated and had ongoing sedation. He was also treated with triple intravenous antibiotics.

Over the night of 17–18 March Master A was febrile and had a low white cell count. On 18 March he went to theatre again to have his dressings changed and silver sulphadiazine cream applied to his perineum. Between 18 and 20 March Master A remained intubated and ventilated. He was fed via a nasogastric tube (a long plastic tube inserted through the patient's nose or mouth into the stomach). Master A also required ongoing intravenous administration of fluids. He continued to have profuse watery diarrhoea, the cause of which was not identified by investigations.

Master A was extubated on 20 March and transferred from ICU to the children's surgical ward in the public hospital on 21 March. Master A's patient record for 21 March indicates that following his transfer he continued to require intravenous fluid replacement and suffered several episodes of diarrhoea, which necessitated frequent revision of his fluid status and close observation. On 22 March he continued to have diarrhoea, with reduced absorption of feed. His fluids and electrolytes were closely monitored.

Readmission to ICU on 22 March 2002
At 1330 on 22 March 2002 Master A was transferred back to ICU, not because of any deterioration in his condition, but because it was difficult for nurses on the children's surgical ward to provide the one-on-one nursing care necessary to manage his fluid and electrolyte requirements.

On his return to ICU Master A was prescribed paracetamol 250mg to be administered by nasogastric tube at four-hourly intervals.

At this time standard formats were used for recording the prescription and administration of medications in ICU. Prescriptions for medications were recorded on a sheet headed

Prescribing Sheet 1 ICU Drug Chart. The administration of those medications was recorded on a separate sheet headed *Drugs and Fluid Record Chart.* A separate *Drugs and Fluid Record Chart* was maintained for each 24 hours a patient remained in ICU.

Additionally, the format of the sheets required the nurses to transcribe the name of each medication to be administered from the *Prescribing Sheet 1 ICU Drug Chart* to the *Drugs and Fluid Record Chart.* In order to ascertain dosage and frequency, it was necessary for nurses to refer back to the separate *Prescribing Sheet 1 ICU Drug Chart* ("ICU Prescribing Sheet").

There was no provision in the *Drugs and Fluid Record Chart* for the calculation of dosage to be recorded.

Most medical staff used what is known as the *Melbourne Booklet* to calculate medication doses by weight.[1] The *Melbourne Booklet* specifies dosages for paracetamol as follows: "Oral: 20mg/kg stat, then 15mg/kg/dose 4H (max 4g/day)."

There is uncertainty as to how much Master A weighed at the time of his ICU admission and it is unclear whether Master A was actually weighed, or whether his weight was estimated (as there is no bed scale in ICU). On the medication chart used dated 21 March 2002 Master A's weight is recorded as 18kg. At the top of Master A's *Prescribing Sheet 1 ICU Drug Chart* there is a note "Weight ([from Master A's home country]) 15 kg".

Day shift — 23 March 2002
At 0700 on 23 March 2002 Ms E was assigned to care for Master A in ICU. Ms E had been a registered nurse since October 1994. She had worked initially in a private hospital as a theatre nurse, then in 1995 moved to the public hospital's plastics, facial and maxilla surgical ward where she remained until 1998. She was then employed by the public hospital's nursing bureau and had worked where assigned throughout the hospital in areas including intensive care, medical, gynaecology, surgical, plastics, gastroenterology, haematology, emergency department and paediatrics.

Master A's care was handed over to Ms E by the nurse who had cared for him during the preceding night shift. During the handover Ms E noted that Master A had been prescribed paracetamol four hourly.

Ms E's impression of Master A at the beginning of her shift was that he was lethargic and quite unwell. He was lying still and grizzling. Master A's mother was present and Ms E involved her in repositioning Master A and giving him fluids. Ms E proceeded to change Master A's dressings with the assistance of another bureau nurse.

[1] The *Melbourne Booklet*'s full title and reference is Shann F, *Drug Doses* (11th edition, 2001, Intensive Care Unit Royal Children's Hospital, Parkville, Victoria, Australia).

Morning ward round — Saturday 23 March 2002
Master A was reviewed at the morning ward round on 23 March 2002 by Dr I, ICU consultant, Dr D, an ICU registrar, and the incoming medical team of Dr C, ICU consultant, and Dr B, ICU registrar. It was noted that Master A was fully conscious, breathing of his own accord with good oxygen saturation, and had a urinary output of 15 mls per hour. He had not had any further diarrhoea. The plan was for paediatric review to determine when feeds should be re-started.

Dr J, a paediatrician, reviewed Master A that day and requested feeds to be re-started slowly at 5–10 mls two hourly with a corresponding reduction of fluids with feeds.

Administration of paracetamol by Ms E
Ms E administered paracetamol to Master A three times during her shift — at 1100, 1500 and 1900 hours.

Ms E said that before administering the first dose of paracetamol at 1100, she checked Master A's body weight in his patient notes so that she could calculate the correct dosage for him. This was done by multiplying his body weight (18kg) by 15, which calculated to a dose of 270mg.

Ms E states that she then checked that 270mg came within the range charted on the *ICU Prescribing Sheet*, which was 250mg. She also checked the strength of the paracetamol on the bottle and noted it to be 250mg per 5ml. Although Ms E calculated that each dose of paracetamol should be 270mg, whereas the prescription was for doses of 250mg, she did not think the discrepancy warranted checking with ICU medical staff. This was because although the prescribed dose of 250mg was lower than she was accustomed to in the children's wards, the four-hourly doses prescribed were more frequent than the six-hourly doses usually prescribed in the children's wards.

Ms E believes that she then drew up the required 250mg of paracetamol. To do this, she took a bottle of paracetamol solution from beside Master A's bed and put some of the solution into a polystyrene cup. She then drew up the paracetamol solution into a syringe to measure the correct dose of 250mg. Ms E then emptied the excess paracetamol solution into the sink beside Master A's bed, washed out the cup and filled it with warm water. She drew up water into the same syringe to dilute the paracetamol. Ms E administered the paracetamol by syringing it into Master A's nasogastric tube.

In Master A's *Drugs and Fluid Record Chart* for 23 March 2002 Ms E recorded that she had administered 1g (as opposed to 250mg) of paracetamol by nasogastric tube at 1100 hours (flushed with 90mls of fluid), 1500 hours (flushed with 65mls of fluid) and 1700 hours (flushed with 60mls of fluid).

Mrs A recalled that on about three occasions on 23 March, and particularly around 1600, she noticed the nurse, who would have been Ms E, administering a large amount of medicine to Master A in a large syringe.

Ms E is confident that, irrespective of what she recorded, she administered only 250mg doses for the following reasons:

- In her experience a 1g dose for a child would have been very unusual and not something she had encountered before. She said that alarm bells would have rung had her calculation indicated that each dose should be 1g.
- The paracetamol mixture is very viscous and sticky and when used in large doses it results in increased pressure when it is administered through a nasogastric tube. The increased pressure is very noticeable when a large amount such as 1g is administered. Ms E calculated that 1g of paracetamol would have equated with a dose of 20mls. Ms E said that she did not notice any pressure and felt that the paracetamol went in very easily.
- The dosage for 1g of paracetamol would be four times the volume of a 250mg dose which would have resulted in a back pressure from the nasogastric tube when the syringe was depressed. Ms E cannot recall any back pressure when administering paracetamol to Master A.

Ms E explained that the recording of the three 1g doses of paracetamol were documentation errors. She suggested that the errors may have occurred because the day before she had been looking after an adult patient who had been prescribed the standard adult paracetamol dosage of 1g four hourly.

Ms E said that she did not record any details of the 1g doses of paracetamol in advance of administering them but recorded them after administration at 1100, 1500 and 1900. She did, however, mark up the *Drugs and Fluid Record Chart* prior to administration by making a small dot in pencil against the times 1100, 1500 and 1900 as an indication of when each dose of paracetamol was due.

With respect to Master A's general condition during her shift, in a note made at 1715 hours Ms E recorded that Master A had been very irritable that morning but was now a lot more settled. His bowels had opened twice and produced a small amount of loose brown faeces. He was draining good amounts of clear amber urine. She also records "Panadol given [because of] temperature [with] good effect."

Night shift — 23–24 March 2002
At 1900 Ms E's shift finished and Ms F, registered nurse, took over Master A's care.

When she commenced her shift, Ms F initially noted on Master A's *Drugs and Fluid Record Chart* that a 1g dose of paracetamol was due at 2300. She said that it was her practice to fill in at least the amount and timing of the next drugs to be administered to remind her of the amounts and timing.

At 2130 hours Master A was reviewed by Dr I, Dr D, and Dr B. The plan to increase feeds was reiterated.

Ms F came to administer paracetamol to Master A for the first time at 2300 on 23 March. She checked the *ICU Prescribing Sheet* and the *Drugs and Fluids Record Chart* and saw that they both indicated that paracetamol was to be administered in doses of 250mg by nasogastric tube every four hours. She then went back to her own entry on the *Drugs and Fluids Record Chart* and changed the 2300 dose to 250mg. She made the alteration before administering the correct dosage of 250mg.

The entry in the *Drugs and Fluid Record Chart* against 0300 on 24 March also appears to have been altered from 1g to 250mg but Ms F maintains that she altered only the entry at 2300 on 23 March.

Ms F is categorical that she administered paracetamol in 250mg doses to Master A at 2300 on 23 March, and 0300 and 0700 on 24 March.

Ms F says that when she checked the *ICU Prescribing Sheet* and the *Drugs and Fluids Record Chart* before administering the paracetamol at 2300 she noticed that Ms E had recorded giving three 1g doses of paracetamol. As a consequence she made a point of observing Master A carefully for any changes such as coldness or clamminess, which might indicate paracetamol overdose, but found him to be warm with good capillary refill and a stable heart rate.

Additionally, during her shift Ms F received laboratory results for Master A which showed abnormal liver function tests (alkaline phosphatase (ALP) of 107 U/L and alanine transaminase (ALT) of 89 U/L). A normal ALT level is 0–45 U/L.

Ms F has stated that she intended to tell the ICU medical staff about the apparent overdoses and of the need to monitor Master A's liver function when they attended for the ward round. However, she became busy assisting another nurse with a patient who had suffered serious burns in a car accident and omitted to advise the ICU medical staff of the possible paracetamol overdose and elevated liver function tests.

Ms F did not write the apparent overdoses in Master A's patient record. She did not raise them with any member of the ICU medical staff or with the shift coordinator, nor did she report them via the public hospital's Complaints and Incidents Management System (CIMS) or complete an incident form.

Ms F says, however, that she did draw the apparent overdoses and Master A's elevated liver function tests to the attention of Ms G, the nurse who took over Master A's care at 0700 on 24 March.

Day shift — 24 March 2002
Ms G maintains that Ms F did not mention the apparent overdoses or Master A's raised liver enzymes during the handover at 0700 on 24 March.

In her response to notice of my investigation, Ms G described the handover process as follows:

> "The night co-ordinator gave the report to all the day staff on all patients that were present in the department. The handover included the care and treatment of the patient and if there were any significant events. There was no discussion in the hand over of patient [Master A], that there had been a paracetamol overdose …
>
> … I was told that the patient had some loose motions during the night and that the dressings were reinforced. The patient slept well overnight and received some morphine to keep him comfortable. There was no mention of raised liver enzymes.
>
> I started my shift with briefly reading the patient's notes. There was no mention of any apparent administration of 1 gram doses of paracetamol in [Ms F's] nurses notes."

Morning ward round — 24 March 2002
Master A was reviewed by Dr C and Dr B during their morning ward round. Dr D is not recorded as having attended.

Dr B's note of the ward round at 1000 records that Master A was breathing on his own with good oxygen saturation. His urinary output was greater than 15mls per hour and his heart rate was 140 beats per minute. The plan was to increase feeds to 40mls per hour and to encourage eating and drinking.

This note suggests that at the time of the ward round, Master A's clinical condition had improved — such improvement being underscored by the plan to increase the feeds he was receiving.

At the end of her shift (1900 hours on 24 March) Ms G recorded that Master A had been quite settled. He had vomited twice and his feeds were stopped for a while then restarted. He had also had three loose greenish bowel motions. His urinary output was 10-15mls/hour. Ms G also transcribed Master A's blood test results from the ICU computer into the clinical notes. These results showed elevated liver function tests (with ALT levels of 176 U/L at 1400 hours, and 313 U/L at 1750 hours). Ms G recalled:

> "The significance of the raised liver enzymes did not alert me to report it, as I was not aware of the paracetamol overdose. Intensive care patients often have elevated liver enzymes. The abnormal liver enzymes for an intensive care patient can be indicative of sepsis or multi-organ failure, [and are] not uncommon in Intensive Care patients, but both [are] complications that do not require immediate action."

Nursing night shift — 24–25 March 2002
At 1900 hours Ms G handed over Master A's care to Ms H who, at the time of Master A's ICU admission, had been working as an ICU nurse for almost five years.

Ms G did not advise Ms H of the apparent paracetamol overdoses (which is consistent with her position that she was unaware of them).
Ms H said that Master A was awake and appeared alert at the beginning of the shift. He was watching television. She recalled that at the beginning of her shift:

> "I also carried out my safety checks in regard to the functioning of bedside equipment appropriate to [Master A's] care, and reviewed his drug chart and flow chart (a 24 hour chart — 0700-0600 — used for documentation in the Intensive Care Unit (ICU)), orientating myself to the needs of [Master A] during the night. I noted that during the day he'd been afebrile with a persistent tachycardia [fast heart rate]. His respiratory rate was within normal limits, as were his oxygen saturations on room air. With a documented weight of 15 kilograms his urine output was marginal at just over ½ml/kg. He had vomited once and had had three bowel motions. He was drinking, as well as having paediatric supplements via his nasojejunal (NJ) tube. Intravenous (IV) fluids were also being given, as well as continuous potassium supplements. The blood tests done at 1710 indicated that a low potassium state remained. Extra supplements were charted and were in progress, prior to the commencement of my shift. I do not recall receiving any information about the abnormal ALT (alanine aminotransferase) result during the handover, nor recall noting it myself on the results chart, where it would have been written in by whoever collected the blood results from the computer."

Evening ward round — 24 March 2002
The evening ward round at 2122 was attended by Dr C, Dr D, and Dr B. The note of the ward round states:

> "Persistent low K [potassium] + despite continuous suppl [supplement].
> Wounds look 'green' Pseudomonas – Biobran
> Pulse 173/min. Awake. Feeding well.
> ↑ [Increase] NJ feed to 40ml/hr — vomited x 1
> L subclavian CVL [central venous line] — reddish — Afebrile.
> P[plan] — Stop D5W
> — C/W [continue with] plasmalyte."

Dr B recalled:

> "The elevated LFTs [Liver Function Tests] would have been noted on the evening ward round [on 24 March 2002] but at this level it was elected to continue to monitor them in view of his unchanged clinical state."

Dr C at this time requested a blood gas to assess any acid-base derangement, and coagulation tests in addition to the routine biochemistry and haematology tests. He did this because of concerns regarding Master A's ongoing diarrhoea and electrolyte losses.

Ms H recorded that Master A became increasingly agitated over the shift. He had hardly slept and was constantly calling out. He had green, mostly liquid diarrhoea five times. His

abdomen appeared tight but not swollen or tender. He had a mild temperature of 37.8°C, was tachycardic, and his urinary output was minimal — the equivalent of 0.5ml/kg.

At 0300 Master A's urinary output was nil. Ms H reported this to Dr D, who instructed her to give Master A a bolus of plasmalyte with the aim of maintaining a urinary output of 0.5ml/kg. Master A's urinary output improved. Ms H said that she also mentioned Master A's restlessness, ongoing diarrhoea and increased temperature at this time.

Liver function tests — 25 March 2002
During this shift Ms H transcribed Master A's laboratory results from the computer into the written clinical record. These results included elevated ALT levels of 653 U/L at 0010 hours and 642 U/L at 0545.

Ms H also recorded against the 0545 time the results of the coagulation tests ordered by Dr C at the previous ward round. These were abnormal with an activated partial thromboplastin time (APTT) result of 77 seconds (normal 25–37 seconds), and an International Normalised Ratio (INR) of 8.4 (normal range 0.8–1.2). Both of these tests assess the clotting time of a patient's blood.

Ms H said that she advised Dr D of Master A's ALT level sometime after collecting the 0545 results. She recalled that Dr D's response was that Master A's liver function tests would be looked at on the morning ward round. She stated:

> "After collecting the results I noticed the abnormal coagulation results and high ALT. These results informed me that [Master A] was experiencing abnormalities within the clotting pathway and that his blood was much thinner than what it should be, and that his liver was not functioning normally. I recall showing these blood results to the doctor and wondering aloud what on earth could be going on. [Dr D] said that they would look at it on the Doctor's round."

Dr D disputes being advised of the results either by the laboratory or nursing staff.

In fact between 23 and 25 March Master A's blood tests showed increasingly abnormal liver function tests, specifically elevated ALT levels. These ALT results were recorded in his ICU Laboratory Results chart as follows:

Date	23/03	24/03	24/03	24/03	25/03	25/03	25/03
Time	2200	0600	1400	1750	0010	0545	1200
ALT (0-45U/L)	70	89	176	313	653	642	746

Ms H's shift ended at 0700 on 25 March and she handed over Master A's care to another registered nurse. Ms H said that she advised the registered nurse of Master A's abnormal ALT and coagulation results.

Morning ward round — 25 March 2002
Dr I, the incoming ICU consultant, Dr C, the outgoing ICU consultant, and the ICU registrar, reviewed Master A at the morning ward round at 0940 on 25 March.

It was noted that Master A had continuing diarrhoea, rising ALT levels, a persistent low-grade fever, he was tachycardic, had reduced urinary output, and had been vomiting. A paediatric review was planned and a swab of his wound requested.

Dr C recalled:

> "There were no major concerns with [Master A] over [the weekend of 23–24 March 2002] other than some difficulty establishing enteral feeding and the ongoing diarrhoea; he had been seen both by one of the paediatric surgeons and by one of [the public hospital] paediatricians. Because of concerns regarding the ongoing diarrhoea and electrolyte losses, I requested a blood gas on the Sunday evening ward round (from a central venous line as he had no arterial line), to assess any acid-base derangement. Unfortunately I was not informed of the abnormal results until I reviewed the patients prior to the Monday morning hand-over Ward Round. I was also not informed of the further rise in ALT on the blood chemistry at Midnight, and I do not know when exactly these results were released to a member of the ICU staff. I had expected the rise in ALT over the previous day to plateau, most likely related to wound infection, (I requested wound swabs to be sent), an inter-current viral infection, (the ongoing diarrhoea), or to a mild to moderate drug reaction. Also the coagulation test results were not available when I handed over on the Monday morning. It is worth noting that these were requested to see how high [Master A's] fibrinogen levels were to try to assess pro-thrombotic risk rather than to look for coagulopathy."

Dr B's evidence also reflected Master A's relative stability over the weekend of 23-24 March 2002. He said:

> "[Master A] showed clinical improvement over the weekend despite ongoing intermittent fever up to 39 degrees C. He had mild derangement of his liver function tests (LFTs) on the evening of [Sunday 24 March 2002] and these continued to deteriorate over the next 36 hours as did his clinical state. …
>
> [Master A's] clinical condition improved rather than declined over the weekend. There was a mild derangement in LFTs which was progressive over the day of [24 March 2002] and at 1750 [on 24 March 2002] his ALT was 313 mmol/L and otherwise his LFTs were normal. Elevation of liver function tests to this level is a very common occurrence in patients in an ICU care setting. There are a multitude of possible causes including sepsis and various antibiotics. These were much higher on the differential than paracetamol toxicity, as [Master A] had had fevers over the weekend and had clinical evidence of infected skin wounds. He was also on antibiotics."

Review by Mr K — afternoon of 25 March 2002
Master A was reviewed by the burns surgeon, Mr K, and Dr L, who was the ICU registrar, early in the afternoon of 25 March.

At 1200 on 25 March 2002 Master A received his final dose of paracetamol.

There is conflict as to who issued the instructions to discontinue the regular doses of paracetamol. Dr M, ICU consultant, says that Dr I informed him on 26 March that he had discontinued Master A's paracetamol because his liver enzymes were elevated and that this was prudent in light of abnormal liver function tests, since paracetamol is potentially hepatotoxic (damaging to liver cells).

Dr L, however, says that he stopped the paracetamol when Mr K, the burns surgeon, commented while reviewing Master A that paracetamol was not good for liver function.

It is unnecessary for me to resolve this conflict since, regardless of who gave the instruction, it is clear that Master A did not receive any paracetamol after 1200 on 25 March 2002.

