Opinion - Case 98HDC17069/VC

Complaint	 Mr and Mrs A complained to the Commissioner concerning the treatment provided to their son, Master A, by Dr B, Staff Nurse (SN) C, Staff Nurse (SN) D and a Public Hospital. The complaint is that: On 21 April 1998 staff at the Public Hospital did not provide services of an appropriate standard to Master A during the administration of a charcoal substance to absorb Pamol. Further to this, the complaint is that Mr and Mrs A were not informed of the risks of the procedure prior to it being carried out on Master A. 	
Investigation Process	The complaint was received by the Commissioner on 14 August 1998 An investigation was commenced on 8 November 1998. Information was obtained from:	
	reviewed. Police	Parents / Complainants Accident and Emergency Medical Officer / Provider Staff Nurse / Provider Chief Medical Officer / Public Hospital Legal advisor, New Zealand Nurses Organisation Chief Executive Officer, Public Hospital elating to the treatment of Master A were obtained and files and a Coroner's report were also considered. The ught advice from an independent emergency medicine

specialist and, upon receipt of responses to the provisional opinion,

sought further advice from an independent nursing specialist.

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Opinion – Case 98HDC17069/VC, continued

Information
GatheredA few days prior to 21 April 1998 Master A, aged two years, four months,
had been unwell and was prescribed 250mg/5ml Pamol by a city general
practitioner. The Pamol was dispensed in a 500ml bottle with a child-
proof cap. During the night of 20/21 April 1998 Master A vomited in
bed. His parents, Mr and Mrs A, gave Master A 5mls of Pamol and put
him back to bed.

At around 7.30am on 21 April 1998 Mrs A found Master A in the kitchen pouring Pamol into a spoon. There was Pamol on the bench, floor, around his mouth and in the spoon. Mr A stated to the Commissioner that two "Handy" paper towels were required to remove excess Pamol from around Master A.

Master A appeared normal and his parents had no immediate concerns for him. After a brief discussion Mr and Mrs A rang the National Poisons Centre.

The Poisons Centre questioned and determined that approximately 125ml of Pamol was missing from the bottle. Given that Master A weighed 16kg the Poisons Centre calculated that he would only need to have swallowed 32mls for there to be a problem. Mr and Mrs A were therefore advised to take Master A to the Emergency Department at the Public Hospital.

The Poisons Centre Treatment Guideline (and the Public Hospital protocol) states:

"Ingested dose < 125mg/kg or if dose unknown:

- Administer single dose activated charcoal if Paracetamol liquid or tablets ingested within 2 or 4 hours respectively.
- Determine blood to Paracetamol levels (at 4 hours according to the Roumac–Matthew nomogram for single acute Paracetamol poisoning).
- If blood Paracetamol level above treatment line, commence N-Acetyl Cysteine (NAC).
- *Emergency Measures:*
- 1) Stabilisation support respiratory and cardio vascular function;
- 2) Decontamination emesis and lavage not recommended.

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Opinion – Case 98HDC17069/VC, continued

Information Gathered During Investigation *continued* 3) Activated charcoal: single dose activated charcoal is the recommended gastrointestinal decontamination procedure: Single dose regimen: Adult 50-100gms; Child 1-2gms per kg. The majority of children will tolerate an oral dose of activated charcoal if given in an encouraging and positive manner, preferably in the presence of a parent/caregiver. For the few children refusing an oral dose, administration using a nasogastric tube should be undertaken."

The family arrived at the Public Hospital Emergency Department at about 8.00am and were met by Staff Nurse C. SN C determined Master A may have had up to 125ml of Pamol and weighed 14kg. SN D joined SN C and the two nurses conferred and concluded that treatment was required and that a medical officer should be consulted.

SN C consulted the Poisons Folder and found the Public Hospital Protocol entitled "Gastrointestinal Decontamination (Children)". SN D and SN C determined that their treatment plan was for activated charcoal orally at a dose of 1-2mg/kg (120ml of the 50g/300ml preparation).

Dr B, Accident and Emergency Medical Officer, was summoned and SN C passed on the information that had been collected. Dr B re-calculated the figures calculated by SN D and SN C and decided that 120ml of a standard solution of activated charcoal in sterile water needed to be administered as treatment. Dr B and SN C agreed they would attempt to administer this orally and if this failed to deliver it through a nasogastric tube.

Dr B, in his Coroner's deposition, stated that:

"Satisfied that situation was being appropriately handled, I left the nurses to try to persuade [Master A] (with his parents) to drink the charcoal and did not go in to meet them. I hoped that the nurses and parents would be successful in persuading [Master A] to drink what is an unpleasant mixture."