Review by Dr J — 1700 on 25 March 2002
Dr J, paediatrician, reviewed Master A at 1700 on 25 March. She noted that he had ongoing diarrhoea, two episodes of vomiting that day, intermittent pyrexia, urinary output of 10ml/hr and rising AST/ALT levels with dark urine and lowered ALB. Dr J considered hepatitis and poor fluid balance as possible causes of his deteriorating condition and adjusted the management plan.

Mr and Mrs A noticed that Master A was passing black urine during this shift.

Evening ward round — 25 March 2002
Master A was further reviewed by Dr I at 2130 during his evening ward round. His plan was to increase Master A's fluids.

Liver failure — 26 March 2002
By the morning of 26 March 2002 Master A had several features of hepatic liver failure including hypoglycaemia (low blood sugar), coagulopathy (abnormal coagulation) and hypoalbuminaemia (abnormally low albumin content in the blood). He was also acidotic (had an accumulation of acid in the blood or body tissue) with a pH of 7.25 as a result of partially compensated metabolic acidosis (where the pH of the blood has been returned to normal by respiratory compensatory mechanisms).

Dr M was the ICU consultant and led the ward round that morning. Master A's abnormal coagulation result was brought to his attention. He instructed that a repeat coagulation profile be performed to confirm the abnormality.

Dr M recalled:

> "… On the ward round [on the morning of 26 March 2002] we spent a long time with [Master A] trying to ascertain the cause of his problems. He had developed a distended abdomen and now had a decreased level of consciousness. He had been admitted for management of a diarrhoeal illness and had deteriorated over the preceding day or so with itching, some confusion and abnormal liver function tests.
>
> As part of his care, [Master A] had been treated with regular paracetamol and [Dr I], the specialist handing over to me, informed me that he had discontinued this because of some elevation in liver enzymes. He did this because he thought it was prudent to discontinue a drug, which was potentially hepatotoxic in the setting of abnormal liver function tests.
>
> In addition on examination it was clear he had become encephalopathic, and suffered episodes of hypoglycaemia, and there was profound metabolic acidosis, all of these are features of liver failure. There were some important features of liver failure which were not present, namely, the bilirubin was not elevated and the ALT, while elevated, was not as high as one might expect after hepatic injury severe enough to cause liver failure. When the repeat coagulation profile confirmed markedly prolonged prothrombin time, it seemed that [Master A's] deterioration was likely to be due to some form of liver failure."

Discovery of apparent overdoses

As part of the search for the cause of Master A's liver failure, Dr O, ICU house officer, reviewed Master A's drug administration records to establish how many doses of paracetamol Master A had received before the paracetamol was discontinued. Dr O noted the apparent overdoses of paracetamol recorded by Ms E on 23 March 2002 and advised Dr M. This appears to have been the first time any of the ICU medical staff were aware of the apparent error.

Dr B noted:

> "It is not standard practice to measure paracetamol levels (usually a very safe drug) unless toxicity is suspected. Paracetamol toxicity was not suspected in the setting of an appropriately charted, weight-adjusted dose. It is also not standard practice for medical staff to routinely check the dose administration sheet, only the dose chart sheet. It is a nursing responsibility to check and administer the correct dose of a drug as charted. With paracetamol toxicity the rise in LFTs and deterioration in clinical state occurs up to 24 hours post insult yet treatment is most effective if given before this occurs – making timely diagnosis dependent on a high level of suspicion (such as an intentional overdose). There was no reason for a high level of suspicion in [Master A's] case ...
>
> The fact that paracetamol toxicity was very low on the differential is evidenced by the fact that a paracetamol level was not ordered till [26 March 2002] despite at least 6 different experienced doctors being involved in his care."

Retrospective testing of paracetamol levels
On receiving information regarding the apparent overdose Dr M ordered retrospective tests of the paracetamol levels in Master A's blood. The results of the retrospective testing showed elevated levels of paracetamol (above the therapeutic range) on 23 March (at 2158 hours) and 24 March (at 0600).

At 1030 on 26 March Dr M started Master A on an N-acetylcysteine infusion on the assumption that he might be suffering from paracetamol-induced liver failure. N-acetylcysteine is the antidote for paracetamol.

Transfer to PICU, the children's hospital
Arrangements were made for Master A to be transferred to the Paediatric Intensive Care Unit (PICU) at the children's hospital. Before and following transfer to PICU Master A's condition deteriorated significantly.

At PICU Master A was reviewed by the Liver Transplant Team but it was decided that he was not a suitable candidate for transplant because his burns made the risk of infection unacceptably high.

Master A died at the children's hospital.

Failure to advise Mr and Mrs A of the existence of the Health and Disability Commissioner's Office and independent advocates
Part of Mr and Mrs A's complaint concerned the failure by ICU medical and nursing staff to inform them of the existence of the Health and Disability Commissioner's Office (HDC) or of the independent advocates provided under the Health and Disability Commissioner Act 1994.

On 28 March 2002 Mr and Mrs A met with Mr K, the plastic surgeon who had operated on Master A, and the public hospital's Burns Co-ordinator. Mr and Mrs A had already been advised that Master A's death may have been due to a paracetamol overdose. They had a number of questions about Master A's care between 23 and 26 March 2002. They felt that Master A's developing problems had not been recognised, and questioned why it had taken so long for ICU staff to respond. They were understandably distressed and angry. Mr K told them that their questions and concerns would be investigated and the investigation process was briefly explained.

The District Health Board advised that in normal circumstances information about HDC and the availability of independent advocates would be provided by its Bereavement Care Team if that information had not already been provided by medical and nursing staff in ICU. It appears that as Master A died at the children's hospital, the need to provide this information was overlooked.

Cause of Master A's death
The public hospital and the doctors at the children's hospital initially attributed Master A's death to liver failure apparently caused by the overdoses of paracetamol. Master A's

parents, Mr and Mrs A, were advised that this was the likely cause of death in the days immediately following Master A's death, and this view was confirmed by the initial report of the Coroner's pathologist who, following autopsy, concluded that Master A's death resulted from the toxic effects of paracetamol on the liver. He noted:

> "I have been informed that the patient received an overdose of paracetamol. The changes in the liver are typical of what I have seen in cases of paracetamol toxicity. The changes in the lung, heart muscle, kidneys and adrenal glands are due to 'shock'."

Subsequently, Ms E engaged Professor Prescott, a renowned international expert on paracetamol toxicity, for the purpose of ascertaining whether Master A's death was caused by paracetamol overdose.

On 10 August 2002 Professor Prescott concluded, with reference to an analysis of the serum concentrations of paracetamol in Master A's blood samples, the ALT results, and the post-mortem findings of the liver:

> "I do not believe that the patient died as a result of liver failure caused by paracetamol. Even if three doses of 1g instead of 250mg were administered on 23 March, it is most unlikely that this would have caused anything other than minor liver damage and the serum concentrations produced were not high enough to cause fatal hepatic failure. The extent of liver damage as shown by the ALT indicated relatively minor transient hepatic injury that could conceivably have been caused by the dosage error. However in the context of paracetamol toxicity it was not severe enough to cause acute fulminant hepatic failure by any stretch of the imagination. The pattern of the abnormalities of liver function test differed markedly from that seen with acute paracetamol-induced hepatic failure. Indeed, there is no sound clinical or post mortem evidence to support a diagnosis of acute hepatic failure or that it was the cause of death. The clinical picture suggests the rapid onset of multi-organ failure caused by severe burn injury and overwhelming sepsis."

In a further letter to Ms E's counsel dated 10 November 2002, Professor Prescott stated:

> "The overall conclusion is that *[Master A] did not die from acute liver failure.* Only minor liver damage was present and this was not nearly severe enough to cause fatal hepatic failure. The observed minor degree of acute hepatic necrosis could conceivably have been caused by an overdose of paracetamol given several days previously. However, this is unlikely as judged by the measured serum concentrations of paracetamol. In addition, the distribution of hepatic necrosis appeared to be atypical. The true cause of death has not been established and this may be relevant to the changes observed in the liver."

Professor Prescott's advice was provided to me by Ms E and was the first indication that the cause of Master A's death was not related to paracetamol.

Professor Begg's report
As part of the Coroner's inquest the Coroner obtained further expert advice from Profession Evan Begg, Professor of Medicine/Clinical Pharmacology at the Christchurch Scholl of Medicine and Health Sciences to consider the conflicting opinions amongst experts on the cause of Master A's death.

Professor Begg supported the opinion of Professor Prescott. In a report for the Coroner dated 28 November 2003 Professor Begg concluded (again with reference to the paracetamol serum concentrations) that an overdose did occur on 23 March and stated:

> "… It can be clearly seen that at the concentrations observed in this patient on the 23rd of March … hepatic toxicity would be unlikely and the antidote would not have been administered … This data clearly supports Professor Prescott's notion that regardless of the fact that a minor overdose did occur the concentrations were not sufficient to make it likely that paracetamol was the cause of the death of this patient. Professor Prescott did not deny that minor hepatic toxicity might have followed this minor overdose, and it is indeed possible, that in association with the multiple other pathologies it may have played a minor contribution. However it is far more likely that the death was due to all the other co-morbidities related to the extensive burns, the extremely variable volaemic state, the possible presence of other infection, and the administration of many other drugs, particularly in association with three episodes of general anaesthesia.
>
> **Conclusion**
>
> 1. I believe that a minor overdose of paracetamol did occur on the 23rd of March.
>
> 2. I agree with Professor Prescott that it is most unlikely that this minor overdose was responsible for the death of the patient, because the levels involved were lower than those usually associated with hepatotoxicity, and below levels where it is recommended to administer N-acetyl cysteine.
>
> 3. It is more likely that the death resulted primarily from multiple co-morbidities that the patient suffered.
>
> 4. It cannot be excluded that the paracetamol may have played a minor aggravating part in the process."

Coroner's inquest
The inquest into Master A's death took place on 2 March 2004. At the inquest, the Coroner's pathologist amended his opinion, accepting the views expressed by Professor Prescott and Professor Begg. He also concluded that it was possible that a drug, Isoflurane, which was administered as part of the general anaesthetic, had caused or contributed to Master A's liver damage.

The Coroner released her decision on 15 September 2004 and stated:

> "… I am satisfied that [Master A] did not die as a result of acute liver failure caused by paracetamol. Further, I am satisfied on the basis of the available evidence that [Master A] suffered from serious burn injuries that had many associated medical difficulties. In addition, I am satisfied that there was evidence of liver damage.
>
> In the light of the above, I consider it appropriate to modify the cause of death to reflect the evidence … Therefore a formal finding will record his cause of death as being: 'the multiple effects of extensive hot water burn injuries associated with liver damage'."

The Coroner also concluded that while paracetamol had been administered at a higher than normal dose on 23 March, this was not the cause of Master A's death and "could amount to no more than a minor aggravating factor in the overall circumstances".

Further actions
Following Master A's death, the public hospital engaged Dr N, a Clinical Director at the public hospital, to undertake a review of Master A's care. The review identified a number of systems failures and made recommendations to improve the deficiencies. A number of the relevant recommendations are attached as Appendix 3.

Independent advice to Commissioner

Intensive care advice
The following expert advice was obtained from Dr Ross Freebairn, intensive care specialist:

> "8 June 2004
>
> Advice to the Health and Disability Commissioner 02/08949/AM
>
> I am Medical Director of Intensive Care Services and Consultant Intensive Care Specialist, Hawke's Bay Hospital, Hastings. I have a MB ChB (Auckland), and am a Fellow of the Joint Faculty of Intensive Care Medicine and of the Australia and New Zealand College of Anaesthesia. I am vocationally registered in Intensive Care Medicine and in Anaesthesia. I have been asked to advise the Health and Disability Commissioner whether [Master A] (deceased) received care of an appropriate standard from the following medical practitioners
>
> - [Dr C]
> - [Dr D]
> - [Dr B].
>
> [Master A] was a 2 year 11 month old child admitted to [the public hospital] on the 17th March 2002 following a 60–70% Burn Injury [overseas]. Following admission the wounds were debrided, under general anaesthesia in the operating theatre on

three occasions. Fluid and vasopressors were required to maintain to treat hypotension. [Master A] was admitted to ICU on the 22nd March, primarily for burns and other nursing care. There were problems with ongoing vomiting, diarrhoea, and possibly wound sepsis.

There was decline in [Master A's] clinical condition over the weekend of the 23rd to 24th of March, which continued over the night of the 25th. There were elevated transaminases on the evening of the 23rd, which became more elevated over the following days. By the Tuesday 26th his condition had deteriorated, with progressive acute liver failure and a decreasing level of consciousness, such that intubation and ventilation was required. About this time a recording of an excessive dose of paracetamol was discovered in the drug record. Subsequent analysis of the serum demonstrated paracetamol levels above the therapeutic range on the 23rd and 24th of March. [Master A] was transferred to [the children's hospital] for further organ support. He died on the 27th March.

The report from Professor Laurie Prescott [the toxiocologist who provided expert advice for Nurse E] states that the liver lesion seen at post mortem, and abnormalities in the liver function tests are not indicative of hepatic failure from paracetamol poisoning. He also states that the paracetamol level, as measured in the samples, although in the toxic range are not likely to cause fatal hepatic damage. Professor Prescott is a world authority on paracetamol poisoning and despite the clinical staff's suspicions of paracetamol overdose and toxicity, I cannot find any evidence that refutes his conclusions. His assessment raises significant doubts that the deterioration and death resulted from a paracetamol overdose.

The Paracetamol Levels

The Rumack and Matthews nomogram used to analyze toxicity of serum levels, was based on data obtained from previously healthy adults who had taken a single large dose of paracetamol.[2] Multiple dosages, with the possibility of intercurrent sepsis and varied individual metabolism, in a child make interpretation of the apparent toxic or overdose level using this nomogram imprecise[3]. Prof Begg's comments that the levels were below the level for which treatment would normally be started supports Professor Prescott's comments about the expected low risk of toxicity of the doses given. I note Dr Fountain's comments about both the dosing regimes and treatment of overdoses. (Dr Fountain's advice is included at p40). The dosing schedule prescribed is consistent with that recommended in paediatric and general texts including the Advanced Paediatric Life support manual, Drug Doses (from ICU Royal Children's Hospital Melbourne, Hand Book of Paediatric Intensive Care.[4] [5] I

[2] Rumack BH, Matthews H. Acetaminophen poisoning and toxicity. *Pediatrics* 1975; 55: 871–876.
[3] Penna A, Buchanan N. Paracetamol poisoning in children and hepatotoxicity. *Br J Clin Pharmacol* 1991; 32: 143–149.
[4] Rogers MC Helfaer MA *Handbook of Pediatric Intensive Care* (2nd edititon 1994 William and Wilkins, Maryland, USA).
[5] Advanced Paediatric Life Support, 2nd edition , BMJ Publishing 1997.

could not find any reference to restricting doses in prolonged use, except in texts published after 2002[6]. While Dr Fountain's belief that the dosing schedule is excessive may be correct, this was not included in commonly available guidelines or recommendations available in 2002.

A fatal iatrogenic paracetamol overdose in a five year old child has been described with 8.5g acetaminophen over a 48 hour period. Fulminant liver failure developed within 60hr and the paracetamol serum levels were low compared to cases with ingestion of one single overdose. Lower doses have resulted in hepatotoxicity, and there is growing evidence of the potential for hepatotoxicity in children given multiple therapeutic or supra-therapeutic doses of paracetamol. [7] [8] [9] [10] [11] However toxicity due to paracetamol given for therapeutic[12] reasons is extremely rare. [13]

Elevated Transaminases and Liver Dysfunction

The elevation of liver enzyme in critically ill patients is extremely common, and while they may be markers of progression of disease, are not pathognomic of any particular syndrome and may have been associated with the burn injury itself. [14] [15] [16] The ALT began rising on the 23rd, about the time of the overdose. It is not usual for ALT to change immediately. Elevated INR and other coagulation abnormality measures may have been the result of severe sepsis. [17] [18] [19] As Professor Prescott

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[6] Soni N, (editor) *Oh's Manual of Intensive Care* 5th Edition 2003 Butterworths, London.

[7] Schoidt FV, Rochling FA, Casey DL, Lee WM. Acetaminophen toxicity in an urban county hospital. *N Engl J Med* 1997; 337: 1112–1117.

[8] Heubi JE, Barbacci MB, Zimmerman HJ. Therapeutic misadventures with acetaminophen: hepatotoxicity after multiple doses in children. *J Pediatr* 1998; 132: 22–27.

[9] Rivera-Penera T, Gugig R, Davis J, et al. Outcome of acetaminophen overdose in pediatric patients and factors contributing to hepatotoxicity. *J Pediatr* 1997; 130: 300–304.

[10] Kearns GL, Leeder JS, Wasserman GS. Acetaminophen overdose with therapeutic intent [editorial]. *J Pediatr* 1998; 132: 58.

[11] Alonso EM, Sokol RJ, Hart J, et al. Fulminant hepatitis associated with centrilobular hepatic necrosis in young children. *J Pediatr* 1995; 127: 888–894.

[12] Bauer M, Babel B, Giesen H, Patzelt D. Fulminant hepatitis associated with centrilobular hepatic necrosis in young children. *J Pediatr* 1995; 127: 888–894.

[13] Bauer M, Babel B, Giesen H, Patzelt D. Fulminant liver failure in a young child following repeated acetaminophen overdosing. *J Forensic Sci*. 1999 Nov;44(6):1299–303.

[14] Herndon DN, Stein MD, Rutan TC, Abston S, Linares H. Failure of TPN supplementation to improve liver function, immunity, and mortality in thermally injured patients. *J Trauma*. 1987 Feb;27(2):195–204.

[15] Miyoshi K, Tsukada S, Yasuda Y, Kawakami S, Sakurai T, Matsuda Y, Ito T, Matsuno H. Hepatic disorder in burn patients. *Burns Incl Therm Inj*. 1985 Oct;12(1):49–53.

[16] Chiarelli A, Siliprandi L, Casadei A, Schiavon M, Mazzoleni F. Aminotransferase changes in burned patients. *Intensive Care Med*. 1987;13(3):199–202.

[17] Shann F. *Drug Doses Tenth Edition* 1998, Collective Pty Ltd ISBN 0-9587434-0-1.

[18] Kinasewitz GT, Yan SB, Basson B, Comp P, Russell JA, Cariou A, Um SL, Utterback B, Laterre PF, Dhainaut JF; For the PROWESS Sepsis Study Group. Universal changes in biomarkers of coagulation and inflammation occur in patients with severe sepsis, regardless of causative micro-organism [ISRCTN74215569]. *Crit Care*. 2004 Apr;8(2):R82–90.

[19] Amaral A, Opal SM, Vincent JL. Coagulation in sepsis. *Intensive Care Med*. 2004 May 18 [Epub ahead of print].

indicates the rise in the ALT was small and does not indicate that there was severe liver dysfunction as a result of the paracetamol poisoning.

Ischemic hepatitis … can occur during illnesses associated with diminished hepatic blood flow and follows a characteristic course that usually can be differentiated from viral or drug-induced hepatitis on clinical and biochemical criteria.[20] Ischemic hepatitis results in a sudden rise in serum transaminases (ALT & AST) followed by resolution to near normal levels within 7 to 10 days, coupled with a smaller transient rise in serum bilirubin levels. A clinically significant coagulopathy occurs in some patients.

Autopsy Findings
However the autopsy findings from the case report of the five year old included pan-lobular liver cell necrosis, while Professor Prescott's reports focal rather than centri-lobular pattern, only 15–20% necrosis on [Master A's] liver histology slides. I understand that the coroner pathologist's revised findings suggest isoflurane toxicity being the cause of the death. This may have been contributed to by the presence of sepsis, and by the secondary effects of liver ischemia. It is not clear what role, if any, the elevated paracetamol levels had in this.

Cause of death
The cause of death is yet to be determined by the coroner. If the conclusion that the child did not die from a paracetamol overdose is accepted, then it is difficult to find that the medical staff failed to detect something which either did not exist, or was present in a very mild form. While there is some evidence of some degree of paracetamol toxicity (raised serum paracetamol level and mild to moderate elevation of liver function tests) these are non-specific changes, and both the cause of the elevation in levels and the effect of this toxicity are undetermined.

Other information
The nursing or other staff did not inform the medical team of the possibility of a drug error having occurred in this patient prior to [Dr O's] review of the notes. The history and other information available to the medical staff on the 23rd to 25th did not put paracetamol toxicity high on the list of likely diagnosis.

Some of the questions below make the assumption that there was an overdose of paracetamol resulting from a drug administration error, or that the liver toxicity and other adverse outcomes were primarily the result of a high level of paracetamol. In the light of Professor Prescott's comments and conclusions which refutes both these assumptions, specific responses to the questions are extremely difficult and cumbersome.

[20] Garland JS, Werlin SL, Rice TB. Ischemic hepatitis in children: diagnosis and clinical course. *Crit Care* Med. 1988 Dec;16(12):1209–12.

Response to Specific Questions

1. Did medical staff act with reasonable skill and care in providing treatment to [Master A] on 23 and 24 March 2002, given the abnormalities in his liver function tests?

There were no abnormalities in the liver function tests until 10 pm on the 23rd March. The results of [the] 24th are mild elevations.

There were twice daily ward rounds by Intensive Care senior medical officers ([Dr C] on the 23rd and 24th, [Dr I] and [Dr C] on the 25th and [Dr M, Dr O and Dr I] on the 26th). In addition there was a consultation requested from, and a review by the paediatrician ([Dr J]), as well as a review by [Mr K], the Burns Surgeon, both on the 25th. In these ward rounds and consultations, consideration of the various diagnostic tests, follow-up of the results of these tests and ongoing care plans were formulated. The clinical condition was a complex one, with a 60–70% body surface area burn in a child with diarrhoea, difficulty with feeding, agitation, wound infection and probably sepsis. The clinical notes, medical reports and interviews all suggest that [Master A] was receiving attention from both medical and nursing staff. It is unfortunate that the diagnosis of paracetamol toxicity was not made on either the 24th following the rise in liver function tests. It is surprising that the deterioration in liver function tests and coagulation did not prompt the disclosure, or recollection from the nursing staff involved that there had been a drug prescribing incident on the previous day. The lack of an incident report did not assist this.

Paracetamol was not considered as a possible cause of the deterioration in liver function tests, until the morning of the 26th. None of the senior medical staff in their reviews considered iatrogenic paracetamol overdose. However given the information available, and that there were other more likely [diagnoses] this is not altogether surprising. Lethal intoxication in children after repeated administration of therapeutic doses is a very rare event.[21] There is only one case report in the literature of iatrogenic overdose from multiple dosing. I do not believe any cases have been described in the New Zealand or Australian literature. [Dr C] and [Dr I] could reasonably expect that, unless they were informed otherwise, the drug administration was as charted on the medication chart.

The Consultant on duty for the unit and the resident medical officers they were supervising provided a reasonable level of care during the time [Master A] was in their care.

[21] Bauer M, Babel B, Giesen H, Patzelt D. Fulminant liver failure in a young child following repeated acetaminophen overdosing. *J Forensic Sci*. 1999 Nov;44(6):1299–303.

2. At what point should the abnormalities in [Master A's] liver function tests have prompted medical staff to investigate further?

Having read the clinical notes and the subsequent reports, I believe that there are a number of possible causes for the rise in the ALT (and other liver function test changes):

- Ischaemic liver, from a hypotensive episode suffered during the period in the Operating Theatre, or soon after compounded by dehydration from the diarrhoea and vomiting.
- Liver dysfunction as part of multiple organ dysfunction, resulting from severe sepsis and the burns. [There] was noted a pseudomonas infection on the wound, for which [an] aminoglycoside antibiotic was administered.
- Isoflurane toxicity compounded by the presence of hypotension and decrease liver blood (as suggested as the cause of death by the pathologist).
- Drug toxicity, including mild Paracetamol toxicity.

However, this opinion is given with the advantage of knowing that the paracetamol levels were elevated. The clinical features outlined above are not highly indicative of paracetamol toxicity. Other intensive care clinicians' response to this scenario frequently mentioned a review of medications, but not specifically measurement of the paracetamol level. If the elevated paracetamol level is the culprit the rise in ALT would be expected to start sometime after the 23rd, not immediately on that day.

The elevated paracetamol levels may have arisen from:

1. Accumulation from the prescribed dose from slower than expected metabolism secondary to:
    I. poor feeding,
    II. diarrhoea and dehydration;
    III. critical illness (burns, ischaemic liver and sepsis)
2. Overdose from inadvertent administration of higher than normal doses.

The elevation of the ALT, may be a marker of myocardial, renal liver or other organ dysfunction, or of severe sepsis. The initial investigations were to repeat the test. The subsequent analysis of the paracetamol levels demonstrates a rise until the 23rd March, then have fallen on the 24th March and continue to fall until the 26th March. This pattern suggests that there was an acute event of change on the 23rd March to cause the rise. The acute event could have been either one or more overdoses given, or an acute event that reduced the metabolic activity of the liver reducing the clearance of paracetamol from the blood stream. A hypotensive or other ischaemic insult, possibly during resuscitation and or the operating theatre may have resulted in ischaemic liver, with increasing dysfunction resulting in both elevated transaminases and reduced paracetamol metabolism.

The rise in ALT was gradual and was present as early as the 23rd, well before any paracetamol toxicity should have been present.

The tests ordered [to] be performed on the 25th and 26th indicate a widening search for a cause of the deterioration. In retrospect it may have been advantageous to perform the tests of paracetamol level on the 25th, but there was little evidence at that time to implicate it as a culprit. Even now it is uncertain what part, if any, the paracetamol had in the decline in [Master A's] clinical condition.
While significant doubt remains about whether the condition ever existed it is impossible to assess if the medical staff failed in their duty to [diagnose] and treat the cause of hepatic dysfunction, whether this was secondary to paracetamol liver toxicity or another cause. The two diagnoses of sepsis and viral hepatitis were being pursued in an appropriate way.

3. What further investigations should medical staff have undertaken at that point?

This question assumes that further investigations should have been performed, given the information available to the medical staff. As above there were tests performed with reasonable attention to the assumed problem. Although the discovery of the potential of increased elevated paracetamol levels was not discovered until the 26th March, there were reasonable steps taken, (cultures, and serology) to establish a diagnosis. Unfortunately Paracetamol toxicity was not contemplated, as it is an uncommon cause of liver toxicity in inpatients. While ideally a paracetamol level should have been taken, and treatment started if the result was elevated, the clinical assessment was that viral hepatitis and sepsis were the two most likely treatable causes of the deterioration. These were investigated.

4. Did medical staff act with reasonable skill and care to establish the cause of the decline in [Master A's] health?

… [T]he … of paracetamol dose that was prescribed was not unduly high. Despite the slight rise in the ALT there was little to indicate deterioration on the 24th. [Dr I] and [Dr L] stopped the dose on the morning of the 25th. This was precautionary because of the liver dysfunction, as paracetamol metabolism in the presence of liver dysfunction may be deranged. It cannot be taken to mean that the clinicians on that ward round suspected or were aware that paracetamol toxicity was a likely diagnosis.

There was a failure of notification of a potential incident at the earliest possible time. It appears that the medical staff were unaware of the possibility that a nurse or nurses had either recorded, or administered and recorded, a four fold higher dose than was charted. This was not discovered until [Dr O] reviewed the charts on the morning of the 26th March. Recording of the medications administered is the responsibility of the health practitioners administering (or directly supervising the administration) of the medication. While prescribing of the medication was a medical responsibility administration of the paracetamol was a nursing responsibility, it is unreasonable and impractical to expect medical practitioners to double-check

the administration of every medication given by nursing staff. Therefore the failure of any of the medical team to discover that an excess dose of paracetamol was charted is not a failure to provide adequate care. There appears to have been a breakdown of communication within the nursing staff or from the nursing to medical staff regarding the drug administration incident. In other respects the care was of a standard expected in a busy tertiary intensive care unit.

5. Did medical staff treat the decline in [Master A's] health in a timely manner?

As above yes. I note that Dr Fountain's expert advice in response to the question 'Were there other factors or medications influential in the decline in [Master A's] health?' does not mention the underlying 60-70% burns, the likelihood of severe sepsis secondary to wound infections, or the hypotension and fluid shifts during the intraoperative periods as factors influential in the decline in [Master A's] health. As outlined above, there were a number of more commonly occurring causes of hepatic failure (and general deterioration) that influenced [Master A's] decline over the period described.

6. What treatment, if any, should medical staff have initiated?

There is no specific treatment of elevated liver enzymes, or hepatic failure except support and establishing and treating an underlying cause. Once the diagnosis of suspected paracetamol toxicity had been made n-acetyl cysteine, a specific antidote for paracetamol intoxication may have been indicated. However Professor Begg's comments suggest the levels were too low to contemplate this. Dr Fountain states [the] threshold from which paracetamol antidotes should be started. When the risk of overdose was recognized by the medical team treatment was started.

The diagnosis was made in the morning of the 26th and treatment was started. [Master A] was on some antimicrobial therapy for pseudomonal infection. As [Master A's] [level of consciousness] had fallen, protection of [his] airway with intubation and ventilation were appropriate on the morning of the 26th. The cause of the deteriorating liver dysfunction, if caused by ischaemic liver, or isoflurane toxicity as suggested by the pathologist, has no specific therapy. The ICU team consulted with the Paediatric intensive care team at an appropriate time, when the massive burns became a secondary issue to the other organ failures developing.

7. Is it correct to describe [Master A's] ALT levels on 23 March and 24 March 2002 as only mildly elevated?

Yes: The upper limit of the normal range of ALT is described as 45.

[Dr B] states that the level was Mild at 176 and later at 313. This is a reasonable description. Abnormal ALT levels can be in the tens of thousands in severe cases, a result 3–7 times normal is mild.

The highest level recorded in [Master A's] case (947) does not occur until the 2000 hrs on the 25th of March and is just over 20 times normal. It is notable that despite the deterioration in [his] general condition the ALT level fell in the last 24 hours leading up to the cardiac arrest and death in [the children's hospital].

The rises noted over the time period could be described as mild to moderate, in contrast to the large elevations normally seen in paracetamol poisoning. Professor Prescott notes and references a text suggesting that describes extremely high levels of ALT.

French's Differential Diagnosis describes transaminase rises as large (using paracetamol as an example) only when they are > 20 times normal.

'The largest increase, 20–100 times normal, are observed in acute hepato cellular damage due to viral hepatitis or toxic damage (e.g. paracetamol overdose)'[22]

Another [text] stratifies transaminase elevations into three categories <5, 5–10 and greater than 10 times normal.[23] The level of 176 falls into the lowest range.

8. Would a registrar or consultant who relied wholly on nursing staff to bring abnormal results of laboratory tests to his or her attention and did not independently check the results be acting with reasonable skill and care?

The question is leading and the answer is considerably more complex than it has been stated. Firstly, the registrar and consultant did not wholly rely upon the nursing staff to bring the results of the laboratory tests to his or her attention. The initial results were taken and transcribed by the nursing staff. The nursing staff reported the result to [Dr D]. They demonstrated a continued trend and [Dr D] deferred any change in management to the ward round two hours later. Medical staff in fact reviewed the blood and other results on the morning ward round of the 25th. Had the reports not been passed on to the registrar they would have still been reviewed at this time. This is confirmed in the letter from [Dr C and Dr D].

Secondly, the reporting and following up of laboratory tests is dependent upon the circumstance. The circumstance is somewhat different from a test performed at the time of admission to hospital, or to investigate an acute deterioration. The blood tests performed in the early hours of the 25th were to ([as] described by [Dr C]) demonstrate a trend of improvement or deterioration, rather than to confirm a specific diagnosis.

[22] Bouchier IAD, Ellis H, Fleming PR Ed, *French's Index of Differential Diagnosis* Butterworth Heinemann, Oxford,1996 p745.
[23] Marshall WJ. Clinical Chemistry 2nd edition 1993 Mosby, London.

Unexpected abnormal results, or [tests] that were specifically ordered to form a diagnosis or specific treatment plan would be followed acutely. [This] would result in the results being reported as soon as they are available in the timeframe. Less severe abnormalities with no specific treatment, in many circumstances, could be reviewed on [the] next ward round. These ward rounds are (at least) twice daily, in contrast to the general wards where even daily rounds are not guaranteed. The [public hospital] Intensive Care Unit has 14 beds and a high degree level of acuity. Each of the critically ill patients requires attention, part of which is the interpretation of blood tests and adjusting care plans based on the results. In a spot survey in another ICU, Intensive Care patients had an average of 14.5 sets of blood tests performed per day. Although only 4–8 sets of blood were drawn, many were subjected to multiple tests and the results of these tests often arrive separately. In total more than 120 individual items of laboratory data being produced per patient. Unless there is a screening mechanism to screen the results in a 24 hour period, the resident would need to review 1500 different results. The screening by nursing staff for unexpected abnormal results on routine tests is commonplace in other units, and does not breach a standard.

The question as to whether this review, the following day on the morning ward round was timely or delayed?

The ALT result[s] were abnormal on the 23rd but the derangement was small, and as [Dr D] has stated in keeping with a number of common scenarios in ICU such as drug or sepsis induced elevation of liver function tests. However, the deterioration in blood results continued though the 24th and on to the night of the 25th. These tests appear to have been taken as a monitor of the patient's condition as indicated in [Dr C's] letter. The result of 610 at 0010 on the 25th, was apparently reported to [Dr D] at about 0630 to 0700am of that morning. It is not clear from the reports why the liver function test[s] were included in this. [Dr D] was not informed of the risk of potential overdose that had occurred on the previous day. The result was a continuation of a trend of deterioration and [Dr D] took no action on these results. As the diagnosis was unclear, the LFT had previously been abnormal and there was no other physiological deterioration at that time his actions are reasonable. This was at about 0630–0700. The ward round in the morning of the 25th (0800–0900) did not add further to the deterioration, although investigation of viral hepatitis as a cause was started. In hindsight, it would have been preferable if a paracetamol level had been ordered, which would have detected the elevated plasma level present, allowing early treatment. However, it is NOT standard practice, to monitor Paracetamol levels, nor is toxicity in the critically ill common.

When [Master A's] results were reviewed by the consultant the following day on the ward round, no report of toxicity or potential overdose was made. The liver function abnormalities, including the coagulation changes, were attributed to a general deterioration. I do not think that the delay was excessive, given the nature of the tests and indication for them.

9. What, if any, standards or guidelines or the like (whether legal, professional, ethical or of any other kind) applied to the medical staff in providing [Master A] with care and treatment?

The medical staff are subject to the laws and statutes of New Zealand, (including the provision of the Health and Disability [Commissioner] Act and its Code, to the Medical Practitioners Act 1995). The operating standard for the ICU would be the Joint Faculty of Intensive Care Medicine [formerly] the Faculty of Intensive Care, NAZCA) Minimum standard for Intensive Care Units (IC1) The standard of care provided by the unit should be that of a Tertiary (Level III JFICM Unit). The standard is non-specific as it covers many different types of unit and therefore does not address the complexity of this case.

The standard that applied at the time was the Faculty Of Intensive Care Minimum Standards For Intensive Care Units IC-1 (1997) which states that level three units should have:

> 'Sufficient supporting specialist(s) so that consultant support is always available to the medical staff in the Unit. There should be sufficient specialist staff to provide for reasonable working hours and leave of all types and to allow the duty specialist to be available exclusively to the Unit; all attending specialists in the Unit should be recognised by the JSAC-IC as specialists in intensive care.'

This standard has been revised in 2003 and the relevant standard now states that at least two specialists should be fellows (of the Joint Faculty). As the standard has been revised to be less restrictive the latest standard can probably be used.[24] [Dr C's] letter of the 1st December states:

> 'I worked as a specialist (Consultant), in intensive care medicine at [the public hospital].'

[Dr C] outlines his qualification[s] in the paragraph above, which includes the Diploma of Fellow of the Royal College of Anaesthetists, and is recognised to have completed training in Intensive Care Medicine (in the United Kingdom). Neither the Diploma or the Royal College nor the Intercollegiate board training recognition automatically qualify a medical practitioner for vocational registration in Intensive Care Medicine (or Anaesthesia), nor are they necessarily equivalent or comparable qualifications to those accepted for Vocational Registration. [Dr C] applied for temporary registration which was granted on the basis of his primary qualification. This ran from January 2002 until January 2003. [Dr C] has returned [overseas] and his registration has since lapsed.

[24] Many ICUs in the country have some difficulty in complying with this staffing standard, and the MOH Intensive Care Services Plan (2003) addresses these issues. The provision for oversight permits the operational requirements of hospitals to be met, while allowing for the current shortfall in vocationally registered intensive care medicine specialists.

[Dr C] was employed on contract by [the public hospital] on a fixed term contract, presumably as a Senior Medical Officer, or Consultant.

However, [Dr C's] letter does not state his registration status at the time, but it could lead to the assumption he was a vocationally registered consultant in New Zealand, when in fact he held temporary (General) registration. The New Zealand medical system has a mechanism for recognising individuals with sufficient qualifications and or experience to work at a consultant level in a vocational branch of medicine, by granting vocational registration. For overseas graduates the time required to complete this process is somewhat protracted and for a variety of reasons (including pragmatism) the system of assessment for vocational registration was bypassed. The public hospital is entitled to employ whom ever they want to provide the care needed. I do not believe that [Dr C] failed to provide reasonable care, but in different circumstances, the absence of an independent assessment of the suitability of his past training and experience may have been an issue for the employer. Apart from this [the public hospital] ICU complied with the standard ICU of 1997.

10. What steps, if any, would you recommend ICU should take to ensure that a similar case does not occur in the future?

I have read with great interest the report compiled by [Dr N] and the ICU team addressing a number of issues that arose from the analysis of this case. The analysis was conducted as part of a quality assurance activity and does not seek to identify individual failings, nor attribute blame for the events that occurred. This report has the advantage that, as a quality assurance activity it does not need to prove the existence of a paracetamol overdose or the cause of toxicity. It uses as a tool the premise that the overdose was administered, and then addresses the various system failures that could have allowed a catastrophe to have occurred. This has allowed the assessment of a number of risks. The report also uses as its standard for care the ideal practice that would have resulted in the best possible outcome. [Dr N's] report also uses the advantages of hindsight. The recommendations for change in that report should not be taken to mean that there was a lower than acceptable standard of care for the patient.

There have been a number of changes recommended as a result of the quality assurance review. These include:

- the changes to the drug charts
- access to electronic results. It appears that the login code of the medical director was used to access records by a number of staff. This makes subsequent tracking difficult, and individual logins would be desirable.

The report makes a number of recommendations, all of which would reduce the risk of error occurring in the Intensive Care unit.

The results included in the laboratory reports provided are printouts from the screen, and are provided without reference ranges or units. The abnormal results are highlighted, but in the absence of a reference range does increase the risk of a vastly abnormal result being interpreted as a minor aberration.

If it is possible for [Dr N] to stylise and render the report completely anonymous, and non identifiable to the unit, circulation of the information to other Intensive care units may aid in the reduction of potential problems in the future.

Ensuring that there is a timely and robust reporting mechanism for drug incidents, with an emphasis on reversing correctable errors, and preventing recurrence.

Summary
It is a tragedy that [Master A] was injured and subsequently died. It appears there may have been a medication administration error, which was not reported to the medical staff. The extent to which this incident and the failure to report it affected the subsequent deterioration and treatment is not clear, even in retrospect. It may have been relatively minor. In my opinion the medical staff, in particular [Dr C], [Dr D] & [Dr B], acted with reasonable skill and care in providing treatment to [Master A] on 23 and 24 March 2002, given the abnormalities in his liver function tests, following up the laboratory results ordered, in establishing a working diagnosis and treating that diagnosis.

Declaration of Interest:
I have no direct association with [the public hospital], or any of the clinicians named in this report. To my knowledge I have never met [Dr B], [Dr D], or [Dr C].

I have in the past provided a report to […] on the Development of a High Dependency Unit and Intensive Care Facility. I have no ongoing association with them."

Nursing advice
The following expert advice was obtained from Ms Janet Hewson, registered nurse:

"31 May 2004

I have been asked to provide an opinion to the Commissioner on case number 02/08949/AM. I have read and agree to follow the Commissioner's Guidelines for Independent Advisors.

I am a Registered General and Obstetric Nurse having recently completed my Clinical Masters in Nursing through the Otago Polytechnic School of Nursing. I have 35 years experience in clinical nursing practice. My background has been mainly in acute care / high dependency nursing.

The purpose of my referral instructions is:
To advise the Commissioner whether [Master A] (deceased) received care of an appropriate standard from the following nurses:

- [Ms E]
- [Ms F]
- [Ms G]
- [Ms H]

The background of this case is as follows:
[Master A] received burns to 60–70 % of his body from boiling water at his home [overseas] on 17 March 2002. He was transferred to [the public hospital] on 17 March 2002. He underwent surgery that same day and was cared for in the Intensive Care Unit (ICU) at [the public hospital] until 23 March 2002. While in ICU he developed diarrhoea and vomiting.

[Master A] was transferred to [the children's ward] on 21 March 2002. [The children's ward] had difficulties managing [Master A's] care because of problems with fluid resuscitation as a result of his diarrhoea and he was readmitted to the ICU on 22 March 2002.

On 24 and 25 March 2002 [Master A] became increasingly irritable. He had dark urine and his ALT levels were increasingly abnormal. By 26 March 2002 he was in hepatic failure and showed a decreased level of consciousness.

[Master A] was transferred to [the children's hospital] on 26 March 2002. He developed renal as well as liver failure and [later died at the children's hospital].