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Opinion – Case 98HDC17069/VC, continued

Information Gathered During Investigation <i>continued</i>	Master A was initially encouraged by the nursing staff to ingest the solution orally. Master A drank a small quantity but refused to drink any more. SN C consulted Dr B and SN D and a decision was made to administer the substance through a nasogastric tube.		
	Dr B observed that of the 120ml charcoal previously prepared approximately 20ml was missing from the cup. In his Coroner's deposition, Dr B stated:		

"I went in and introduced myself to [Master A's] parents and [Master A]. I confirmed from them that the information given to me by the nurses, particularly regarding the quantity of Pamol consumed. I explained why we needed to insert a nasogastric tube."

At the Coroner's inquest held during November 1998 Dr B was subject to cross-examination by the Coroner. During this cross-examination Dr B stated:

- "Coroner At the time you had that discussion did you have any perception that the process of introducing carbon into [Master A's] body by tube was itself risky?
- Dr [B] I knew there were some risks involved as in any medical procedure. But I honestly thought they were very low.
- Coroner What did you see the risks as being then?
- Dr [B] I didn't have any numbers in my head. I just thought it was very low and I recall I may have mentioned this to Mr and Mrs A that it is quite a common procedure in hospitals for giving charcoal like this and also in newborn units and maternity units for giving milk to babies who are having trouble sucking or drinking or whatever.

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Opinion – Case 98HDC17069/VC, continued

Information Gathered During	Coroner	<i>Did you in your mind address the risks of aspiration?</i>
Investigation continued	Dr [B]	No can
commutu	Coroner	<i>Did you address in your mind the risks of aspiration?</i>
	Dr [B]	That's also in your mind that is why you make sure the tube is in the right position when you do the procedure.
	Coroner	<i>What about the risks of aspiration from regurgitation?</i>
	Dr [B]	I don't remember thinking specifically about that, This is on my recollection of 6 and a half months ago.
	Coroner	Had you known that as a risk of the procedure?
	Dr [B]	Yes.
	Coroner	When you were addressing the risks that [Master A] was then exposed to, is it fair to say that you put greater weight on the risk that he was exposed to from the paracetamol than you put on the risks that he was exposed to from the procedures you were about to undertake?
	Dr [B]	Yes if I really felt the risk of the charcoal was that much higher I wouldn't have done it.
	Coroner	Did you give the parents any comment on the risks of the procedure?

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Opinion – Case 98HDC17069/VC, continued

Information Gathered During Investigation <i>continued</i>	Dr [B]	No, and in retrospect I wish I had balanced the risk of the procedure with the risk from paracetamol accidental ingestion and really helped them to make the decision. I guess I was driven by the way we treat paracetamol accidental poisoning from a variety of sources. I meant medical information.
	Coroner	If [Master A] had not had the charcoal solution administered to him, what did you perceive may have happened?
	Dr [B]	What we would have done and what I was going to do had not this terrible business have happened would have been to put some anaesthetic cream over a vein and get his parents to take him away and bring him back over 4 hours and take a blood level. I mean 4 hours post ingestion from 7.30 am. Then we would have acted on the paracetamol blood level to the standard curve that is available (graph) from a number of sources and seeing if treatment was necessary with the antidote. The antidote being NAC [N-Acetyl Cysteine].
	Coroner	Did you have NAC in the hospital and available?
	Dr [B]	We keep it in the cupboard next to the charcoal with the few other antidotes we have for other chemicals."
	Coroner	Did the parents authorise the procedure or did you just assume it was authorised and carried on?
	Dr [B]	we had that brief conversation I guess it was one of those situations which happen often in this job where there is no formal agreement but I felt there was the intent to continue.

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Opinion – Case 98HDC17069/VC, continued

Information Gathered	SN D in her Coroner's deposition recalls:			
During Investigation continued	"Dr [B] came in during this time. I remember Dr [B] saying we'll give the child some charcoal."			
commute	Master A was positioned horizontally across a hospital bed. SN C and SN D wrapped Master A in a blanket to restrain his arms. SN C held Master A's head and SN D held his body. Mr A assisted with holding Master A still.			
	Having estimated the length of the tube needing to be inserted by measuring it against Master A, Dr B passed the nasogastric tube via Master A's left nostril. According to Dr B the tube was fed to the length pre-determined with ease and on the first attempt. Dr B in his Coroner's deposition stated:			
	"I checked [Master A's] mouth to ensure the tube had not come out of his mouth as can sometimes happen. His mouth was clear. I then checked the position of the tube."			
	Dr B attached a 50ml syringe to the nasal end of the nasogastric tube and attempted to aspirate gastric secretions to determine that the tube was placed in the stomach. However, this was unsuccessful, as he could not withdraw any gastric contents to enable him to perform a litmus test.			
	Dr B stated that he passed his stethoscope under the blanket and listened over Master A's epigastrium while injecting some air into the tube. Mr A stated to the Commissioner that he could not recall Dr B using a stethoscope and advised that Master A was wearing three layers of clothing, which Dr B did not remove during the procedure. Dr B was noted by all present to indicate that he was satisfied that the tube was in the stomach following this manoeuvre. Dr B states in his Coroner's deposition:			
	"I listened as air was pushed into the tube by the syringe and I was able to satisfy myself that there was a temporal (time) relationship between the expected sound that I was hearing over			