[Master A] was cared for in [the public hospital's] ICU at the relevant times by the following nurses:

- [Ms E]
- [Ms F]
- [Ms H]
- [Ms G].

[Master A] was prescribed 250mg of paracetamol at 4 hourly intervals. [Master A's] patient record indicates that [Ms E] administered 3 1gm doses of paracetamol at 1100, 1500 and 1900 on 23 March 2002.

[Ms E] denies administering the recorded 1gm doses of paracetamol and says that she actually administered the prescribed dose of 250mg on each occasion but erroneously recorded the dose as 1 gm in [Master A's] patient record.

[Ms F] took over [Master A's] care from [Ms E] at 2200 on 23 March 2002. She initially recorded a 1gm dose of paracetamol at 2300 on 23 March 2002 but

amended this to a 250gm dose and maintains that she administered only 250gm of paracetamol.

[Ms F] has stated that she noted that [Ms E] had recorded having administered 3 1gm doses of paracetamol. She intended to report this but became busy assisting with another patient and did not do so. Instead she says that she advised the nurse who took over from her at 0700 on 24 March 2004, [Ms G], of the apparent overdose.

[Ms G] disputes that [Ms F] advised her of the apparent paracetamol overdose.

Tests of blood taken from [Master A] showed the following results:

Date	23/03	24/03	24/03	24/03	25/03	25/03	25/03
Time	2200	0600	1400	1750	0010	0545	1200
ALT (0-45U/L)	70	89	176	313	653	642	746

These results were transcribed from the computer into a handwritten Laboratory Results sheet by the nurses caring for [Master A]. The abnormally high ALT results were not brought to the attention of medical staff until the 0545 result was recorded by a nurse.

I have been asked to advise the Commissioner whether, in my opinion, [Ms E], [Ms F], [Ms G], and [Ms H] provided [Master A] with services of an appropriate standard.
I have been asked to address particular questions about the care provided by each individual nurse. I will separate each question as it has been asked.

1. Did [Ms E] provide reasonable care and skill when she, as the patient record indicates, administered three 1 gram doses of paracetamol?

If [Ms E] did administer three 1-gram doses of paracetamol to this child, she has not provided reasonable care and skill. This would constitute a serious medication error as wrong dose. This would be seen as a major failure to provide safe medication administration and meet with severe disapproval by the nursing profession.

Drug administration is a nursing domain. It is expected that a competent nurse ([Ms E] is certified as a level 2, competent nurse) will follow the fundamental procedures for safe drug administration. The minimum competency for this procedure includes: the right patient, the right drug, **the right dose**, the right route of administration and the right time.

The New Zealand Nurses Organization (NZNO) Standards for Nursing Practice (1998) state the nurse is responsible for the safety and well being of their client group. More specifically in relation to the administration of medicines standards, NZNO standards state that the nurse shall exercise professional judgement and apply

knowledge and skill to the situation that pertains at the time and, acting in the interests of the patient the practitioner will **carefully consider the dosage**, method of administration, route and timing of administration in the context of the condition of the specific client at the time (Guidelines for Nurses on the Administration of Medicines, NZNO 1998).

Comment:
[Ms E] gives a descriptive account of her dose calculation and preparation of the paracetamol. The child had a paediatric sized feeding tube in situ. The volume needed to administer 250mg of paracetamol is 5 ml. The volume of water flush only needs to be enough to clear the tube. This would generally be 10 ml for a paediatric feeding tube (e.g. 5ml paracetamol + 10 ml flush = 15 ml total volume). However I note on the drug and fluid record for 23/3/2002 the following:

– 1100 hours — 90 mls of medication recorded as given
– 1500 hours — 65 mls of medication recorded as given
– 1900 hours — 60 mls of medication recorded as given.

Apart from the paracetamol administered at these times, the other medications given were very small intravenous volumes. I question the excessive volumes recorded for the small amount of volume required for 250mg of paracetamol and flush. If [Ms E] gave a large amount of flush, this would seem inappropriate, as the child was restricted to a feeding volume of 10 ml per hour due to vomiting.

It was never clear the size of syringe [Ms E] used to administer the paracetamol and the flush. To accurately measure 250mg of paracetamol and to accurately measure the flush volume in a small child, it would have been the safest practice to use a 5 or 10 ml syringe. I am aware in the statement made by [Ms E] and the observation from the parents, that a larger syringe may have been used.

2. Did [Ms E] provide reasonable care and skill when as she claims, she administered three 250mg doses of paracetamol but recorded that she administered three 1-gram doses of paracetamol?

If [Ms E] did administer the correct dose prescribed [but] nevertheless documented another dose, this would be seen as a minor failure to provide reasonable care and skill and would be met with mild disapproval from the nursing profession. NZNO does expect competent nurses to make clear and accurate recordings of the administration of medicines (Guidelines for Nurses on the Administration of Medicines, NZNO 1998).

Comment:
I note that [Ms E] said she had looked after an adult the day before that was receiving 1 gram of paracetamol and she commented, 'it is almost like breathing, writing it (1 gram) down'. This unconscious automatic documentation can happen in such a circumstance, however [Ms E] also stated that she referred to the ICU flow sheet numerous times during her shift. I would expect that she would have noticed her incorrect documentation of the paracetamol as it **occurred on three occasions** during her duty.

3. Did [Ms F] provide reasonable care and skill when she failed to report the apparent medication errors made by [Ms E]?

[Ms F] did not provide reasonable care and skill by not reporting the apparent medication errors. In the circumstances, this would be seen [as] a major failure on her part and would meet with moderate to severe disapproval by the nursing profession.

This apparent error was particularly serious in the context of a young child who had **received three overdoses** over a short period of time. The expected standard would be that Ms F follows organizational policy on reporting medication errors. Where an apparent error has occurred, all efforts must be made to minimise the impact of the error on the patient. The matter must be discussed immediately with the person in charge and in the case of a serious medication error, the registrar should have been notified for advice and immediate patient management (Otago District Health Board, Management of Nursing Medication Errors).

The NZNO Standards for Nursing Practice (1998) state that nurses are accountable for their practice through safe practice that responds to the changing health needs of the client. Specifically NZNO expects nurses to monitor incidents and protect clients from physical danger and avoidable risk. As well the Nursing Council of New Zealand (NCNZ) Code of Conduct for Nurses (2001) states that the nurse takes care that a professional act or any omission does not have an adverse effect on the safety or well being of patients (Principle 4). Although it was [Ms E] that documented 1 gram of paracetamol on 3 occasions, [Ms F] discovered this apparent error and was required to act. I note in the draft document currently out for consultation from the NCNZ (2004) entitled 'Continuing Competencies for the Nurse' the following competency:

Domain 3, Competency 3.3 Promotes an environment, which maximizes client safety, independence, quality of life and health.

- Takes action in situations where client safety and wellbeing are compromised
- Takes responsibility for errors when they occur and takes appropriate action to maintain client safety.

[Ms F] noted in her statement that she was concerned enough about the apparent paracetamol overdoses to monitor the child for signs and symptoms yet she failed to report the situation to professionals who could take definitive steps in the management of this potentially serious state.

4. Did [Ms F] provide reasonable care and skill when she failed to record the apparent medication errors in either the nursing notes or an incident report?

[Ms F] did not provide reasonable care and skill when she failed to record the apparent medication errors. In the circumstances, this would be seen [as] a major failure on her part and would meet with moderate to severe disapproval by the nursing profession.

The expected standard would be that [Ms F] follows organizational policy on recording medication errors. Regardless of local variations in policy, all district health boards expect medication error matters to be documented. [Ms F] stated she was aware of her hospital policy on incident reporting.

Generally the objective of incident reporting policy is to provide a verifiable account of the event, and of actions taken so that the legal rights and the personal well being of patients are protected. As well, incident reporting provides records that can be individually and collectively analysed to identify areas of concern and develop successful strategies to minimise and prevent future incidents (Otago District Health Board, Incident Reporting Policy).

A 2001 report to the Director-General of Health from the sentinel events project working party advises that when an event occurs the investigation should establish the chain of events and determine the factors contributing to the event. To be most effective and to enable trending, minimum data sets should be collected, documented and reported. Investigations should begin soon after the event while memories are fresh and where there is interest in addressing the problem immediately.

This apparent overdose is considered a serious event in light of the age and condition of the child. From the apparent last dose of 1 gram paracetamol on 23 March to the discovery of the apparent overdose on 26 March, over 58 hours had passed. Because the apparent overdose was not recorded the investigation was delayed.

The NZNO Code of Ethics (1995) describes the underlying value of non-maleficence (doing no harm) as demonstrated when the nurse participates in monitoring programmes to enhance the quality of care provided and prevent/minimise harm as well as to participate in organizational activities which ensure that the organizational environment is physically safe for clients. Furthermore, the NCNZ Code of Conduct for Nurses (2001) expects nurses to act ethically and maintain standards of practice by accurately maintaining required records related to nursing practice (Principle 2).

And finally, NZNO Continuing Competencies for the Nurse (Draft 2004) state the nurse maintains concise, accurate, current, timely and dated client records within a legal and ethical framework (Domain 2, Competency 2.1).

5. **Did [Ms F] provide reasonable care and skill when if her account of events is accepted, [she] responded to the apparent medication errors only by advising them to the nurse who took over [Master A's] care on the shift following hers?**

[Ms F] did not provide reasonable care and skill if, as she has stated [she] only advised the oncoming nurse of the medication errors. As she failed to report or record the apparent medication errors, only advising another nurse is not the expected standard and would be met with moderate to severe disapproval by the nursing profession.

Verbally passing on serious information of this nature is fraught with potential problems, one of which is highlighted in this case because the oncoming nurse had no recollection of being told this information. [Ms F] has stated herself that she 'intended to tell the doctors', 'call the nurse' ([Ms E]), make out an incident form and 'put it in the patient notes'. However she said it 'slipped her mind' and she 'totally forgot' to follow through with her intentions. This is an example of how vulnerable the system can be when staff do not follow organizational policy on reporting and recording events. It was [Ms F's] responsibility, and only hers, to pass on this information in the appropriate way and not expect such a serious event to be handled in an informal manner as verbally passing it on. It would be expected that [Ms F] pass on this information to the oncoming nurse in her shift handover, however this would never be instead of the formal reporting and recording of the event.

6. **Did [Ms G] provide reasonable care and skill when on the basis that [Ms F] informed her of the apparent paracetamol overdose, as [Ms F] claims, [she] failed to take any action to report the apparent overdose?**

It would be the expected standard of care to follow up all potentially serious information such as the apparent paracetamol overdose because the nurse would be expected to be involved in the assessment, decision-making, planning, intervention and evaluation of the child. If [Ms F] had not reported the information in the correct manner, then it would be a priority for [Ms G] to do so **before** the ward round.

If [Ms G] did know about the overdose and did not immediately relay this information to the medical staff, it would be considered a major failure to meet the expected standard and would meet with moderate to severe disapproval by the nursing profession.

7. **Did [Ms G] provide reasonable care and skill when she failed to draw attention of medical staff to [Master A's] increasingly abnormal ALT levels during her shift?**

[Ms G] failed to provide reasonable and safe care by not alerting the medical staff to the increasingly abnormal ALT levels. This is minor failure of standard and would be met with mild disapproval by the nursing profession.

Although the blood result was collected by [Ms G] from the computer and transcribed to the bedside chart, the entire health care team had the same access to this information. I do note that [Ms G] did acknowledge the ALT levels. She justified her decision not to point this out to the medical staff because she commented that sepsis or multi organ failure was not uncommon in ICU patients, both complications that do not require immediate action. However there was no indication that [Master A] was septic or in multi organ failure. This in itself is a reason to point out the rising ALT to the medical staff who is responsible for investigation and treatment.

I refer to the Critical Care Nurses' Section (NZNO) standards for nursing practice in critical care (2002). Standard one indicates that it is the nurse who promotes continuity and transition of care between health care providers while standard two implies that it is the nurse who is responsible for the coordination of care. Although the whole health team was responsible for the overall care of [Master A], it is the nurse at the bedside who has the opportunity to organize and detail the care. This would include relaying information and referring care to the appropriate people.

8. Did [Ms H] provide reasonable care and skill when she on the basis that she claims but [Dr D] denies, drew his attention to [Master A's] increasingly abnormal ALT levels?

[Ms H] did show reasonable care and skill in reporting the raised ALT to the medical registrar. She took the routine early morning bloods (0545 hours) then retrieved the results from the computer sometime before 0700 hours. She states she 'showed them to the doctor on duty'. She claims she also told the oncoming nurse of the abnormal ALT and also told this nurse she had reported the ALT level to the doctor. If this is the case, she met the expected standard at that time.

Comment:
I note she also took bloods at 0010 hours but did not notice the elevated ALT. The ALT at 0010 hours had doubled since the last level at 1700 hours and this ALT was actually slightly higher at 0010 hours than the level at 0545 hours that she reported to the doctor. [Ms H] states she did not recall the ALT level at 0010 hours but acknowledges in her statement that she would have expected herself to pick up the abnormal level. It would be the expected standard that she reviewed all blood results at 0010 hours and report abnormal results to the doctor on duty.

9. Did [Ms H] provide reasonable care and skill when on the basis that as [Dr D] claims and [Ms H] denies … [she] failed to draw [Dr D's] attention to [Master A's] increasingly abnormal ALT levels?

If [Ms H] failed to notify the doctor of the elevated ALT after she took the result from the computer sometime before 0700 hours, she did not provide reasonable care and skill. This would be considered a minor failure and meet with mild disapproval from

the nursing profession. Although the nurse is responsible for relaying abnormal blood results, the medical staff also has the responsibility to review all blood results they have ordered on a patient.

(a) Is it appropriate for nurses to exercise discretion as to which abnormal results they report to medical staff? If the exercise of discretion is appropriate, what should determine which results are reported to medical staff and which are not?

Yes it is appropriate for nurses to use discretion as to which results they report to medical staff. What determines this discretion is based on the experience and knowledge of the nurse in interpreting the meaning of the abnormal result. Experienced and knowledgeable nurses know which laboratory results are in need of urgent attention, those that are a single result 'just out of normal range' and those that are abnormally trending up or down. Laboratory results that indicate urgent attention and those that are trending up or down, well out of normal range, do need to be brought to the medical staff attention at the time they are retrieved by the nurse. Generally nurses working in the ICU will have one or perhaps two patients. The nurse is in the best position to monitor for changes and trends that need to be shared with the doctor. The doctor has several patients to look after and in this case other duties that take them out of the ICU. Standard One of the Critical Care Nurses Section (NZNO, 2001) state that the nurse continuously monitors and assesses clinical situations and recognizes changes in patient status and responds appropriately. The appropriate responses to laboratory values that are requiring urgent attention or are trending in a significant manner need to be reported to the medical staff.

(b) In my opinion, was the care provided to [Master A] by the nurses involved in this complaint appropriate given his condition, regardless of whether cause of death was excessive doses of paracetamol or not?

The personal care given to [Master A] and his parents was appropriate for his age and condition. The nurses seemed caring, attentive and mindful of the stress the parents were going through during this time. As I have stated in earlier questions, the issue of not reporting and not recording the apparent paracetamol overdose was not appropriate. I also believe the laboratory results were not reported to the standard I would expect in an intensive care / high dependency area.

12. Was it appropriate for [Ms E], [Ms F], [Ms G] and [Ms H] to assess [Master A] as a 'high dependency' rather than an 'intensive care' patient? Would it be appropriate for nurses to respond differently to abnormal results reported for a high dependency patient as opposed to an intensive care patient?

I did not get the impression these nurses decided [Master A's] status as either high dependency or intensive care. This decision would generally have been made by the person in charge of the unit and used to determine staffing numbers and skill mix. I note that [Master A] always had one nurse assigned to him and this would be an appropriate level of care for the child noting that he needed frequent attention to his

dressings, fluid needs, pain relief, general cleanliness due to the diarrhoea and the support required for his parents.

Regardless of the category assigned to a patient, high dependency or intensive care, the expected standard of practice would be that abnormal laboratory results (as described in question 10) are reported to the medical staff.

13. In my opinion, how should a nurse acting with reasonable care and skill have responded on discovering the apparent overdose of paracetamol?

I believe I have answered this question previously. I would expect immediate reporting of the apparent error to the person in charge of the unit and, in this case, the medical staff on duty. I would have followed hospital policy in recording the error (incident from) and I would have documented the apparent error in the patient notes. I would also discuss with senior staff the appropriate time and manner in which to inform the patient or their representative.

14. Please comment on any other aspects of the care provided by [Ms E], [Ms F], [Ms G] and [Ms H] which in your opinion the Commissioner should take into account in determining whether the nurses provided care to [Master A] with reasonable skill and care.

I believe the circumstances of this very unfortunate event could have been managed better if the communication methods between the nursing staff in the Intensive Care Unit was improved. By this I mean the handover between nurses from one shift to the other. If there was an expected standard of transferring patient-care information between shifts, most of the issues I have commented or may not have occurred or the consequences would have been much less. This is a particular risk to this ICU as they may often use bureau nurses who are not familiar with the expected standard.

Handover between nurses should have a systematic approach to allow nursing staff to give a clear, concise, and consistent transfer of care. This handover of care would all include details of the patient, the history, significant events and interventions to be transferred. Handover consists of, but is not limited to, a top to toe systems handover, test and investigation completed (includes review of laboratory results), a thorough review of the ICU flow chart, looking for trends and variations. Fluid balance charts are thoroughly reviewed and the drug chart is reviewed and each drug charted is checked for when last given, when next due, that all drugs were signed for and if not given, question why. This last review would pick up any apparent errors at that time. I suggest guidelines for nursing handover in the Intensive Care Unit be formulated, included in orientation and a copy given to all bureau nurses as they would be less familiar with the routine.

I would also recommend that the documentation method in the ICU be of a set format to ensure all nurses collect the same essential information on all shifts. There are variations to the documentation noted in [Master A's] notes. Such information as to

when laboratory results were reported and to whom would have provided documented evidence for many issues in this case.

In regard to the alteration of the dose of paracetamol given to [Master A] by [Ms F]. The proper way to alter an error in documentation is to draw a single line through the wrong information, write in error and initial this. Then fill in the correct information. I am sure [the public hospital] has a standard to this effect. It is not acceptable to 'write over' and try to alter the original information.

In conclusion, this sad case reflects unsatisfactory communication methods between the nursing and medical staff and the lack of adherence to hospital policy in regard to incident reporting and recording. Thank you for the opportunity to review this case and provide the Commissioner with my opinion based on experience and national standards and codes of practice."

Toxicology advice
Dr John Fountain, toxicologist, provided the following advice:

"24 December 2002

Was paracetamol prescribed appropriately?
The dose administered was within generally applied guides, but in this case was approaching a level some have proposed as hazardous.

Paracetamol was prescribed in accordance with generally accepted criteria for dose (15mg/kg/dose). This was reviewed by (presumably) a pharmacist who annotated prescription notes stating '15mg/kg/dose' equivalent to '270mg' [per dose]. This was calculated from a child's weight of 18 kg (18 kg x 15mg = 270mg/dose).[25]

Daily doses of less than 90mg/kg/day are generally applied as a reasonable paracetamol dose for children. However, in this case the child did have risk factors for paracetamol toxicity; diarrhoea and poor nourishment. Sustained dosing over many days may place an individual at increased risk of paracetamol toxicity.

Was [Master A] given too much paracetamol?
Yes.

The information that I reviewed outlines that the patient died from fulminant hepatic failure, with biochemical and histological findings strongly indicating the cause as being paracetamol overdose. Information supporting paracetamol overdose as a cause of death include:

- Histological findings
- Autopsy report

[25] Medication Chart, [from the public hospital for Master A]. Dated 21 Mar 2002.

- Biochemical records
- Prescription records

[The District Health Board] Investigation report

Histology Findings
The histology finding of acute centrilobular necrosis is characteristic of paracetamol hepatotoxicity.[26]

Autopsy Report
The subsequent Coronial autopsy report stated the cause of death as a result of the toxic effects of paracetamol on the liver.[27]

Biochemical findings
Biochemical abnormalities characteristic of paracetamol poisoning including:
Elevated hepatic enzymes [transaminases] – indicating acute damage to liver cells
Elevated International Normalised Ratio [INR] — indicating the liver was no longer producing blood clotting factors.

Further evidence of acute liver failure including: hypoglycaemia and acidosis.

A retrospective review of paracetamol plasma concentrations revealed a markedly elevated level on the 23rd of March:

Table 1:

Date	23-Mar-2002	23-Mar-2002	24-Mar-2002	25-Mar-2002	26-Mar-2002
Time	05:20	21:58	06:00	05:45	08:30
Day:	Saturday	Saturday	Sunday	Monday	Tuesday
Paracetamol mmol/L	**0.06**	**0.40**	**0.24**	**0.11**	**<0.02**

From: Anonymous. Report for the family of [Master A]. Dated September 2002. page 16.

(The normal range for a therapeutic serum level of paracetamol provided by [the public hospital] laboratory is stated as 0.10 to 0.16 mmol/L.[28])

Prescription records
The raised plasma paracetamol level found on the evening of the 23rd of March coincides with prescription records detailing administration of an overdose (1,000mg instead of 250mg) on three separate occasions on that day. Three further doses of 250mg were also given on the 23rd. If the patient's weight was 18 kg, on which the original paracetamol dosing was based, then a cumulative total of 208mg/kg was administered that day.

[26] Coronial Autopsy Report for [Master A].
[27] Coronial Autopsy Report for [Master A].
[28] Laboratory report: Paracetamol Serum. [The public hospital].

Names have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

There is debate as to what total dose constitutes a hazard in chronic administration of paracetamol. The New Zealand National Poisons Centre recommends that any dose of greater than 150mg/kg/day will place the recipient at risk of paracetamol poisoning and they should therefore be treated with the antidote (N-acetylcysteine).[29]

In this particular case the patient had been administered high therapeutic levels of paracetamol for six days prior to this event (potentially lowering resistance to paracetamol toxicity); and was also suffering risk factors making him more susceptible to paracetamol poisoning (diarrhoea and poor nourishment).

The District Health Board Investigation Report
The District Health Board has accepted that a paracetamol overdose occurred.[30]

If so, is it possible to identify when and how/why this occurred? Was the overdose cumulative or did it occur on one occasion?

From the retrospective plasma paracetamol concentration results outlined in table 1 it is apparent that therapeutic levels were recorded at 05:20 hours, but by 21:58 hours that evening the levels were clearly elevated. It therefore appears that an overdose(s) occurred at a time during this period.

Review of the prescription records shows 1,000mg doses were detailed as being administered at 11:00, 15:00 and 19:00 hours on the 23rd of March. These doses should have been of 250mg as prescribed in the notes. Such doses are supra-therapeutic and would lead to elevated plasma paracetamol concentrations. If these records are accurate then such dosing would explain the biochemical results.

Again, if the details in the records are an accurate reflection of drug administration, then it would appear that the overdose was cumulative due to the repeated administration of supra-therapeutic doses.

What was the impact of the overdose on [Master A's] health?
From the information as outlined in question 1 it is apparent that the paracetamol overdose suffered by this child led to a fatal fulminant hepatic failure.

Were any other factors or medications influential in the decline in [Master A's] health?
The child was suffering diarrhoea and poor nourishment which are recognised as risk factors for the onset of paracetamol toxicity as they reduce the liver's ability to remove the toxic metabolite of paracetamol which causes hepatic damage.

[29] www.toxinz.com
[30] Report of meeting. Dated 20 June 2002.

The high level of therapeutic dosing for the six days prior to the period of overdosage could potentially reduce the liver's ability to remove the toxic paracetamol metabolite.

When could the overdose first reasonably have been noted and treated?
As I am not familiar with accepted standards within an intensive care unit it is not appropriate for me to comment on when an overdose should first be noted.
Treatment should however have been initiated with the paracetamol antidote N-acetylcysteine as soon as it was apparent that an overdose had occurred. The actual level accepted as an overdose requiring intervention does vary from country to country. Importantly, in New Zealand, the National Poisons Centre recommends that antidote be administered in any case where more than 150mg/kg is administered in any 24 hour period. This threshold would have been reached after the third 1,000mg paracetamol administration at 1900 hours on 23rd March.

Had antidote been commenced it is possible the fatal fulminant hepatic failure may have been averted.

Any other issues raised by the supporting documentation.

Inadvertent overdosage of paracetamol, both in the hospital and in the home, is an unfortunate reality. It would seem that paracetamol's almost ubiquitous availability has led to a lack of recognition of its potential hazards. Paracetamol is potentially fatal in untreated overdose and should be treated with the same respect as afforded any other drug by both prescribers and those administering doses."

Additional toxicology advice
Dr John Fountain provided the following additional advice on 12 April 2003 in respect to the following questions:

Could the same retrospective plasma paracetamol concentration results have been reported in either or both of the following two scenarios:

1) If 1,000mg doses had been administered at 11:00, and 15:00 and 19:00 hours on 23 March 2002, and also at 23:00 hours on 23 March 2002 and 3:00 hours on 24 March 2002? Please elaborate on your answer.

I feel it reasonable to accept that a paracetamol overdosage occurred at some time, or times, between 05:20 and 21:58 on the 23rd of March 2002. It would seem less likely further overdosage continued at 23:00 hours on the 23rd of March and 3:00 hours on the 24th of March.

A serum paracetamol level was obtained at 05:20 hours on the 23rd of March. According to the drug administration chart this level was taken 2 hours and 20 minutes after the last dose of paracetamol and was not elevated (0.06 mmol/L measured — laboratory reported therapeutic range 0.10 to 0.16 mmol/L). The next

level, taken at 21:58 hours on the 23rd of March and 3 hours after the last dose of paracetamol according to the drug administration chart, was significantly elevated from the first (0.4 mmol/L). It seems this elevation must be due to an overdose(s) occurring in the time period between these two paracetamol measurements.
The next plasma paracetamol level taken at 06:00 hours on the 24th was similarly measured three hours subsequent to a paracetamol dose and one hour prior to the next — again according to the drug administration chart. This second level was 0.24 mmol/L, a significant decline from that level found at 21:58 hours the previous day. It would seem reasonable to conclude that if 1 gram dosing led to the first elevated level, and this dosing had continued, then the second level would be at least the same as the 21:58 level (0.40 mmol/L), and most likely higher, particularly given it was taken at a similar time in relation to the administered doses.

2) If [Master A] had received the correct prescribed 250mg doses at all times … This dosing regimen does not explain the reported paracetamol levels. Had the paracetamol been administered in equal doses one would not expect the degree of increase and subsequent decline of measured paracetamol concentrations.

The patient had received 250mg paracetamol four hourly for a number of days. If the only paracetamol administered was 250mg consistently 4 hourly during the period in question the plasma paracetamol levels would not be expected to both:

a. increase from 0.06 mmol/L (as measured 05:20 23 March 2002) to 0.40 mmol/L, then;
b. decline from 0.40 mmol/L to 0.24 mmol/l (as measured 06:00 24 March 2002).

Particularly as these levels were taken at identical times relative to the dosing regimen.

…

In the past guidelines have been promulgated indicating a paracetamol dose of 90mg/kg/24hrs or 15mg/kg 4–6 hourly. I have attached a copy of such a dose regimen from the Paediatric Pharmacopoeia handbook published by the Royal Children's Hospital, Melbourne, Australia. Guides detailing paediatric drug administration are not common in Australasia and it is my experience that this regimen has been adopted by New Zealand hospitals and incorporated into their in-house dosing guides.

It is believed this dosage schedule is excessive and more recent editions of the Royal Children's Hospital handbook have lowered the recommended paracetamol dose. This change may not have been realised by all hospitals."

Further advice

I obtained the following additional advice on matters raised in the responses to my provisional opinion:

Dr Freebairn

> "10 December 2004
>
> … I have provided to you a report with my advice on the actions of the medical staff in relation to the treatment of [Master A] in [the public hospital]. I have also read and considered the Coroner's findings.
>
> I can confirm that the advice I would now give is unchanged from the previous advice given."

Ms Hewson

> "13 December 2004
>
> I have reviewed my original report on case number 02/08949/AM, the final coroner's decision dated 15 September 2004 and the submission from [Ms E].
>
> [Ms E's] submission regarding the amount of fluid she recorded on 23/2 was for flushing the feeding tube. She states that the volume was entirely for flushing to avoid blockage of the feeding tube. My experience and that of my paediatric specialist colleagues (procedure #28823, Otago District Health Board) is that flushing does not need to exceed 10 mls (before and after the medication) in general circumstances. This would bring the total per medication administration of 250 mg of paracetamol to 25 mls. For each of the fluid volumes recorded this still leaves excess volume to account for. However, [Ms E] has stated that it is her practice to amply flush the tube to ensure blockage did not occur, which would not account for the extra volume recorded.
>
> In regard to my comment that the amount of flush volume given seemed inappropriate for this child is still valid. My recall of the treatment plan (23/2) was that the child was on a feeding volume restriction to minimise gut problems he had been experiencing. I did not interpret this to mean his oral fluid intake or nasogastric flushes was unrestricted and as such, total volume going into the stomach should be kept within a low range.
>
> My comment about the smaller syringe size to accurately measure the paediatric dose of 5ml is best practice in my opinion and that of my paediatric specialist colleagues. It would be difficult to accurately measure such a small volume of medication (5 ml) in a 50 ml syringe.

I was referring to measuring the medication not administering the medication into the tube. [Ms E] is correct that a large syringe (eg 50 ml) is to be used on small bore feeding tubes to avoid high pressure. In my opinion, and that of my paediatric colleagues, the medication should have been transferred to the large syringe once it had been precisely measured in the smaller syringe.

The final Coroner's decision on the cause of the liver damage reported this was possibly [due] to Isoflurane (not paracetamol as indicated in the provisional report). Medical expert opinion do not support that the paracetamol given would have caused the liver damage seen in this case.

However I have been asked to comment on whether a medication administration error had occurred, not if paracetamol caused the liver damage. Hence this Coronial report does not alter my thinking about whether an error occurred and if so did [Ms E] provide reasonable care and skill.

[Ms E] has given her rationale for flushing with the volume she recorded. I have questioned this amount in the light of my experience and that of my colleagues. I do not recall if the other nurses caring for this child flushed with the same amounts of water when they gave the other doses of paracetamol. If there was a consistent practice (to flush with 60-90 mls of water, less the medication) by other nurses this needs to be taken into account in [Ms E's] favour. Nursing practice varies from unit to unit, nevertheless I would expect there would be a written procedure to support flushing paediatric feeding tubes as [Ms E's] practice indicates.

If [Ms E] did administer the correct dose of paracetamol, and used the amount of water flushes recorded, then she has provided reasonable care and skill in this case. The variation in water flushes for feeding tubes is not the issue here and I note [Ms E's] explanation of her rationale for the amount of fluid recorded for medications.

However her failure to document correctly would still be seen as a minor failure to provide reasonable care and skill."

Code of Health and Disability Services Consumers' Rights

The following Rights in the Code of Health and Disability Services Consumers' Rights are applicable to this complaint:

RIGHT 4
Right to Services of an Appropriate Standard

1) Every consumer has the right to have services provided with reasonable care and skill.

2) Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.

…

5) Every consumer has the right to co-operation among providers to ensure quality and continuity of services.

RIGHT 10
Right to Complain

6) Every provider, unless an employee of a provider, must have a complaints procedure that ensures that —

…

(a) the consumer is informed of any relevant internal and external complaints procedures including the availability of —

(i) independent advocates provided under the Health and Disability Commissioner Act 1994; and
(ii) the Health and Disability Commissioner.

Names have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

Opinion

Introduction

At the outset I extend to Mr and Mrs A my deepest sympathies on the tragic loss of Master A, a loss all the more difficult because it occurred so far away from their home and in a country where English is the dominant language.

Clarification of Commissioner's role

Role of Commissioner
My role as Health and Disability Commissioner under section 35 of the Health and Disability Commissioner Act 1994 (the Act) is to investigate any action of any health care provider where that action is, or appears to be, in breach of the Code of Health and Disability Services Consumers' Rights (the Code). In relation to Master A's treatment and the complaint made by Mr and Mrs A , the focus of my investigation has been on whether the treatment provided to Master A was of an appropriate standard as required by Right 4 of the Code.

It is not my role to establish the cause of Master A's death, which is the jurisdiction of the Coroner. I appreciate that the cause of Master A's tragic death is a central issue for his parents, Mr and Mrs A. However, I can only act within the functions given to me by Parliament in the Act.

Notwithstanding the limits of my jurisdiction I have included within this report an outline of the various views and expert opinions on the cause of Master A's death.

It is important to note that both Dr Freebairn and Ms Hewson, my expert ICU and nursing advisors, were provided with copies of Professor Prescott's and Professor Begg's reports at the time I requested their advice.

Additionally, I referred the Coroner's findings (which became available after my Provisional Opinion was issued) to Dr Freebairn and Ms Hewson to ascertain whether the conclusions on the cause of Master A's death altered their advice. They did not.

The Commissioner's jurisdiction with respect to Mr and Mrs B's home country
In his response to the provisional opinion, Mr A outlined additional concerns relating to the handling of Master A's evacuation, treatment and death by the authorities in his home country and the public hospital in New Zealand.

Mr A also criticised the authorities in his home country for failing to provide him and his wife with support and assistance after Master A's death.

My jurisdiction under the Act is restricted to determining whether the acts and omissions of health and disability service providers *in New Zealand* are in breach of the Code. My investigation and this report have, therefore, not considered the actions of the authorities in Mr and Mrs A's home country.

In addition, I have not considered the arrangements between authorities in Mr and Mrs A's home country and the public hospital for the treatment of burns patients.

Commissioner's jurisdiction with respect to damages
In his response to the provisional opinion, Mr A also sought penal and financial sanctions for the moral wrong, professional and psychological damage, and financial losses suffered as a result of Master A's death.

The Commissioner's powers after investigating a complaint are limited to those specified in section 45 of the Act and I have no power to award penal or financial sanctions or damages of any kind.

I have annexed a copy of Mr A's response to the Provisional Opinion as Appendix 2.

Opinion: No breach — Dr C, Dr D, Dr B

Under Rights 4(1) and 4(2) of the Code, Master A had the right to have services provided with reasonable care and skill and in compliance with relevant standards. The complaint against Dr C, Dr D and Dr B (the ICU medical staff) is that they did not provide services of an appropriate standard to Master A and, in particular, that they:

- failed to detect the paracetamol overdose and the decline in Master A's health in a timely manner;
- failed to respond to the paracetamol overdose and the decline in Master A's health and did not treat it in a timely and effective manner.

Prescription of paracetamol for Master A
On 22 March 2002 Master A was prescribed paracetamol 250 mg, four hourly.

Mr A has complained that the paracetamol dosage prescribed for, and administered to Master A was inappropriate given his weight. He maintained that Master A received 420mg too much paracetamol on 17, 21, 22, 23, 24 and 25 March 2002. Mr A was particularly concerned at the discrepancies in the records of Master A's weight, especially as paracetamol dosage is calculated by reference to weight. The overseas hospital recorded Master A's weight as 15kg, while the public hospital recorded 18kg in some places and 15kg in one. The children's hospital recorded Master A's weight as 17kg.

The evidence is that medical staff at the public hospital relied on a guide known as the *Melbourne Booklet* to calculate paediatric doses by weight. Dr Fountain's advice was that the *Melbourne Booklet* was an appropriate reference for calculating doses and that:

> "[p]aracetamol was prescribed in accordance with generally accepted criteria for a dose (15/mg/kg/dose). This was reviewed by (presumably) a pharmacist who annotated prescription notes stating '15mg/kg/dose' equivalent to '270mg' [per dose]. This was calculated from a child's weight of 18kg (18kg x 15mg = 270mg/dose) …

> Daily doses of less than 90mg/kg/day are generally applied as a reasonable paracetamol dose for children."

Dr Fountain noted, however, that more recent editions of the *Melbourne Booklet* have lowered the recommended paracetamol dose on the basis that the previous dosing schedule was excessive.

Dr Freebairn also confirmed that the dosing schedule utilised by the medical staff for Master A was consistent with that recommended in paediatric and general texts at the time. Additionally he stated:

> "While Dr Fountain's belief that the dosing schedule is excessive may be correct, this was not included in commonly available guideline[s] or recommendations available in 2002."

In my opinion, it was appropriate for the ICU medical staff and nurses to rely on the *Melbourne Booklet* in calculating the appropriate dose of paracetamol for Master A. I accept Dr Freebairn's advice that the dosage prescribed for Master A was within the range identified by the texts and guides available in 2002. The suitability of the prescribed dosage must be judged in the light of the information available to the ICU medical staff in March 2002, not in the light of information that has become available since.

I note Mr A's concerns at the disparity in the clinical record as to Master A's actual weight, which was relevant to determining the appropriate dose. On the evidence available it is not possible to determine Master A's actual weight at this time. Additionally, there is no information available to ascertain whether Master A was specifically weighed at any point during his admission.

The paracetamol dose of 250mg is less than would have been prescribed had Master A weighed 18 kgs and more than had he weighed 15 kgs. None of the experts, or involved medical personnel, have commented on the appropriateness of the dosage given the differences in recorded weight.

I cannot, therefore, make any finding on what the appropriate dose ought to have been. Additionally, I am unable to determine whether Drs C, B and D breached the Code by permitting the ongoing administration of 250mg paracetamol where there were discrepancies in Master A's recorded weight. In my view this matter highlights a systems issue relating to weighing and recording of weight and, accordingly, is discussed more fully in relation to the District Health Board later in this report.

Failure to detect paracetamol overdose and/or decline in Master A's clinical condition
One issue for me to determine is whether Master A displayed clinical signs and symptoms that should have alerted Drs C, B and D (or any of the other medical staff) at an earlier stage to consider the possibility of paracetamol overdose. In addressing this issue I am satisfied that these doctors and other medical staff were not advised by any of the nursing staff of the apparent administration of excessive paracetamol on 23 March.

Dr C was the ICU consultant, and Drs B and D were the ICU registrars on duty over the weekend commencing Saturday, 23 March 2002.

The medical notes indicate that ALT levels (a liver function test) began to rise on 23 March. The normal ALT range is 0-45U/L. Between 23 and 25 March increasingly elevated ALT levels were recorded in Master A's Laboratory Result sheet as follows:

Date	23/03	24/03	24/03	24/03	25/03	25/03	25/03
Time	2200	0600	1400	1750	0010	0545	1200
ALT	70	89	176	313	653	642	746

Master A also had ongoing diarrhoea, intermittent vomiting, mildly elevated temperature and reducing urine output over 23–25 March. Additionally, there was evidence of infection in Master A's burn wounds. It is apparent from the twice-daily ward rounds that the elevated ALT results were noted by the medical team. On the evening ward round of Sunday 24 March, Dr C ordered additional blood gas and coagulation tests. He has stated that these tests were ordered because of concerns regarding Master A's ongoing diarrhoea and electrolyte losses. They were not ordered on suspicion of coagulopathy (a sign of liver failure).

Despite the symptoms/signs described, both Dr C and Dr B advised me that they regarded Master A as relatively stable over the weekend. I note that the plans of the medical team (including the paediatrician who reviewed Master A on 23 March) were to increase nasogastric feeds and to start Master A eating and drinking. This is consistent with their impression that Master A was stable at this time.

In the early hours of Monday 25 March Master A's urinary output ceased and Ms H recorded increased ALT levels (653 U/L at 0010 hours, and 642 U/L at 0545). Additionally, the coagulation test results (INR/APTT) recorded in the clinical record at 0545 were abnormal. Ms H states that she brought the abnormal results to Dr D's attention, although he disputes this.

The ward round notes on Monday 25 March clearly indicate that the incoming team were aware of the raised ALT levels. In response to Master A's condition at this time a paediatric review was planned.

It is clear from the clinical record that over the period that they were involved in Master A's care Dr C and Dr B were aware of Master A's elevated ALT levels, although they regarded the elevations as 'mild'. They have advised me that they considered a number of possible causes for the elevation, namely:

- wound infection or sepsis
- intercurrent viral infection
- a mild to moderate drug reaction
- the antibiotics with which Master A was being treated.

Following their involvement, medical reviews were undertaken by the paediatrician, the ICU registrar and the burns surgeon throughout the day of 25 March.

Dr J, the paediatrician, queried at this time whether Master A had hepatitis and whether his fluid balance was adequate.

While liver failure was suspected at the morning ward round of 26 March, Master A did not have all the clinical features of liver failure, and his ALT levels were not as high as one would expect to indicate hepatic injury severe enough to cause liver failure. It was the results of repeated coagulation tests on 26 March together with other symptoms (hypoglycaemia, acidosis, and low albumin) that signalled Master A's deterioration as likely due to liver failure, and that prompted a search for the cause (and ultimately resulted in the discovery of the paracetamol overdose).

With this context in mind, an important issue for me to consider is the significance of the rising ALT levels (that is, should paracetamol toxicity have been suspected on the basis of these results), and whether the results were appropriately responded to by the ICU medical team.