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administration of air via the syringe."

the epigastrium [upper central region of the abdomen] and the

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Opinion – Case 98HDC17069/VC, continued

SN D in her Coroner's deposition recalls: Information Gathered During "Dr [B] put the stethoscope down the 'cuddly' to listen to the Investigation stomach while he inserted air down the tube. He told us he was continued happy that it was in the stomach and started to put charcoal into the syringe. The child wriggled and at some point put his hand out which I re-wrapped." Dr B then loaded the syringe with half the charcoal needing to be installed and injected this via the nasogastric tube. The nursing staff reported that Master A was not coughing, gagging or vomiting at this time. However, he was noted to be moving and "grinding his teeth". The second syringe full was delivered in a similar manner, the procedure taking about 30 seconds. SN D in her Coroner's deposition recalls: "I tried to comfort Dad who was obviously distressed. He let go of the child and stood back a little. I held the child. Dr [B] said 'Turn him towards me on his side'. The child ground his teeth." SN C in his deposition recalls: "At some time during the procedure Dr [B] asked us to put the child on his side and we did keeping the child restrained. The child didn't look abnormally distressed. When Dr [B] had finished he pulled the nasogastric tube out. Dr [B] then withdrew the nasogastric tube and lifted [Master A] off the stretcher, handing him to SN [D] who held him only shortly before handing on to his father to hold." At this point Master A began to make gasping sounds. Mr A noted that Master A was pale and not breathing and notified SN D. SN D also noted that Master A had evidence of circumoral cyanosis (turning blue around the mouth). *Continued on next page*

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Opinion – Case 98HDC17069/VC, continued

Information Gathered	SN D took Master A from his father and informed the team that there was a problem. They went to the resuscitation room and immediately began to
During Investigation	initiate resuscitation, including a team call out.
continued	Dr B states in his Coroner's deposition:

"I also noted there was no charcoal around his nose or mouth. [Master A] was placed on the bench. He started to cough and splutter. It was at this point charcoal began to emerge from his nose and mouth."

At this point, Master A was noted by Dr B to have an oropharynx (middle portion of the throat) full of charcoal solution that was running up from his oesophagus and apparently obstructing his airway.

Dr B attempted to establish a direct airway but was unable to do so due to the charcoal obstructing his pressing of Master A's airway. Dr B continued to aspirate charcoal from Master A's oropharynx in an attempt to clear his airway.

On arrival, the resuscitation team noted that Master A was in profound bradycardia (slowing of the heartbeat), was not spontaneously ventilating and was deeply unconscious. In his deposition to the Coroner a doctor recalled:

"I found the pharynx flooded with black material which I attempted to suck out and despite my assistants providing cricoid pressure [pressure on the cartilage which forms part of the larynx], material continued to come up into the pharynx. Although I could see the epiglottis I couldn't see the vocal cords and I asked [the anaesthetist] to be called to assist."

The Charge Nurse recalled:

"I returned to the Resus Room to gain an overview of the situation. Dr [B], whose resuscitation role had been taken over by the anaesthetist and paediatrician, indicated that he needed to go and inform the parents of what was happening. I accompanied Dr [B] to see the parents and inform them of the gravity of the situation."

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Opinion – Case 98HDC17069/VC, continued

Information	The anaesthetist was able to establish an airway by successful intubation.		
Gathered	He found charcoal to be present within the trachea (windpipe). In his		
During	Coroner's deposition, the anaesthetist recalled:		
Investigation continued	"I immediately attempted to intubate the trachea. This was impossible as the laryngeopharynx was full of charcoal mixture and the anatomy was obscured. I suctioned the fluid but it continued to well up from the oesophagus (no doubt caused by the continued external cardiac massage). The cords were abducted (open) and the larynx was clearly soiled with charcoal."		

He further recalled:

"I experienced extreme difficulty forcing air into the lungs. I introduced a suction catheter via the endotracheal tube [tube inserted into the windpipe] and aspirated charcoal mixture from the trachea. I then introduced the large bore nasogastric tube into the stomach and aspirated air and charcoal."

During the resuscitation attempt Dr B spoke to Mr and Mrs A, informed them that the situation was grave and stated he did not know what had gone wrong. Dr B then departed the hospital.

Following the resuscitation effort by the team of more than 40 minutes and given the fact that Master A was noted to be in a dying heart rhythm (i.e. broad complex bradycardia) the efforts were stopped and Master A was pronounced dead at 9.10am. At this point the nursing staff, who were in significant distress, were permitted by the charge nurse to go home.

Dr B, SN C and SN D returned to the Hospital later that day. SN C signed the notes he had taken that morning while Dr B and SN D completed their notes of the morning's events. The notes completed by Dr B and SN D were not annotated as being recorded after the event.