My expert advisor, Dr Freebairn, has advised me that Master A's elevated and rising ALT levels from 23 March onwards were correctly described by Drs B and C as 'mild'. Subsequent rises on and after 25 March could be described as 'mild to moderate'. Moreover, elevated ALT levels are common in critically ill patients and are not, of themselves, indicative of any particular syndrome or condition. Dr Freebairn advised:

> "The elevation of liver enzyme in critically ill patients is extremely common, and while they may be markers of progression of disease, are not pathognomic of any particular syndrome and may have been associated with the burn injury itself. The ALT began rising on the 23rd, about the time of the overdose. It is not usual for ALT to change immediately. Elevated INR and other coagulation abnormality measures may have been the result of severe sepsis. As Professor Prescott indicates the rise in the ALT was small and does not indicate that there was severe, liver dysfunction as a result of the paracetamol poisoning."

Additionally, Dr Freebairn described the derangement of liver function as in keeping with a number of common scenarios in ICU such as drug- or sepsis-induced elevation of liver function tests. The elevation of the ALT may also be a marker of myocardial, renal, liver or other organ dysfunction, or of severe sepsis. While rising ALT levels can be associated with paracetamol overdose, there were other more likely diagnoses and Master A's clinical features were not highly indicative of paracetamol toxicity. Dr Freebairn stated:

> "… None of the senior medical staff in their reviews considered iatrogenic paracetamol overdose. However given the information available, and that there were other more likely [diagnoses] this is not altogether surprising. Lethal intoxication in children after repeated administration of therapeutic doses is very rare."

Dr Freebairn is not critical of the medical team's responses over the weekend (or indeed in the days following) to the rising ALT levels. It is important to note that there is no specific treatment for elevated ALT and the indicated response is to identify and treat the underlying cause of the elevation. Dr Freebairn considered that reasonable steps were taken to establish a diagnosis (cultures and serology) and that there was an appropriate widening of investigations to determine the cause of Master A's deterioration. Dr Freebairn also commented that, in hindsight, it would have been preferable for a paracetamol level to have been undertaken on 25 March. However, it is not standard practice to monitor paracetamol levels, and paracetamol toxicity in the critically ill is not common. There was nothing to indicate to the medical team that paracetamol overdose was the culprit for Master A's deteriorating condition.

A further matter of relevance concerns Dr D's actions early on the morning of 25 March.

Nurse H has stated that she advised Dr D of Master A's elevated ALT levels sometime after 0545 hours. She said that Dr D decided to discuss the further elevation in ALT level at the ward round that morning. Dr D disputes that Ms H brought the elevated ALT levels to his attention.

It is not necessary for me to make a determination in relation to these conflicting accounts. Dr Freebairn has opined that even if Dr D was advised of the ALT level before the morning ward round on 25 March, it was reasonable for him to decide to wait until the ward round. This was because the elevated ALT level indicated a continued trend of deterioration rather than a sudden change from the earlier results, and there were no other physiological signs of deterioration at that time. Moreover, I note that the rising ALT levels were considered during the ward round that morning.

Master A's condition appropriately monitored
In his complaint and again in his response to the provisional opinion, Mr A queried whether appropriately serious and systematic monitoring of Master A was undertaken.

As already outlined, the evidence is that Master A was reviewed at ward rounds twice daily between 23 and 26 March by at least one ICU consultant, who was accompanied by one and sometimes two registrars. ICU medical staff also sought advice from a paediatric consultant, Dr J, on 23 and 25 March. In addition, Mr K, a burns surgeon, reviewed Master A on 25 March.

Dr Freebairn advised:

> "In these ward rounds and consultations, consideration of the various diagnostic tests, follow-up of the results of these tests and ongoing care plans were formulated. The clinical condition was a complex one, with a 60-70% body surface area burn in a child with diarrhoea, difficulty with feeding, agitation, wound infection and probably sepsis. The clinical notes, medical reports and interviews all suggest that [Master A] was receiving attention from both medical and nursing staff."

Master A's condition deteriorated significantly over 25-26 March. At that stage the possibility of hepatitis was considered and blood was sent for testing. In addition, the contribution of poor fluid balance was questioned, with Dr J noting that Master A looked dry and instructing an increase in his fluids.

Dr Freebairn advised that the tests ordered to be performed on the 25th and 26th indicate a widening search for a cause of the deterioration and were appropriate. Unfortunately, Master A progressed to acute liver failure, which was diagnosed on 26 March. The investigation for a cause included a review of the *Drugs and Fluid Record Chart*, resulting in the discovery of the paracetamol overdose.

I have considered whether medical staff should have considered an earlier review of the *Drugs and Fluid Record Charts*. I am satisfied on the evidence and having considered Dr Freebairn's advice, that there was nothing in Master A's condition or laboratory test results that should have prompted the ICU medical staff to review the drug administration charts before the morning of 26 March when it was clearly evident that Master A was suffering liver injury. Dr Freebairn has advised me that the ICU medical staff were entitled to assume that Master A's medications had been administered as charted. He also opined that "it is unreasonable and impractical to expect medical practitioners to double-check the administration of every medication given by nursing staff. Therefore the failure of any of the medical team to discover that an excess dose of paracetamol [appeared to have been administered] is not a failure to provide adequate care."

I accept Dr Freebairn's advice. In my opinion, medical practitioners working in a hospital setting such as the public hospital's ICU are entitled to rely on nursing staff to administer medications in the dosages charted. The obligation for medical practitioners to check drug administration records arises only if there are grounds for suspecting that a medication error of some kind has been made. In this case, there were no grounds for such suspicions until the indication of likely liver failure on 26 March.

No breach

Having considered the evidence and the advice of Dr Freebairn I am satisfied that during the period that Master A was in their care Drs C, B and D treated and managed his condition with reasonable care and skill, and accordingly did not breach Rights 4(1) and 4(2) of the Code. In my opinion, it was reasonable for them to consider other diagnostic possibilities (rather than paracetamol toxicity) as more likely causes of Master A's rising ALT levels. I am also satisfied that over the weekend 23-24 March Master A's clinical condition was relatively stable and that he was monitored in a timely and diligent fashion over this time by Drs B, C and D. In my opinion the management/treatment and diagnostic plans including ongoing cultures and serology tests, fluid replacement and management of food intake was appropriate. I also consider that the deterioration over the early hours of 25 March, up to and including the ward round at 0945 on 25 March (when all three doctors ceased to be involved in Master A's care), was appropriately responded to and handed over to the incoming team.

I am also satisfied that Master A was appropriately monitored and treated on 25 and 26 March by other medical staff, and that they were diligent in their investigations to ascertain the cause of Master A's condition. I do not consider that there was, as Mr A suggests, no response to Master A's condition or that there was "serious medical diagnostic error" or any breach of "their moral duty to explore all the possible avenues to explain and treat Master A's liver failure". In my view ICU medical staff reacted appropriately to Master A's condition, conducted appropriate tests and investigations, and considered a range of possible causes for his failure to improve.

Delay in stopping paracetamol/not administering antidote earlier
Mr and Mrs A have asked why Master A's paracetamol was not stopped earlier or the dose reduced when, as they see it, the laboratory results were suggestive of a paracetamol overdose. They have referred to laboratory test results that indicate elevated paracetamol concentrations. In his submissions in response to the provisional opinion, Mr A also suggested that the antidote for paracetamol poisoning — N-acetylcysteine — was not commenced until after Master A's transfer to the children's hospital.

I have outlined above my view that the laboratory results (including the blood tests indicating deranged liver function tests) were appropriately interpreted and responded to by the medical team. In the absence of specific information regarding the overdose, the tests were not, of themselves, indicative of paracetamol toxicity.

It is also important to note that the possibility of paracetamol toxicity was not suspected by the ICU medical staff until the morning of 26 March when, as part of the search for the cause of Master A's liver injury, Dr O in a review of the clinical record discovered the apparent overdoses. *Retrospective* tests were then undertaken (on 26 March) on Master A's past blood samples, which indicated elevated paracetamol concentrations on the preceding three days. This was information not previously known to the medical team and obviously could not have had any role to play in deciding whether or not to stop the paracetamol earlier.

It is to be noted that Master A's paracetamol was stopped on the afternoon of 25 March because of concerns about his deranged liver function tests, not because of any awareness of the apparent paracetamol overdoses. This was an appropriate step at that time.

I am also satisfied, on the basis of Dr Freebairn's advice, that it was reasonable not to undertake earlier testing of paracetamol levels, as such testing is not standard practice (unless positively indicated).

In my opinion, therefore, I do not consider that Drs C, B, D, or other members of the medical team failed to provide a reasonable standard of care by not stopping Master A's paracetamol before 25 March, or not undertaking earlier testing of Master A's paracetamol levels.

In respect of the administration of N-acetylcysteine (paracetamol antidote), Master A's patient record indicates that as soon as the apparent overdoses were discovered an N-

acetylcysteine infusion was commenced by Dr M (at 1030 on 26 March). This response was based on the assumption that Master A might be suffering from paracetamol-induced liver failure.

I note, however, that Professor Begg advised the Coroner that Master A's serum levels were below the level at which administration of the antidote would normally be started.

In my view, administration of N-acetylcysteine occurred as soon as reasonably possible and was an appropriate clinical response.

Opinion: Breach — Ms E

I have made a finding that, on the balance of probabilities, Ms E did administer Master A a paracetamol overdose. In my opinion, Ms E failed to provide services to Master A with reasonable care and skill and in compliance with professional standards when she administered to Master A an overdose of paracetamol and used inappropriate quantities of flushing fluid to do so. It is important to note that in reaching these conclusions, and for reasons outlined earlier in this opinion, I have made no finding that Master A's death was caused by the overdoses of paracetamol.

Administration of paracetamol
Ms E recorded in Master A's *Drugs and Fluid Record Chart* for 23 March 2002 that she administered three 1g doses of paracetamol to Master A at 1100, 1500 and 1900 hours. She says that although she recorded the three 1g doses, she in fact administered only the prescribed dose of 250mg on each occasion.

Ms E said:

> "I am convinced that I only administered 250mg doses during my shift on Saturday 23rd March 2002. Why I say this is because:
>
> a) a one gram dose of Panadol for a 3 year old would be very unusual and not something I have encountered before. Alarm bells would have rung had my calculation indicated one gram. My calculation was 270mg and I only administered 250mg, less than the calculated dosage. I did the calculation and 270mg was the result which was within the range prescribed and indicated on the drug sheet. I referred to the ICU sheet numerous times during my shift to compare readings taken on the previous shift. These would be such things as previous medications including [paracetamol] to ensure I was giving them on time and things like temperatures and outputs to check for any major changes in the patient's status, ie any increases of diarrhoea or changes in respirations.
>
> b) The [paracetamol] mixture is very viscous. It is a sticky solution, which when used in large doses results in increased pressure when trying to put it into a naso-gastric

tube. This is very noticeable when administering large amounts such as one gram such as an adult would have.

One gram of [paracetamol] would have equated with a dose of 20ml ie 250mg = 5ml, 1 gram = 20ml.

c) The volume dose of 1 gram would have also rung alarm bells for me, as children are not, as a rule administered such large doses. The dosage for 1 gram of [paracetamol] would be four times the volume of a 250mg dose, which is what I calculated to give the patient. The volume would also have resulted in a back pressure from the naso-gastric tube when one depresses the syringe. I can not recall any back pressure whilst administering the 250mg doses of pamol during my shift."

There is, however, evidence that supports the contrary view — that Ms E did administer three 1g doses of paracetamol on 23 March.

It is clear from the retrospective testing of serum levels of paracetamol in Master A's blood that there were abnormally high levels at 2158 on 23 March (0.40 mmol/L), and 0600 on 24 March (0.24 mmol/L). The normal range for therapeutic serum levels is 0.10–0.16 mmol/L. These results coincide with the recorded administration of three 1 g doses on 23 March, and show a marked increase from previous levels (on that day), with subsequent and significant decline in those levels over 24/25 March.

Dr Fountain advised me that had Master A received the correct dosages of 250mg at all times one would not expect the degree of increase and subsequent decline of measured paracetamol concentrations. This is consistent with Professor Begg's advice to the Coroner that, on the basis of his calculations, it was almost certain that Master A received 1g of paracetamol on the three documented occasions on 23 March.

My expert nursing advisor, Ms Hewson, also questioned the excessive volumes of water flush administered and recorded by Ms E for the small amount of volume required for 250 mg of paracetamol. For the three doses of paracetamol administered by Ms E on 23 March, flush volumes were 90mls, 65mls and 60mls respectively. Ms Hewson opined:

"The volume needed to administer 250mg of paracetamol is 5 ml. The volume of water flush only needs to enough to clear the tube. This would generally be 10 ml for a paediatric feeding tube (e.g. 5ml paracetamol + 10 ml flush = 15 ml total volume).

… Apart from the paracetamol administered at these times, the other medications given were very small intravenous volumes. I question the excessive volumes recorded for the small amount of volume required for 250 mg of paracetamol and flush. If [Ms E] gave a large amount of flush, this would seem inappropriate, as the child was restricted to a feeding volume of 10 ml per hour due to vomiting."

I note that administration of larger amounts of flushing fluid is consistent with the administration of a larger volume of paracetamol through the nasogastric tube.

However, this is disputed by Ms E. In response to the provisional opinion, Ms E's counsel said:

> "... It is not accepted that the 'large amounts of fluid' were administered by [Ms E]. [Ms E] responds to this finding in the following way:
>
> – nasogastric tubes get blocked
>
> – flushing the tube prevents blocking
>
> – replacing the tube would have required further general anaesthetic and is thoroughly unpleasant for the patient, and has significant risks
>
> – The notes did not say to continue nil by mouth but rather 'continue with supportive care/fluid balance.' [Ms E] understands this to mean supportive care to allow [Master A] to have oral fluids for comfort as tolerated. In the notes prior to [Ms E's] shift on 23 March it is noted 'drinking water, tolerates well, no vomiting'. In the following shift it was noted 'taking oral fluids'.
>
> – Fluid volume and feed volume are not the same thing. Fluids are to replace water and sodium losses whilst feeds are a nutritional support.
>
> – Nurse Hewson suggested high volume of fluid is inappropriate when a patient has vomiting or diarrhoea. [Master A] did not vomit on [Ms E's] shift on 23 March. The only time vomiting is mentioned in the clinical notes is on 19 March.
>
> – That [Ms E] used amounts of 90ml, 60 and 60ml with the medication is not inappropriate as the same was to clear the tube of the viscous paracetamol solution, and to complement his fluid intake. Whether the additional water was ingested orally by sipping drinks or via the nasogastric tube is irrelevant. Administration of the fluids as recorded was appropriate and in accordance with the instructions to provide supportive care.
>
> – Ms Hewson suggests a volume of 5mg of paracetamol would require only 10ml to flush the tube. The manufacturers of the tube used instruct that in infants and children 10–15ml of flush is used before and after the medication, before and after feeds or interruptions in feeding and 4 hourly to ensure the tube remains unblocked. When one adds the medication mixed in warm water as used by [Ms E] the volumes are not inappropriate at all as is suggested.
>
> – Ms Hewson further finds that the safest practice would be to use a 5 or 10ml syringe and that she was aware a statement had been made by the parents about a large syringe being used. The manufacturers of the tube used instruct that a 50–60ml syringe be used to administer medication and flush.

> A syringe any smaller can cause too much pressure inside the tube and damage it, burst it. [Ms E] used a syringe as instructed by the manufacturers of the tube. Annexed hereto is a copy of the manufacturer's instruction sheet which accompanies the tube."

I asked Ms Hewson to respond to Ms E's explanation. She stated:

> "… [F]lushing does not need to exceed 10 mls (before and after the medication) in general circumstances. This would bring the total per medication of administration of 250 mg of paracetamol to 25 mls. For each of the fluid volumes recorded [by [Ms E] this still leaves excess volume to be accounted for. However, [Ms E] has stated that it is her practice to amply flush the tube to ensure blockage did not occur, which would account for the extra volume recorded."

Ms Hewson also queried the practice of the other nurses in relation to the administration and flushing of medication commenting that if there was a consistent practice of nursing staff flushing similar amounts of fluid this should be taken into account in [Ms E's] favour. An analysis of the notes shows that the other nurses administered significantly less fluid with Master A's medications.

Ms Hewson maintained, despite Ms E's explanations, that the amount of flush was inappropriate in view of the gut problems Master A had been experiencing. While I accept Ms E's statement that Master A did not vomit during her shift on 23 March, he is recorded as having done so on 19 and 22 March. He is also recorded to have had diarrhoea every day from 19 to 26 March 2002. Ms E, through her counsel, also asserts that the administration of the volumes of fluid was appropriate and in accordance with the instructions to provide supportive care. However, I note that the plan to continue with supportive care/fluid balance was recorded on 22 March and that Master A feed's were stopped that day. During Ms E's shift a new plan was put in place by Dr J which directed that feeds be restarted slowly at a rate of 5–10 mls two hourly and requested that fluids be *decreased* as the feeds were re-commenced.

In respect of this issue Ms Hewson advised:

> "… [M]y comment that the amount of flush volume given seemed inappropriate for this child is still valid. My recall of the treatment plan (23/2) was that the child was on a feeding volume restriction to minimise gut problems he had been experiencing. I did not interpret this to mean his oral fluid intake or nasogastric flushes was unrestricted and as such total volume going into the stomach should be kept within low range."

Having considered Ms E's response and Ms Hewson's further advice, I remain of the opinion that the amount of fluid Ms E administered with each dose of paracetamol was excessive, and that the use of a larger volume of fluid for flushing is consistent with the administration of a greater volume of paracetamol.

After considering the evidence of Dr Fountain and Professor Begg, which is corroborated by the clear documentation of three 1g doses of paracetamol being administered, together

with the larger volumes of flushing fluid, I find on the balance of probabilities that Ms E did administer three 1g doses of paracetamol at 1100, 1500 and 1900 hours on 23 March 2002.

In my opinion, by administering overdoses of paracetamol to Master A, Ms E failed to provide him services with reasonable care and skill and therefore breached rights 4(1) and 4(2) of the Code. I agree with Ms Hewson's expert advice that such overdose constitutes a serious medication error and is a major departure from an appropriate standard of care. Of particular concern is that the error occurred on three separate occasions — despite Ms E's statement to me that she referred to the ICU sheet (which included previous paracetamol administration) numerous times during her shift. My expert advisor noted that such an error is in breach of the standards defined in the *Code of Conduct for Nurses and Midwives* (1999) and *Guidelines for Nurses on the Administration of Medicines* (NZNO 1998).

I am also concerned at Ms E's administration of high volumes of fluid with the paracetamol when she knew, or ought to have known, that Master A had been suffering from vomiting (albeit he did not vomit during her shift on 23 March), had ongoing diarrhoea, and was on restricted feeding and fluid volumes. In my view, Ms E's actions in this respect also breached right 4(1) of the Code.

Opinion: No breach — Ms F

Administration of paracetamol
The complaint against registered nurse Ms F is that at 2300 on Saturday 23 March 2002, and at 0300 on Sunday 24 March 2002, she administered 1g doses of paracetamol to Master A, instead of the prescribed 250mg doses.

The *Drugs and Fluid Record Chart* shows that notations of 1g doses of paracetamol during Ms F's shift have been crossed out and amended to 250mg. Ms F is categorical that she administered only 250mg of paracetamol to Master A (at 2300, 23 March 2002 and 0300, 24 March). While she accepts that she amended the 2300 entry from 1g to 250mg, she maintains that she did not alter the subsequent entry at 0300.

The testing of Master A's paracetamol levels over this period show that the levels peaked at 2158 hours on 23 March at 0.40 mmol/L. Thereafter the levels declined, with the next level recorded at 0600 on 24 March at only 0.24 mmol/L. In relation to this information my expert advisor Dr Fountain opined:

> "It would seem less likely that further overdosage continued at 2300 on the 23rd of March and 0300 hours on the 24th of March …
>
> It would seem reasonable to conclude that if 1 gram dosing led to the first elevated level, and this dosing had continued, then the second level would be at least the same as the [2158] level (0.40mmol/L), and most likely higher, particularly given it was taken at a similar time in relation to the administered doses."

I am satisfied, therefore, on the basis of Dr Fountain's opinion and Ms F's evidence, that it is probable she only administered the prescribed 250mg of paracetamol to Master A, and that Ms F complied with professional standards in relation to the paracetamol administration. Accordingly, Ms F did not breach the Code in this respect.

Opinion: Breach — Ms F

Alteration of patient record
Another aspect of the complaint against Ms F is that she failed to provide Master A with services of an appropriate standard when on two occasions she altered his *Drug and Fluid Record Chart* to state that she had administered Master A the prescribed 250mg doses of paracetamol (instead of 1g).

It is clear that two entries in the *Drugs and Fluid Record Chart* have been altered (2300, 23 March and 0300, 24 March). Ms F admits altering the entry for 2300 on 23 March (the 2300 entry) but denies altering the subsequent one. There is no other evidence to shed light onto who altered the second entry. In these circumstances Ms F must be given the benefit of the doubt, and accordingly, I am not able to be satisfied on the balance of probabilities that Ms F altered the 0300 entry.