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Opinion – Case 98HDC17069/VC, continued

Coroner's Report	The Coroner held a Coroner's inquest on 3, 4 and 27 November 1998 releasing his report on 4 February 1999. The Coroner's conclusion was that: "The short finding which is required to be made is that [Master A] who was born on 26 November 1995 and whose home was at [] died at [the Public] Hospital on 21 April 1998. The cause of his death was accidental aspiration of a charcoal solution into his trachea and lungs when such solution was being administered through a naso gastric tube at the Accident and Emergency Department at [the Public] Hospital to counteract suspected accidental Paracetamol poisoning which had occurred at home."	
	The Coroner in the body of his report also found:	
	23 "There is a delay (which will be referred to later) in Paracetamol levels in blood peaking. Taking into account that delay Ms [] [a forensic scientist who provided an analysis of Master A's blood after his death] conclusion was that while the concentration of Paracetamol in the blood of [Master A] was higher than was normally to be expected in a therapeutic dose it was not as high as would be expected in a fatal overdose. [The	

expected in a therapeutic dose it was not as high as would be expected in a fatal overdose. [The paediatrician/emergency physician expert witness at the Coroner's inquest] (whose evidence will be referred to later) was of the view that the dose which [Master A] had taken would have caused him no harm whatsoever."

32 "The reality is that Doctor [B] in setting out to administer the charcoal solution by naso gastric tube was acting entirely in accordance with the then appropriate conventional practice. The then conventional belief was that the practice was reasonably safe. Given the uncertainty about the amount of Paracetamol consumed and given the then protocols, it was reasonable for Doctor [B] to proceed as he did."

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Opinion – Case 98HDC17069/VC, continued

Coroner's Report continued	41	"I am satisfied that Doctor [B] did test the position of the terminal end of the tube by introducing air. I have reached this conclusion having regard to the evidence of Doctor [B] and Staff Nurses [C] and [D] each of whom said that this happened. Mr [A] also saw something which was consistent with this having happened in that he said that he saw the Doctor put his hand down to feel [Master A's] stomach and then make some reassuring comment. I am further satisfied that on the basis of what he heard Doctor [B] believed that the tube was correctly in position. The air expulsion method of determining the placement of the terminal end of the tube was in my view a reasonable test for Doctor [B] to use having regard to the then knowledge."
	50	"Having carefully considered all of the evidence,

- 50 "Having carefully considered all of the evidence, unsatisfactory although some of it is, I have reached the conclusion that it is more probable that the tube was correctly placed."
- 51 "I therefore find, although it is not free from doubt, it is more probable that the charcoal solution which entered [Master A's] larynx and blocked his trachea had been delivered into his stomach, had left his stomach, had passed up his oesophagus and had then been drawn into his larynx, trachea and lungs."

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Opinion – Case 98HDC17069/VC, continued

Coroner's Report <i>continued</i>	57	"It seems possible that the nature of the treatment itself, the horizontal position of [Master A] and the unnatural presence of a tube in his oesophagus and at the entry to his stomach could have been factors in the loss of stomach contents into his oesophagus and the draining of those stomach contents into his larynx."
	60	"It seems apparent that the various restraints to which [Master A] was subject had the effect of suppressing or disguising the physical reactions of [Master A] to having the charcoal solution enter his air passages. The evidence in its totality points to the aspiration having occurred during the treatment and not during the period in time when [Master A] had been handed back to and was being held by his father."

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Opinion – Case 98HDC17069/VC, continued

Advice	Mr and Mrs A provided the Commissioner with	a copy of advice they had
obtained by Mr and Mrs A	obtained from a medically qualified lawyer. lawyer stated:	The medically qualified

"... I guess if there was no procedure he would still be alive.' This statement of [Master A's] father at the inquest (p 11,4,5), referring to the insertion of a nasogastric tube and the instillation of activated charcoal via this tube, summarizes the precipitating event which led to the death of his child.

We know that a nasogastric tube was inserted. We do not know what the passage of the tube was after it entered the nose; whether it entered the oesophagus or the trachea. This is a matter of speculation and all the theories of how charcoal came to enter the lungs are also the product of speculation. We know that, at autopsy, charcoal was found in the stomach and duodenum and in both lungs extending into the 'terminal bronchioles' and 'the peripheral and subpleural lung'. (Statement of [the] Pathologist, [...].)

The decision by Dr [B] to insert a nasogastric tube in order to instil activated charcoal was based solely on it being standard procedure according to guidelines at that time for the treatment of accidental ingestion of Paracetamol by children. It cannot be emphasised too strongly that the repeated assertion of reliance upon such guidelines and this procedure as 'standard' are the foundation upon which its justification is laid. In reply to this, the question that must be asked is: do guidelines protect a doctor against exercising a reasonable standard of care?

Should the facts of each case not be considered on their merits? The disclaimer on the database of the NZ Poisons & Hazardous Chemical Information Centre states: '... each user should review the information in specific context of the intended application'. Although neither Dr [B] nor the nurses at [the Public] Hospital's emergency department contacted the Poisons Centre for the latest information at the time of [Master A's] admission, it nevertheless acts as a clear indication that guidelines alone are not considered to be sufficient reason to act upon them in the absence of consideration of the facts of each case.

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Opinion – Case 98HDC17069/VC, continued

Advice obtained by Mr and Mrs A continued A medical student or house-surgeon, both only permitted to work under supervision of qualified medical practitioners, may be expected to follow protocol or guidelines without question. A qualified doctor is expected to use judgement and use protocols only as guidelines and not as gospel, to assess each case on its facts, to weigh risk and benefit, to withhold from doing something if doing nothing would be less likely to cause harm – primum non nocere. This is what may be reasonably expected to arise from the duty of care owed by a doctor to a patient.

Do doctors' compliance with practice guidelines create an impenetrable shield against legal liability? If they follow recognised guidelines to the letter, does this excuse negligence?

Does this excuse failure to reasonably foresee dangers and not act on this foresight or refrain from acting, if this be the appropriate course? Do these guidelines conspire to defeat the duty of care that contractually arises from a medical professional's offer to help and a patient's consent to this help? Are they to be seen as an acceptable defence against reasonableness of action? Do they replace or substitute for reasonable action? Do they, in fact, represent the standard of care reasonably required?

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Opinion – Case 98HDC17069/VC, continued

Advice obtained by Mr and Mrs A continued 'I guess I was driven by the way we treat paracetamol accidental poisoning from a variety of sources.' This statement by Dr [B] during the inquest (p 81, 8-10) illustrates my point that he was relying blindly and without question or professional critical appraisal on what he believed at the time to be the guidelines for treatment of this condition. What were the Poisons Centre guidelines at the time that Dr [B] and the nurses could have, indeed should reasonably have, accessed but did not? In the key section on 'Health Hazard Information' under 'Toxicity' it states: 'Estimates of the amount of paracetamol ingested are often unreliable, so that predictions of hepatotoxicity should be based on serum paracetamol concentrations'. It continues: 'Children appear to be less susceptible to hepatotoxic effects even with blood concentrations that would be potentially toxic in adults'. In its section headed 'Signs and Symptoms', it states that liver necrosis occurs in Stage III but that in Stage IV there are patients who recover with 'normalisation of liver function tests' and 'hepatic architecture returns to normal within 3 months'. It would be instructive to ask the Intensivists: what percentage die in Stage III? What percentage survive? Adults vs children? Of children who may have died in Stage III and had not been given charcoal, was there a causal link established between the absence of charcoal treatment and the ensuing liver necrosis and/or death? *Of those who received charcoal and survived Stage III unscathed,* was there a causal link established between this and their survival?

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Opinion – Case 98HDC17069/VC, continued

Advice obtained by Mr and Mrs A continued

The critical question is: did Dr [B] believe the situation was lifethreatening and did he believe giving charcoal was life-saving? None of the counsels put this question explicitly. Dr [B], however, gives us a clue as to his thinking on this matter when he said at the inquest: '... If I really felt the risk of the charcoal was that much higher I wouldn't have done it' (p 81, 3-4). When a doctor believes a life-saving procedure is immediately required, then that procedure demands to be undertaken in the face of all other risks. Clearly, Dr [B] did not feel this was such a situation but was 'driven' to intervene by 'standard procedure'. In fact, he recalled that he might have told Mr & Mrs A 'that it is quite a common procedure in hospitals for giving charcoal like this ...' (inquest p Significantly, he comments later that, had the 80, 18-19). complication not have intervened, he would've instructed the parents to take [Master A] home and bring him back 4 hours later for a paracetamol blood level and adds: 'Then we would [have] acted on the paracetamol blood level either way having given charcoal or not ...' (p 81, 18-19). Importantly, he adds: 'The antidote being NAC' [N-Acetyl Cysteine].

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Opinion – Case 98HDC17069/VC, continued

Advice obtained by Mr and Mrs A continued

What does this tell us? That he did not believe charcoal was a *life-saving treatment.* He acknowledges that having given charcoal or not would've made no difference to waiting for the paracetamol blood level 4 hours post ingestion. He acknowledges that, according to the level on the 'graph' (Rumack-Matthew nomogram [...]), he would've decided on use of the antidote, which he knew to be NAC. So, when [Master A] would not drink any more charcoal, why did Dr [B] not send him home with his parents, get him back 4 hours post ingestion, do the paracetamol blood level, read it off the graph, assess toxic or non-toxic level, assess the need for NAC? Despite acknowledging he knew 'there had been spillage' (p 105, 4) [evidence by [Master A's] parents was of spillage of paracetamol on the floor and desk when they found him], he stated, 'I wanted to get the charcoal in sooner rather than later ...' because he was interested in 'getting on and getting [the] job done ...' (p 105, 7-8). He did not wait to ascertain the paracetamol blood level, he did not hesitate to insert a nasogastric tube and instil charcoal because 'that would contradict the guidelines at the time' (p 105, 34). I must emphasise, however, that this was merely an assumption on his part (and that of the nurses) at the time because [the Public] Hospital did not have the current Poisons Centre CD-ROM, nor had he (or the nurses) made any effort to contact the Poisons Centre to acquire the current information. So, not only were they following guidelines blindly, they were following guidelines which they had not even bothered to ascertain were the current guidelines. Was this reasonable? I submit not.