In relation to the amendment of the 2300 entry I note Ms Hewson's advice that:

> "… [t]he proper way to alter an error in documentation is draw a single line through the wrong information, write 'in error' and initial this. Then fill in the correct information. I am sure [the public hospital] has a standard to this effect. It is not acceptable to 'write over' and try to alter the original information."

Ms Hewson also opined that the failure to correct the clinical record in this manner breached standards specified in the *Code of Conduct for Nurses and Midwives* (1999).

I accept my expert nursing advice. To anyone reading the record, the manner in which Ms F altered the 2300 entry leaves doubt as to how much paracetamol Master A received at 2300 on 23 March. The amended entry has also created confusion and hampered investigations into Master A's care. In my view the lack of clarity regarding the amendment created a risk that Master A's treatment would be prejudiced. The primary objective of health professionals' documenting care must be to provide a clear and accurate record of that care. The 2300 entry made by Ms F does not fulfil that objective.

In my opinion, Ms F's manner of alteration to the 2300 entry amounts to a failure to provide services with reasonable care and skill, and also fails to comply with professional standards, in breach of Rights 4(1) and 4(2) of the Code.

Failure to report apparent overdoses
It has been alleged that Ms F, having altered Master A's patient record, failed to notify anyone that the nurse on the preceding shift, Ms E, had apparently administered three 1g doses of paracetamol to Master A instead of the prescribed 250mg doses.

I am satisfied that Ms F did notice the recorded overdoses but failed to report them which, in my view, is a failure by Ms F to: provide services with reasonable skill and care; comply with professional standards; and communicate effectively with her nursing and medical colleagues.

Accordingly, she breached Rights 4(1), 4(2) and 4(5) of the Code.

Ms F accepts that she was aware, from reading Master A's clinical record, of the apparent administration of excessive paracetamol. She has stated that she was sufficiently concerned about the apparent overdoses to monitor Master A for signs and symptoms. She also advised that she had previously nursed a patient who had had an overdose of paracetamol. She can, therefore, be taken to have been aware of the potential for compromise to Master A's safety and well being.

Ms Hewson's advice was clear that Ms F should have reported the apparent overdoses in accordance with organisational policy for reporting and recording medication errors. She stated:

> "… Regardless of local variations in policy, all district health boards expect medication errors to be documented. [Ms F] stated she was aware of her hospital policy on incident reporting."

In response to the provisional opinion, Ms F's counsel suggested that Ms Hewson's advice inappropriately applied the standards of another District Health Board to Ms F. However, I am satisfied that Ms Hewson's opinion was that Ms F should have followed the organisational policies put in place by the District Health Board for reporting apparent errors. Ms F acknowledged to me that at the time she was caring for Master A she was aware of the importance of reporting the apparent overdoses and of the District Health Board's formal reporting procedures.

In fact, the public hospital's *Medication Error Moratorium* policy in force at the time required the apparent overdoses to be reported either via the public hospital's Complaints and Incidents Management System or by completing an incident form. Ms F did not utilise either of these processes. A copy of the relevant parts of this policy is annexed at Appendix 1.

As Ms F did not complete an incident form I consider that minimum reasonable practice required Ms F to document the apparent overdoses in Master A's patient record. She should also have notified her shift coordinator or any member of the ICU medical staff of the apparent overdoses. She did not take either of these actions.

Ms F has said, however, that when she handed over Master A's care to Nurse G at the end of her shift, she advised Ms G of the apparent overdoses and that Master A's ALT levels were elevated. Ms G disputes being advised of either of these matters.

It is unnecessary for me to attempt to resolve this conflict in the evidence since, in my view, even if Ms F did advise Ms G of the apparent overdoses and elevated ALT levels, this would not have been sufficient reporting of the error.

Ms Hewson's advice on this point was unequivocal:

> "[Ms F] did not [use] reasonable care and skill if as she has stated [she] only advised the oncoming nurse of the medication errors. As she failed to report or record the apparent medication errors, only advising another nurse is not the expected standard and would be met with moderate to severe disapproval by the nursing profession.
>
> Verbally passing on serious information of this nature is fraught with potential problems, one of which is highlighted in this case because the oncoming nurse had no recollection of being told this information. [Ms F] has stated herself that she 'intended to tell the doctors'. However she said it 'slipped her mind' and she 'totally forgot' to follow through with her intentions. This is an example of how vulnerable the system can be when staff does not follow organisational policy on reporting and recording events. It was [Ms F's] responsibility, and only hers, to pass on this information in the appropriate way and not expect such a serious event to be handled in an informal manner as verbally passing it on. It would be expected that [Ms F] pass on this information to the oncoming nurse in her shift handover, however this would never be 'instead of' the formal reporting and recording of the event."

Ms F's counsel has expressed concerns that Ms Hewson's advice was given in the context of a belief that Master A died of paracetamol poisoning. I note, however, that Ms Hewson was provided with the reports from Professors Prescott and Begg (and later with the Coroner's findings) which determined that paracetamol poisoning was not the cause of Master A's death. I am satisfied that Ms Hewson has appropriately applied the accepted professional standards of care to Ms F's actions without regard to the outcome or cause of death.

Additionally, I do not accept Ms F's counsel's suggestion that the risk to Master A was low because repeated administration of therapeutic doses of paracetamol are unlikely to result in lethal intoxication in children. Any overdose must be regarded as a serious matter, regardless of the risk of lethality.

I further accept my expert advice that Ms F failed to comply with relevant professional standards, namely criterion 4.3 of Principle 4 of the New Zealand Nursing Council's *Code of Conduct for Nurses and Midwives* (1999) when she did not report the apparent overdoses in accordance with the public hospital's *Incident Process and Resolution Procedures* policy, document them in Master A's patient record, or notify her shift coordinator or a member of the ICU medical staff.

In my view Ms F's failure to record or report the apparent overdoses was a major departure from the accepted standard of care, which had the potential for serious consequences. Her failure to pass on vital information regarding the apparent overdoses contributed to the delay in ICU medical and nursing staff recognising and responding to the apparent overdoses. Accordingly, Ms F failed to provide services with reasonable skill and care and in compliance with professional standards, in breach of Rights 4(1) and 4(2) of the Code.

When she failed to report the apparent overdoses, Ms F also failed to discharge her responsibility under Right 4(5) to communicate effectively with the doctors and other nurses involved in Master A's care, so as to ensure the quality and continuity of care.

I wish to acknowledge Ms F's counsel's advice to me that "since this case Ms F appreciated that a review and period of up-skilling of her practice was appropriate". She has undertaken an Advanced Critical Care course at Unitec and participated in a paediatric study group convened by the Intensive Care Unit at the public hospital.

Opinion: No breach — Ms G

Failure to detect and report apparent overdoses
Ms F said that she advised Ms G of the apparent overdoses when she handed over Master A's care at the end of her shift on 24 March 2002. Ms G disputes this.

As noted earlier, I am unable to resolve this evidential conflict. I consider it likely, however, that if Ms G had been advised of the apparent overdoses, at a minimum, the way in which she cared for Master A would have reflected the need to monitor Master A for the development of signs and symptoms of paracetamol overdose. There is nothing in Ms G's note in Master A's patient record to suggest any increased vigilance on her part. In fact, Ms G's note indicates that she simply maintained Master A's care according to the plan already in place.

Ms G said that, had she known about the apparent overdose, she would have alerted ICU medical staff to the elevated ALT levels that she transcribed into Master A's Laboratory Results sheet against the times 1400 and 1750 on 24 March 2002. This was because she was aware that a paracetamol overdose could lead to changes in liver function and bilirubin levels.

In addition, I think it likely that Ms G would have raised the apparent overdoses when she spoke to the registrar on duty during her shift about Master A's vomiting, and handed over to Ms H at the end of her shift at 1900 on 24 March.

I have considered whether Ms G should have checked Master A's records including his *Drug and Fluid Record Chart* as far back as Ms E's shift on 23 March (two shifts before her own shift), but have concluded that she could not reasonably have been expected to make such a check, and therefore, could not reasonably be expected to have discovered the

apparent overdose by that means. Although I would expect an oncoming nurse to check a patient's records for the immediately preceding shift, I would not expect a check to be made beyond that unless there is a particular trigger for such a check. There was no such trigger in this case.

In light of the evidential uncertainty outlined it cannot be established that Ms G breached the Code.

Opinion: Breach — Ms G

Failure to report abnormal ALT levels
Ms G cared for Master A between 0700 and 1900 on 24 March. During her shift Ms G transcribed abnormal ALT levels of 176 U/L at 1400 hours and of 313 U/L at 1900 hours from the computer onto Master A's Laboratory Results sheet.

Although the ALT levels were abnormal, Ms G did not alert the ICU medical staff to them. In her view it was a medical responsibility to check the Laboratory Results sheet, identify any abnormal results and respond to them. In addition, her experience was that patients in ICU often had high ALT levels in the context of sepsis or multi-organ failure that did not require immediate action.

Ms Hewson advised:

> "… [I]t is appropriate for nurses to use discretion as to which results they report to medical staff. What determines this discretion is based on the experience and knowledge of the nurse in interpreting the meaning of the abnormal result. Experienced and knowledgeable nurses know which laboratory results are in need of urgent attention, those that are a single result 'just out of normal range' and those that are abnormally trending up or down. Laboratory results that indicate urgent attention and those that are trending up or down, well out of normal range, do need to be brought to the medical staff attention at the time they are retrieved by the nurse."

In Ms Hewson's opinion, Ms G failed to provide reasonable and safe care by not alerting the medical staff to the increasingly abnormal level although she considered this failure to be a minor departure from the standard of care. While acknowledging Ms G's explanation regarding the high incidence of ICU patients with sepsis or multi-organ failure, Ms Hewson opined:

> "However, there was no indication that [Master A] was septic or in multi organ failure. This in itself is a reason to point out the rising ALT to the medical staff who is responsible for investigation and treatment. …

> Although the whole health team was responsible for the overall care of Master A, it is the nurse at the bedside who has the opportunity to organise and detail the care. This would include relaying information and referring care to the appropriate people."

Ms Hewson further advised me that Ms G's conduct in this respect did not comply with NZNO's *Standards for Nursing Practice in Critical Care* or the Nursing Council's *Code of Conduct for Nurses and Midwives.*

I accept my expert nursing advice. Ms G was responsible for coordinating Master A's care during her shift. This responsibility included collecting and transcribing Master A's laboratory results and alerting ICU medical staff to any abnormal results requiring attention. Ms G should have based her assessment of which abnormal results required immediate attention on Master A's particular clinical circumstances at that time, not on her view that generally ICU patients have elevated ALT levels as a result of sepsis or multi-organ failure. Neither sepsis nor multi-organ failure was a feature of Master A's presentation at that time. Accordingly, Ms G should have reported the abnormal ALT levels.

In addition, Ms G was the member of the nursing and medical team best placed to coordinate Master A's care because he was her only responsibility. She was able to focus her attention solely on Master A in a way that the ICU medical staff, who were responsible for all the patients in ICU, could not.

In failing to immediately report the abnormal ALT levels to the ICU medical staff Ms G failed to provide services to Master A with reasonable care and skill and in accordance with professional standards, and therefore breached Rights 4(1) and (2) of the Code. I accept, however, that Ms G's failure in this respect was a relatively minor departure from the standard of conduct expected of a registered nurse.

Opinion: No breach — Ms H

Reporting abnormal ALT levels
Ms H was the nurse responsible for Master A's care between 1900 on 24 March and 0700 on 25 March. Ms H transcribed the results for blood tests received by the laboratory at 0010 and 0545 on 25 March into Master A's Laboratory Results sheet.

Ms H recorded that Master A had an ALT level of 653 U/L at 0010 and of 642 U/L at 0545 on 25 March. The normal range is 0-45 U/L. Ms H did not notice that the ALT level of 653 U/L at 0010 was high, but did note the ALT level of 642 U/L at 0545. She also recorded under the 0545 time Master A's abnormal INR and APTT results (coagulation tests). Ms H has stated that she advised Dr D of the abnormal results and that his response was that they would be looked at on the morning ward round.

Dr D disputes that Ms H brought the abnormal results to his attention, stating:

> "In the case of [Master A] no abnormal results were ever brought to my attention by either the laboratory or nursing staff or on the handover rounds. … I am now aware that the liver function tests were abnormal but these were never brought to my attention by any nursing, laboratory or medical staff and I did not note that they were abnormal at the time."

Ms H says she also advised the nurse who took over Master A's care at 0700 on 25 March of the abnormal ALT, INR and APTT results.

Regardless of whether Ms H advised Dr D of the abnormal ALT level, it is clear that Master A's ALT levels were considered by Dr I, Dr C and the ICU registrar during the ward round at 0940 on 25 March as evidenced by the clinical note of that ward round.

Ms Hewson advised that if Ms H reported the abnormal ALT level to Dr D and to the oncoming nurse, she met the expected standard and showed reasonable skill and care. If, however, Ms H did not notify the doctors of the abnormal ALT level she did not provide reasonable care and skill. In Ms Hewson's opinion such a failure "would be considered a minor failure and meet with mild disapproval from the nursing profession".

I am unable to determine whether Ms H's or Dr D's evidence should be preferred. Their evidence is in direct conflict and there is nothing in the surrounding circumstances, the documentation, the statements made in response to the complaint, or the evidence given during interviews that assists me.[31] In these circumstances it cannot be established that Ms H breached the Code.

The District Health Board

Complaint
The complaint against the District Health Board was that in the following respects it did not provide services of an appropriate standard:

- *While Master A was in the public hospital from 17 to 26 March 2002, medical and nursing staff failed to monitor Master A's medications properly.*
- *Master A suffered a paracetamol overdose.*
- *Medical and nursing staff failed to detect the paracetamol overdose and the decline in Master A's health in a timely manner.*
- *Medical and nursing staff failed to respond to the paracetamol overdose and the decline in Master A's health and did not treat it in a timely and effective manner.*

[31] I note that if Dr D was told about the elevated ALT levels, he made an appropriate decision to discuss them at the morning ward round and, therefore, it is not necessary for me to make a determination — see discussion on page 50.

- *Although the public hospital knew that Mr and Mrs A were dissatisfied with Master A's treatment, they did not advise Mr and Mrs A of the existence of the Health and Disability Commissioner's Office or of the independent advocates provided under the Health and Disability Commissioner Act 1994.*

Vicarious liability of the District Health Board
Under section 72(2) of the Health and Disability Commissioner Act 1994 the employer of health care providers, such as ICU medical staff and nurses, is liable for ensuring that employees comply with the Code. Section 72(2) states:

> "Subject to subsection (5) of this section, anything done or omitted by a person as the employee of an employing authority shall, for the purposes of this Act, be treated as done or omitted by that employing authority as well as by the first-mentioned person, whether or not it was done or omitted with that employing authority's knowledge or approval."

Under section 72(5) it is a defence for an employer to prove that it took such steps as were reasonably practicable to prevent the employee from breaching the Code. Section 72(5) states:

> "In any proceedings under this Act against any employing authority in respect of anything alleged to have been done or omitted by an employee of that employing authority, it shall be a defence for that employing authority to prove that he or she or it took such steps as were reasonably practicable to prevent the employee from doing or omitting to do that thing, or from doing or omitting to do as an employee of the employing authority things of that description."

The District Health Board was the employer of Dr C, Dr D, Dr B, Ms E, Ms F, Ms G, and Ms H.

Failure by ICU medical staff to monitor Master A's medications properly
As I have found that none of the ICU medical staff breached the Code with respect to the monitoring of Master A's medications, there can be no question of finding the District Health Board vicariously liable for their actions.

Failure to detect paracetamol overdose and decline in Master A's health in a timely manner
Similarly, given my findings that the ICU medical and nursing staff did not breach the Code in failing to detect the apparent overdoses and decline in Master A's health until 26 March 2002, the question of vicarious liability for this aspect of the complaint does not arise.

Failure by ICU nursing staff to monitor Master A's medications properly
I have found that Ms E breached Rights 4(1) and 4(2) of the Code when she administered three 1g doses of paracetamol to Master A at 1100, 1500, and 1900 hours on 23 March 2002.

In my view, the District Health Board is vicariously liable for the breaches by Ms E. There are a number of steps that would have been reasonably practicable for the District Health Board to take, which may have prevented the error or, at least, reduced the likelihood of its occurrence.

One of the more significant weaknesses in the District Health Board's processes and systems was the physically separate prescription and medication administration sheets in ICU. In Master A's case, the prescription for paracetamol 250mg every four hours was entered on his *ICU Prescribing Sheet 1 Drug Chart* on 23 March. The paracetamol actually administered to Master A was recorded in a separate *Drugs and Fluid Record Chart*.

First, the separate sheets required nursing staff to transcribe the prescribed medication from one sheet to another (from the *Prescribing Sheet* to the *Drugs and Fluid Record Chart*), raising the possibility of transcription error.

Secondly, a review of the medications prescribed for a patient did not immediately reveal whether the medications had been administered as prescribed. This is one of the reasons why the apparent overdoses were not discovered until 26 March, three days after they had apparently been administered. Although ICU medical staff checked the *Prescribing Sheet Drug Chart* on which prescriptions were recorded, they did not routinely check the *Drugs and Fluid Record Chart*. It was, therefore, possible for ICU medical staff to miss a medication error, as indeed happened in this case.

Other weaknesses in the District Health Board's processes and systems in this respect included:

- failure to provide for dosages to be recorded on the *Drugs and Fluid Record Chart*;
- failure to provide a formal process for calculating and charting paediatric doses, and a place to document the calculated dose either on the *Prescribing Sheet Drug Chart* or the *Drugs and Fluid Record Chart*;
- provision of only limited access to software for calculating paediatric doses;
- a degree of complacency about the toxicity of paracetamol, leading to its exclusion from the rule for double-checking of medications.

Additionally, I have already noted Mr A's concerns regarding the discrepancies in the recording of Master A's weight and my inability to ascertain whether Master A was actually weighed or his weight estimated. This is an important issue given that the calculation of the paracetamol dose was based on weight.

The discrepancies in the recording of weight were compounded by the District Health Board's failure to provide a facility to weigh children in ICU, and the fact that there was no standard place in the prescription sheets for the recording of weight.

Accordingly, in my view, it would have been reasonably practicable for the District Health Board to ensure that:

- the standard prescription and medication sheets used in ICU provided for the dose prescribed and the amount administered to appear on the same sheet;
- there was a standard process for calculating and charting paediatric doses;
- a bed scale was available in ICU;
- there was a standard place for recording a paediatric patient's weight.

These steps may have gone some way to preventing (or reducing the likelihood of) Ms E's error occurring. In my view, in failing to take these steps, the District Health Board failed to take all reasonably practicable steps to ensure Ms E did not breach the Code. The District Health Board is therefore vicariously liable for Ms E's breaches of the Code.

The public hospital has advised me that since these events ICU has developed an ICU Medication Chart, which combines the prescribing and administration of medication sections in one area.

I have also found that Ms F breached Rights 4(1), 4(2) and 4(5) of the Code by:

- failing to alter her record of administering paracetamol to Master A at 2300 on 23 March 2002 in a manner that showed clearly the quantity of paracetamol she had administered;
- failing to report the apparent overdoses administered by Ms E on 23 March 2002.

At the time of Master A's admission, the District Health Board had in place the following policies addressing issues relating to reporting medication errors and establishing procedures for such reporting:

- *Medication Error Moratorium policy*
- *Incidents Process and Resolution policy*
- *Incidents Process and Resolution Procedures policy.*

In these policies, the District Health Board clearly articulates its requirement for staff to report incidents such as apparent overdoses using the Complaints and Incidents Management System. Ms F was aware of these policies and of the requirement for reporting incidents.

In my opinion, in instituting these policies, the District Health Board took some of the necessary steps to ensure that the apparent overdoses were reported. However, I am of the view that it could and should have instituted a formal system of handover between nurses at

the end of the shifts. This would have significantly increased the likelihood that information about the apparent overdoses would be passed on by Ms F.

My expert nursing advisor, Ms Hewson, commented:

> "I believe the circumstances … could have been managed much better if communication methods between the nursing staff in the Intensive Care Unit was improved. By this I mean the handover between nurses from one shift to the other. If there was an expected standard of transferring patient-care information between shifts, most of the issues I have commented on may not have occurred or the consequences would have been much less. …
>
> Handover between nurses should have a systematic approach to allow nursing staff to give clear, concise, and consistent transfer of care. This handover of care would [include all] details of the patient, the history, significant events and interventions to be transferred. Handover consists of, but is not limited to, a 'top to toe' systems handover, test[s] and investigation[s] completed (includes review of laboratory results), a thorough review of the ICU flow chart, looking for trends and variations. Fluid balance charts are thoroughly reviewed and the drug chart is reviewed and each drug charted is checked for when last given, when next due, that [all] drugs were signed for and if not given, question why. This last review would pick up any apparent errors at that time."