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Opinion – Case 98HDC17069/VC, continued

Advice obtained by Mr and Mrs A continued

This brings me back to my earlier consideration of whether blindly following guidelines without reference to the facts of each case is sufficient to establish evidence of reasonable medical practice. If this is so, then critical thought and analysis of each set of facts and each situation is redundant and common sense may be dispensed with. If this is so, then doctors are bound to act only according to didactic training and, while acting within these bounds, are safe from legal challenge. If this is so, then there is no reasonable basis to proceed with an action in this case. I believe, however, that if the medical experts who gave evidence at the inquest had been asked whether they act blindly on guidelines or recommend their trainees to do likewise, there answer would have been in the negative. Certainly, had they been asked whether they act on guidelines before having ascertained whether these are current, they would've answered in the negative. Had they been asked the same questions about Dr [B's] behaviour, they would have been bound to answer in the negative. They would have answered that it was not reasonable medical practice.

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Opinion – Case 98HDC17069/VC, continued

Advice obtained by Mr and Mrs A continued

Dr [B] himself stated during the inquest, firstly, '... there is giving charcoal and putting a nasogastric tube in. Charcoal itself is harmless unless it finds its way in the wrong place thru [sic] Charcoal had been given. whatever means' (p 109, 30-32). [Master A] had drunk an unknown volume of this charcoal. This volume had been considered by Dr [B] to have been inadequate. At this stage, [Master A] was well. At this point, 'driven' by the guidelines and eager to be 'getting [the] job done', Dr [B] proceeded to insert a nasogastric tube. From this act and, in fact, from the decision to proceed with this act, all the complications leading to the death of [Master A] flowed. Patients may reasonably expect a doctor not to act blindly but to apply his mind to each case. Dr [B] did not do this, even though he admitted at the inquest: 'every child is slightly different; no two children the same.' (p 133, 3). He misled [Master A's] parents into believing that the insertion of a nasogastric tube in this case was vital and indispensible to saving [Master A's] life or, at least, preventing serious liver damage; consequences which might not have any causal link with giving or withholding charcoal (see questions above). He did not inform them of the life-threatening complication of charcoal entering the lungs (by aspiration or directly). He led them to believe the nasogastric tube insertion was 'routine', which it is generally but not in such a case where the purpose is to instil He failed, therefore, to allow them a reasonable charcoal. opportunity to weigh the risks against the benefits. Consequently, he cannot reasonably be said to have obtained informed consent.

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Opinion – Case 98HDC17069/VC, continued

Advice obtained by Mr and Mrs A continued The insertion of the nasogastric tube and the instillation of charcoal:

Having inserted the nasogastric tube, Dr [B] would have reasonably been expected to check that it terminated in [Master A's] stomach. What did he do? We know from the evidence that he attempted to aspirate fluid in order to test it with litmus paper. If the litmus paper changed colour to indicate acidity, that would indicate that the fluid was most likely to have originated from the stomach, gastric fluid being known to be acidic. Did he succeed in aspirating fluid? No. As a result, he was not able to test for acidity. Therefore, he was bound to discard this test as a failed test. The arguments by counsels to ascertain the precise length of tube introduced are irrelevant and based, I submit, on their unfamiliarity with clinical phenomena. It is not uncommon for nasogastric tubes to curl back on themselves during insertion when this is not done under direct vision. Most often this is seen in the mouth. Given the soft narrow nature of the tube inserted into [Master A] and the fact that nothing was aspirated following insertion, it is not unreasonable to postulate that the tube might have curled back on itself at some point, whether in the oesophagus, trachea or one of the main bronchi. As a result, whatever occurred, arguments based on the length of tube inserted cannot confirm whether the distal end of the tube came to rest.

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Opinion – Case 98HDC17069/VC, continued

Advice obtained by Mr and Mrs A continued What did he do next? According to his evidence, he used a 60ml syringe to inject air down the nasogastric tube for the purpose of insufflating air into [Master A's] stomach while he listened over the stomach with a stethoscope to confirm that the air he was injecting was, in fact, passing into the stomach, thus confirming the presence of the terminal end of the tube to be in the stomach. Was this test successful? We know from his evidence as well as that of the nurse assisting him and [Master A's] parents that Dr [B] used one hand to inject the air down the tube. We do not know what type of connection the syringe had or whether it fitted the proximal end of the tube snuggly and airtight or whether Dr [B] had achieved an airtight fit between the syringe and the tube. Why is this important? Because if there was not an airtight fit, then air would've escaped between the syringe and tube. Depending on the presence of a leak, only some or none of the air injected would've reached the stomach, if the tube was in the stomach. This would've reduced the possibility of hearing air injected into the stomach or made it impossible. Either way, it would've rendered this test inadequate or useless.