In my view, it was reasonably practicable for the District Health Board to have a formalised and systematic handover procedure in place at the time Master A was a patient in ICU, which would likely have increased the chances that information regarding the apparent overdoses would have been passed on. The failure to have such a procedure in place makes the District Health Board vicariously liable for Ms F's breaches of Rights 4(1), 4(2) and 4(5) of the Code.

Direct liability of the District Health Board — Failure to advise Mr and Mrs A of the existence of the Health and Disability Commissioner's Office and independent advocates
The District Health Board may also be found directly liable for any systemic failure in its provision of care.

Mr and Mrs A complained that ICU medical and nursing staff did not inform them of the existence of the Health and Disability Commissioner's Office (HDC) or of the independent advocates provided under the Health and Disability Commissioner Act 1994.

The District Health Board advised that in normal circumstances information about HDC and the availability of independent advocates would have been provided by its Bereavement Care Team if it had not already been provided by medical and nursing staff in ICU. It appears that as Master A died at the children's hosptial, the need to provide this information was overlooked.

I accept that Master A's death at the children's hosptial disrupted the processes (including advice about HDC and the advocates) that would normally follow. However, in the days

following his death, ICU medical staff met with Mr and Mrs A to discuss the circumstances surrounding his death. In my view, the support offered to Mr and Mrs A should have involved provision of information about HDC and the independent advocates. The Code's requirement for providers to ensure that consumers are informed of their right to complaint to HDC and to have the assistance of independent advocates means that providers should promote awareness of HDC and advocates beyond dedicated bereavement teams.

It was very clear from the public hospital's meeting with Mr and Mrs A on 28 March 2002 that Mr and Mrs A had concerns about the course of Master A's treatment between 23 and 26 March 2002. At that meeting they questioned why staff had not recognised and responded to Master A's developing problems more rapidly. They were told that their questions were reasonable and there would be an investigation. In my view, the public hospital ought to have at least checked whether Mr and Mrs A were aware of this Office and the independent health advocates at this stage. This check should have been made regardless of the fact that Master A died at the children's hosptial.

The failure to provide this information amounts to a breach of Right 10(6) of the Code.

General level of care provided to Master A
Mr and Mrs A were also concerned with the general level of care provided to Master A by the nurses in the public hospital's ICU.

Ms Hewson advised:

> "The personal care given to [Master A] and his parents was appropriate for his age and condition. The nurses seemed caring, attentive and mindful of the stress the parents were going through at this time."

Special efforts were made to ensure that Master A and his family felt as comfortable and involved in his care as possible. Ms E even provided videos from her home for Master A to watch. Her willingness to go the extra mile for Master A is commendable.

I accept Ms Hewson's advice that Master A's general care was of an appropriate standard and accordingly find that the District Health Board did not breach the Code in this respect.

Other Comment

Laboratory testing at the public hospital and results sheet
Following Master A's death, the public hospital conducted a sentinel event review of the circumstances surrounding Master A's care. This was undertaken by Dr N, the Clinical Director at the public hospital. One of the issues he examined related to the system for relaying and reporting laboratory results, which highlighted some systems deficiencies.

The process involved several steps:

"• The nursing or medical staff ordered routine bloods usually at 6am and 6pm so that the results were available at ward rounds.
- The medical team on their twice-daily ward rounds (9am and 9pm) ordered any other blood tests.
- Usually the nurse, but sometimes the registrar or consultant, would check the results on the computer — this is distant from the patient.
- Whoever checked the results logged on [to the ICU computer] as the Clinical Director and this person's name appeared on the computer as having 'signed-off' the results.
- The results were then handwritten on to a results sheet with no discrimination between those that were abnormal [and] those that were normal.
- The times that the laboratory received the test was documented but not the time that ICU staff retrieved the result, and not who retrieved it.
- This results sheet was taken to the patient's bedside.
- Abnormal results were identified and these were generally conveyed to the Registrar if they were in the unit, or noted at the ward rounds. Abnormal results were not highlighted on the results sheet.
- The results sheet was double sided and results continued 'over the page'."

Dr N noted that the format of the Laboratory Results sheet at the time of Master A's admission had a number of deficiencies, as follows:

1. The Laboratory Results sheet did not provide any means of highlighting abnormal results. On the computer screen abnormal results appear in red and flashing and the normal range is shown in brackets beside abnormal results. This means that the nurse transcribing the results from the computer will be alerted to abnormal results. There was nothing to highlight abnormal results to the ICU medical staff on the Laboratory Results sheet itself.

2. Laboratory results were recorded against the time at which blood samples were received by the laboratory. There was no provision for the nurse to record the time at which the results were transcribed. In the event of a complaint or investigation, information as to the time at which the results were transcribed are an important part of reconstructing a patient's care and determining whether changes in a patient's clinical status were responded to in a timely manner.

The District Health Board has advised me that laboratory results are no longer transcribed by hand from the computer but are printed out in colour (with abnormal results appearing in red). All ICU staff have been given individual computer log-ons so that there is individual accountability for responding to abnormal laboratory results. The risk of laboratory results being incorrectly transcribed has therefore been eliminated and the likelihood of abnormal results being overlooked has been reduced by the use of the colour printer.

Nurses have also been reminded that they are responsible for highlighting any abnormal laboratory results with medical staff.

In his response to the provisional opinion, Mr A stated:

> "[Dr N's] report … exposes several errors that took place during our son's stay in Intensive Care. One does not drastically change regulations unless errors have been established. That report is an admission of the human failures of the medical team in charge of [Master A] from March 23 to 25. It is not on to use the death of a child as an argument to improve the level of care in the ICU Dept and at the same time to admit that professional mistakes happened in the department."

While appreciating Mr and Mrs A's pain at the fact that their son's death has been the catalyst for systems' improvements at the public hospital, in my view it was entirely appropriate for the District Health Board to undertake a detailed review of the circumstances of Master A's deterioration and death and to address the shortcomings identified in the review. I hope that Mr and Mrs A can take a small measure of comfort from the fact that the changes implemented are likely to improve patient safety in the future.

Recommendations

1. I recommend that the public hospital:

   - Formulate guidelines for nursing handovers in ICU providing for a standardised programme of handover between nurses covering:

     – systems;
     – tests and investigations completed and awaited;
     – review of the ICU flow charts and other patient records by incoming nurses;
     – checks of fluid balance and drug charts, including the time drugs were last given, when they are next due, and dosages.

   - Include these guidelines in the orientation programme offered to nurses new to ICU and provide copies of them to bureau nurses.

   - Apologise to Mr and Mrs A for its breaches of the Code. The apology is to be sent to my Office for forwarding to Mr and Mrs A.

   - Circulate a summary of the generic issues and findings noted as a result of its sentinel event investigation to all hospitals with Intensive Care Units in New Zealand.

2. I recommend that Ms E, Ms F, Ms G and Ms H review their practice in light of this report.

3. I recommend that Ms E apologise to Mr and Mrs A for her breaches of the Code. The apology is to be sent to my Office for forwarding to Mr and Mrs A.

4. I recommend that Ms F:

    - apologise to Mr and Mrs A for her breaches of the Code. The apology is to be sent to my Office for forwarding to Mr and Mrs A ;
    - undertake a continuing education programme approved by the Nursing Council.

Follow-up actions

- This matter will be referred to the Director of Proceedings in accordance with section 45(f) of the Health and Disability Commissioner Act 1994 for the purpose of deciding whether any proceedings should be taken against Ms E and Ms F.

- A copy of my final report will be sent to the Medical Council, the Nursing Council and the Auckland Coroner.

- A copy of my final report, with details identifying the parties removed, will be sent to all New Zealand hospitals with intensive care departments.

- A copy of my final report, with details identifying the parties removed, will be sent to the College of Nurses (Aotearoa) Inc, the New Zealand Nurses Organisation, the Joint Faculty of Intensive Care Medicine, the Royal Australasian College of Physicians and the Australia and New Zealand College of Anaesthetists, and placed on the Health and Disability Commissioner's website, www.hdc.org.nz, for educational purposes, upon completion of the Director of Proceedings' process.

Referral to Director of Proceedings

A number of individual and systemic failures contributed to the shortcomings in the care Master A received. In my view the systemic failures, well documented in the District Health Board Sentinel Events Report, were primary contributory factors. However, these failures have since been addressed by the District Health Board which has made a diligent effort to meet the recommendations of Dr N's report. I see no public interest in referring the Board to the Director of Proceedings for possible Human Rights Review Tribunal proceedings.

Names have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

Ms E and Ms F have both been found in breach of the Code for conduct that in my view warrants referral to the Director of Proceedings for possible consideration of professional disciplinary proceedings.

Addendum

The Director of Proceedings issued proceedings before the Health Practitioners Disciplinary Tribunal and, at a hearing on 3 April 2006, a charge of professional misconduct was upheld against the two nurses. The Tribunal determined that, while not all instances of erroneous medication by nurses necessarily constitute professional misconduct, in this case Ms E's actions amounted to professional misconduct because she had administered the wrong dose on three separate occasions and because all competent nurses should be aware that 1g of paracetamol would be an excessive dose for a young child. Ms E was censured, but no other orders were made. Ms F's lack of response when she discovered that the child had probably received three overdoses of paracetamol amounted to professional misconduct. Ms F should have alerted other health professionals, recorded her finding in the patient's clinical notes, and reported the incident via the hospital's procedure for notifying medication error. The Tribunal held that Ms F's failure to respond strongly indicated a lack of fundamental nursing skills. It ordered that should Ms F return to New Zealand, she practise under supervision for six months, at the end of which period the Nursing Council assess her competence. The Tribunal also ordered Ms F to contribute $5,000 towards the costs of the hearing and prosecution.

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Appendix 1

The District Health Board *Medication Error Moratorium*

The sections of the policy relevant to this investigation are:

*"**Roles and responsibilities …***
If an error should occur, the overall objective is that the patient receives the required corrective care, systems are reviewed and the staff are supported and educated to prevent reoccurrence.

Definition
A medication error involves incorrect:

- *Dispensing*
- *Prescribing*
- *Calculation*
- *Administration of a medication.*

Action
Where an error occurs:

	Action
1	*An incident must be reported, either via CIMS or completing an incident form. …*
2	*Each situation is considered on an individual basis with the health professional involved having the opportunity to discuss the circumstances leading to the error.*
3	*As for any clinical incident, circumstances are taken into account before corrective action is taken. This is decided by the Group Manager, Clinical Director, Head of Department and Director of Nursing or Midwifery Practice.*
4	*The incident will, where appropriate, lead to education, counseling and support of the staff members involved.*
5	*For repeated incidents involving the same staff member, restriction of supervision of practice may be instituted.*
6	*Staff involved in such incidents may be subjected to censure by outside authorities, such as their professional bodies or the Health and Disability Commissioner, if these bodies consider that they are culpably negligent.*

The District Health Board *Incident Process and Resolution Policy*

The sections of the policy relevant to this investigation are:

"***Policy Statements …***

4 The staff member observing or involved in an Incident is responsible for taking any immediate or appropriate action to manage that Incident or contain a situation. This staff member must also complete an Incident and Complaint Form. For Incidents relating to Patients please complete the Complaints and Incident Form and for Incidents relating to staff please complete a Staff Incident Form.

Definitions

Incident (Reportable Events)

Term	***Definition***
Incident	*Any occurrence which has given or may give rise to actual or potential personal or patient injury, property damage/loss, hazard in the workplace, contravenes [DHB] policy, protocol or procedures or anything out of the ordinary which could cause harm.*
Major Incident	*Anything that is an actual or potential cause or source of serious harm or death.*
Minor Incident	*Anything that is not a major*
Open incident	*An open incident is one that has been received into the organization and is unresolved.*
Resolved/closed incident	*An incident is considered to be resolved/closed where the General Manager has liaised with the reporter as needed, completed its investigation, and informed the reporter of actions that ha[ve] or will be taken to address the issues raised.*
CIMS	*Complaints and Incidents Management System*

Incident Categories

Harm Incidents (Adverse Events)
A Harm Incident is one that created an adverse outcome for the patient that may be minor or more serious depending on the event and not related to the natural course of the consumer's illness or underlying condition.

Harm incidents often occur under the following circumstances:
- *A system failure resulting in a reduction in the quality of service*

- *Signification deviation from the organisation's usual process*

Sentinel Events
A Sentinel Event is an undesired event that signals that something serious has occurred and warrants in-depth investigation.

The characteristics of a sentinel event include:
- *Major system failure*
- *Multiple teams, departments or services are involved*
- *The potential for serious adverse media attention*
- *The potential to seriously undermine public confidence …*

Categorisation
All incidents will be categorized according to severity and type.
Severity includes major, minor, harm and sentinel events:

Incident Categorisation	***Examples***
Documentation Error	*… Incorrectly filled out form*
Medication error	*See next page*
Others	*This list is not exhaustive and is at the discretion of the Clinical Director and General Manager.*

Suggestions for Classifications of Medication Errors

CIMS [Complaints and Incidents Management System] will automatically default any reports of medication error to MAJOR."

The District Health Board *Incident Process and Resolution Procedures*

The sections of the policy relevant to this investigation are:

"Completion of Complaint and Incident Form or Staff Incident Form

> *When an incident occurs either a Complaint and Incident or a Staff Incident Form is to be completed by the staff member involved and then given promptly to the immediate manager/supervisor.*
>
> ***Persons required to complete a Complaint and Incident Form***
>
> *1 The employee who first becomes aware of the incident*
> *2 The employee most involved in the incident*
> *3 The employee to whom an incident is reported (if a form is not already completed). …*

The reporter is required to provide information to describe the incident to managers. …

Informing patients

1 Consumers/patients are to be informed if an incident affects their care and treatment and the incident must be documented in their personal clinical record.
2 …
3 When a consumer/patient is unable to comprehend some/all of the information provided about the incident, where practical, the consumer/patient representative is informed. …"

Names have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

Appendix 2

Response from Mr A to Provisional Opinion

Mr A provided a lengthy response to the provisional opinion. However, much of it comprised a list of Master A's clinical records. An excerpt from Mr A's response appears below:

" … In the aftermath of the events, many questions remain unanswered:

1) Why was N-Acetylcisteine not administered (to counteract the toxic and or deadliness of Paracetamol/Panadol) to our child in [the public hospital] (ICU & [the children's ward]) but in [the children's hospital] after the assessment of his condition?

…

2) Why were we not informed of the different problems faced by our child in the Operating Room during the procedures of 17, 18, 19 and 20/03/02?

3) Why, on 25/03/02 at 16:00H., Paracetamol has been withdrawn from the drug prescription list and liver function tests were requested?

4) Why, although Paracetamol was stopped and liver function tests requested, no serious and systematic monitoring of our son has been ordered?

5) Why move our child from ICU to [the children's ward] on 21/03/02 if his general condition did not allow it?

6) Was the shortage of nursing staff at [the children's ward] the only reason our child was returned to ICU?

7) Absence of X-rays, urine and faeces tests?

8) Why has Paracetamol been discontinued between 18/03 and 20/03?

9) Why was Paracetamol discontinued on 25/03 at 16:00H., after liver function tests were requested but before the results were back? And, if the result was positive, why was the observation not increased and instrumental monitoring not performed to allow our child a fighting chance during the last nights of hospital stay?

…

10) Why was Paracetamol not discontinued on 23/03 as a result of the medical examination of 23/03/02 showing an adverse reaction to Paracetamol?

…

Names have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

11) Why has Paracetamol not been discontinued or the doses decreased following the medical laboratory results on 23/03 — 24/03 — 25/03 who had evidenced worrying reactions to Paracetamol overdose?

…

12) Why no nurse, doctor, head of department, registrar, paediatrician has responded to the critical condition of my child, when all the technical and medical elements were pointing to the seriousness of his condition?

…

And to think it was a real parade during all of his stay in ICU.

13) How, on the morning of 26/03/02, was [the public hospital] able to get in touch with the good consultants [the children's hospital] and transfer the child at such short notice?

XIV Conclusions

- Inadequate competence or lack of it
- Training and lectures to the Students and house doctors using our child during his hospital stay
- No initiative taken about Paracetamol overdose
- No reaction whatsoever to our child's condition, despite repeated medical investigations and the physical evidence of danger.
- No thorough control (ie. hepatic) after Paracetamol prescription
- Serious medical diagnostic error, causing our child's death.
- Repeated serious professional errors from the nursing staff.
- Negligence, obvious lack of professional behaviour, very little sense of duty.
- Negligence in the way our child's medical files were kept.

We are demanding:

Penal sanctions: If concealment, before or after our child's death, of documents proving the various medical errors, can be proven.

Professional sanctions: If medical and professional errors (monitoring, reactions) can be proven.

Financial sanctions for:

Moral wrong:
- Loss of our child
- Witness the healing, then the agony and death of our child, without being given a chance to help him or even to understand why he died.

- The lies, dissimulations or total silence of the nursing staff about the seriousness of [Master A's] condition.

Professional damage:
- My wife teaches 3–4 year old children and has only been able to resume her work at the start of the school year in August 2003 with older children.

Physical damage:
- We are forever bruised and marked in our very flesh
- We are psychologically wounded

Financial damage:
- Funeral costs
- Legal expenses
- Travel expenses […]
- Travel expenses […]
- Hotel bills

…"

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Appendix 3

Recommendations from Dr N's Sentinel Event Review

The recommendations relevant to this investigation, and the actions taken by [the public hospital] by November 2004, are:

Medication Prescribing and Administration in ICU

Recommendation	Action
1. Medication forms to be redesigned to incorporate prescribing and administration components	ICU Medication Chart developed combining prescribing and administration sections. Further refinements to chart likely.
2. Way in which other ICUs manage problem of frequent doses to be investigated	
3. Medication forms to be redesigned to allow space for calculation of doses based on weight.	Medication Chart altered to include paediatric dosing requirements.
4. Place on form for recording weight to be specified.	Medication Chart altered to include paediatric dosing requirements.
5. Bed scale or other weighing device suitable for children to be obtained for ICU.	Paediatric scales have been purchased.
6. Organisational commitment to be sought to improving access to software for paediatric medication calculations.	
7. Increase involvement of clinical pharmacists.	
8. Place of electronic prescribing in ICU setting to be investigated.	
9. Education on Board policy of double checking medications to be provided.	Charge Nurse has reminded all ICU nurses of policy requirements for double checking and ensured that all new staff are orientated appropriately.
10. Clinical Board policy re paracetamol to be reviewed, especially with respect to toxicity in the very young and others who may be susceptible, and education to be given to all clinical staff.	November 2004 pharmacy bulletin focussed on paracetamol poisoning. Danger of paracetamol poisoning presented at Medicine Quality Meeting.

Laboratory results

1. Decrease reliance on hand transcribed laboratory results to avoid transcription errors.	Laboratory results computer programme amended to incorporate ICU changes. Transcription of results no longer necessary. Colour printer obtained to assist with visibility of abnormal results which are indicated in red on computer screen.
2. Define explicitly the roles of medical and nursing staff in relation to transcription and recognition of abnormal results. Provide training for nurses if nurses to be charged with recognising and relaying abnormal results.	ICU associate charge nurses reminded that individual nurses who review laboratory results are responsible for highlighting abnormal results with doctors. Nurse in charge of shift is responsible for ensuring that this has occurred.
3. Review policy re laboratory staff advising abnormal results by telephone.	Policy of laboratory telephoning abnormal results clarified and confirmed with laboratory.

Paediatric ICU competency

1. Rebuild relationship with the children's hospital Paediatric Intensive Care Unit and utilise to upskill nursing and Senior Medical Officer expertise through rotations through [Paediatric Intensive Care Unit].	Senior Medical Officers and nurses are rotating through [Paediatric Intensive Care Unit] and time in [Paediatric Intensive Care Unit] is included routinely in orientation programmes for new staff. Closer relationship with [Paediatric Intensive Care Unit] and involvement of ICU staff in treating small infants with bronchiolitis has given ICU team a greater degree of comfort in treating paediatric ICU cases.
Formalise involvement of [the public hospital] paediatricians in care of ICU paediatric cases.	Paediatricians are more involved in patient care. Government approval has been given for National Burns Unit at the public hospital. Roles and responsibilities of Plastic Surgery, Paediatric and ICU areas will be defined as part of the establishment of the National Burns Unit.

Language and cultural barriers

Clearly define role of interpreter with particular regard to reporting of queries made by patients and families and provision of cultural support to [families	Interpreting service has been advised of issues.

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from overseas].

Adverse event reporting

1. Education regarding incident reporting, and particularly reporting medication errors.
2. ICU to develop ICU specific event form.
3. ICU to create its own database of ICU errors.

ICU has established its own adverse event review process which is successfully highlighting areas for improvement or change.