These points were not raised at the inquest. It would be instructive to ask an Anaesthetist or Intensivist whether all 60ml syringes make an airtight fit with a size 10 french nasogastric tube, whether a person with reasonable dexterity could effect an airtight fit using only one hand and whether an airtight fit is a prerequisite for performing this test to a reasonably adequate standard. Would the lack of an airtight fit lead them to reject the result of this test?

How did Dr [B] listen for air entering the stomach? With a stethoscope over the upper abdomen, we are told, though there is no clear evidence of this except Dr [B's] assurance of his tactile identification of the correct anatomical area. Did Dr [B] use an adult or paediatric stethoscope and which side of the bell did he use? These would each provide different nuances on ausculation as regards sound reception. It would be instructive to ask an Anaesthetist or Intensivist whether such differences might be significant.

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Opinion – Case 98HDC17069/VC, continued

Advice obtained by Mr and Mrs A continued Did Dr [B] place the bell of his stethoscope against the skin of [Master A's] epigastrium? He says he did but no-one else present could confirm this. All that is agreed is that his hand was seen to go under the cuddly. Why is it important to know that the bell of the stethoscope was in contact with the skin of the epigastrium? We know that Dr [B] did not undress [Master A] and that [Master A] had 3 layers of clothes covering his torso. On top of this was the cuddly, tightly wrapped. There is no evidence to corroborate Dr [B's] assertion that his stethoscope's bell was against [Master A's] skin. The diaphragm of a stethoscope is designed to be used against the skin. Any intervening material reduces the clarity of sound reception and procedures extraneous sound. At best, if the stethoscope bell was against the skin, ausculation of the insufflation of air would've been interfered with by the movement of 3 layers of clothing and the cuddly against one another and the innermost layer against the skin and the stethoscope (bearing in mind that [Master A] was struggling against his restrainers).

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Opinion – Case 98HDC17069/VC, continued

Advice obtained by Mr and Mrs A continued Then there is the question of the contribution the congenital heart defect, patent ductus arteriosus (PDA), might have made to the sounds Dr [B] heard. The PDA was dealt with perfunctorily at the inquest, only being cited and accepted as having made no contribution to [Master A's] death. No-one questioned whether the PDA produced a 'murmur' and, if so, whether such murmur might have impinged on Dr [B's] ausculation of [Master A's] epigastrium. Dr [B], though he said he was aware of the PDA, never examined [Master A]. Therefore, he would not have known whether a murmur existed or not and, if it did, what its nature was, especially how loud it might have been. It is well known in little children of [Master A's] age that chest and upper airway sounds are easily transmitted and may be clinically confusing when ausculation is undertaken, sometimes being mistaken for abnormal sounds. The PDA commonly, though not invariably, produces a 'machinery-like' sound over the precordial area of the chest. I submit that it is quite possible that, if there was a murmur, it might have been transmitted to the close proximity of the adjacent epigastrium. In the presence of the other interfering sounds mentioned above, it is not unreasonable that it might have contributed to confusing Dr [B] to mistakenly interpret the sound he claims he heard as that of the insufflated air. It will be useful to get the opinion of a Paediatric Cardiologist on this matter

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Opinion – Case 98HDC17069/VC, continued

Advice obtained by Mr and Mrs A continued

How useful is the air insufflation test in determining the correct placement of a nasogastric tube? It is one of the tests routinely used for this purpose but is not regarded as a definitive test. In fact, as [the paediatrician/emergency physician expert witness at the Coroner's inquest] said, it is the least reliable of all the tests. An argument was made that this test is used routinely, nevertheless, for determining the placement of a nasogastric tube in operating theatres. We must be careful to distinguish its use in these circumstances from its use as a conduit for the instillation of In theatre, firstly, it is inserted by Anaesthetists, charcoal. specialist or registrar, for whom it is an almost daily procedure; secondly, it is inserted into an immobile patient under general anaesthesia, often paralysed by muscle relaxants, i.e. ideal condition; thirdly, the patient is mostly already intubated with an endotracheal tube, thus leaving the oesophagus as the only unoccupied aperture in the throat; fourthly, and perhaps most importantly, the nasogastric tube is inserted to serve as an outlet from the stomach to facilitate decompression or the aspiration of gastric contents by the Anaesthetist. It is not inserted for the purpose of instilling fluid, especially not charcoal, which, if the tube was misplaced in the trachea instead of the oesophagus, could lead to this fluid entering the lungs, thus leading to chemical pneumonitis or death. Furthermore, the tube is not infrequently inserted under direct vision, i.e. with the benefit of direct laryngoscopy.

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Opinion – Case 98HDC17069/VC, continued

Advice obtained by Mr and Mrs A continued

In the circumstances, I submit that there was no reasonable basis for Dr [B] to have believed that this test had confirmed the placement of the tube in the stomach. The standard of care expected from Dr [B] was higher than that which would have been expected from him in theatre circumstances, for the following reasons. Even if we concede that the insertion of a nasogastric tube is a routine procedure, the instillation of charcoal down the tube demands a standard of care commensurate with the foreseeable complication of charcoal entering the lungs via a misplaced tube with the foreseeable result of that complication being death. This should be the same as the standard of care required when intubating someone with an endotracheal tube: 'when in doubt, pull out', is the maxim used by Anaesthetists, especially to those in training. The reason is obvious: if one is not completely sure that the tube is in the trachea, pull it out and repeat the procedure. If this is not done and the tube has inadvertently been placed in the oesophagus, the patient will become hypoxic and die. So too when inserting a nasogastric tube for the purpose of instilling charcoal. If not completely sure the tube is not in the trachea, the only reasonable course of action is to pull it out before instilling the charcoal and reinsert it. [The paediatrician/emergency physician expert witness at the Coroner's inquest] makes this clear twice, in his statement and at the inquest.

Further questions might be asked:

If he was not sure, why were small test doses of, eg. sterile water/saline not first instilled down the tube?

Why were the available specialists not called to assist when he was not sure? They took only 10min to get to the hospital when summoned to resus and Dr [B] admitted there was no rush.

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Opinion – Case 98HDC17069/VC, continued

Advice obtained by Mr and Mrs A continued Why did he not get an Xray to confirm the position of the tube? Much was made of the reluctance to expose the child to Xray and the time factor. Firstly, we know no rush was required. Besides, in a small hospital during normal working hours, it would have been a quick and easy matter to obtain an Xray. Secondly, only one plain Xray – which in [Master A's] case would've fitted both chest and abdomen on one cassette – was all that was required. It is far-fetched to suggest that is potentially harmful, besides the fact that this type of Xray causes minimal exposure effects. It would be instructive to get the opinion of a Radiologist on this matter. Most important, however, should have been the consideration that the minimal risk of the Xray was far outweighed by the benefit accruing from its result, which may have enabled the avoidance of a life-threatening complication.

[The paediatrician/emergency physician expert witness at the *Coroner's inquest*], *in his statement, described the complication of* charcoal aspiration as 'very rare' (p 7). This indicates it occurs very infrequently but does not imply that it is a trivial complication. He does not indicate whether this complication arises from aspiration or direct instillation via a nasogastric tube into the trachea but one may assume that this possibility is covered. While the frequency with which it occurs may be 'very rare', its seriousness demands that it be regarded as a reasonably foreseeable complication. When faced with the foreseeable complication of death, the only acceptable standard of care is that which requires all reasonable precautions to be taken in order to be completely sure, to have no doubt, that this complication is In this case, 100% certainty is the only sufficient avoided. condition that will satisfy reasonableness and the duty of care owed the patient. Anything less fails the duty of care and, therefore, must be regarded as negligent. Dr [B] failed to meet this standard and, therefore, must be regarded as having acted negligently.

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Opinion – Case 98HDC17069/VC, continued

Advice obtained by Mr and Mrs A continued The question of how the charcoal came to enter [Master A's] lungs is, as I said, a matter of speculation but, on a balance of probability, the pattern of careless and negligent behaviour exhibited by Dr [B] establishes a presumption that the entry of charcoal into [Master A's] lungs, causing his death, resulted from a failure by Dr [B] to exercise a reasonable duty of care towards [Master A].

I shall, nevertheless, address the speculation surrounding the entry of charcoal into [Master A's] lungs.

We know the following:

[Master A] swallowed from a cup either '2 x mouthful' of charcoal (Dr [B's] hospital notes) or '4 big gulps' of charcoal (Mr [A's] statement, p 6) prior to insertion of the nasogastric tube. There were no observed ill-effects. From this we may infer that he had no pre-existing neural or mechanical defects interfering with normal swallowing.

[Master A] was observed to have stopped making sounds after insertion of the nasogastric tube. This may be important for the support of the theory that the nasogastric tube was inserted down the trachea, i.e. that it passed between the vocal cords. From an anaesthetic point of view, I know that patients who awaken with an endotracheal tube still in place often struggle and produce blowing sounds through the tube but nothing louder or more specific than this. The same may be true of an awake patient with a nasogastric tube between the vocal cords, albeit in this case a narrow tube. In my opinion, this might provide the most logical and probable explanation for the reported disappearance of sounds following the insertion of the NG tube. Blowing sounds, if they were present, might have been easily obscured in a small struggling child with those restraining him. I suggest that you seek clarification on this point from a Speech Therapist who has experience with rehabilitation of patients in ICU's. A Paediatric Anaesthetist or Intensivist might also be of assistance

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Advice obtained by Mr and Mrs A continued	After insertion of the nasogastric tube, Dr [B] instilled 120ml charcoal via the tube in approx 30sec (rate of approx 4ml/sec) by means of two 60ml syringes. [Master A] was restrained in the supine position during the instillation of charcoal; a patient having fluid instilled via a nasogastric tube is ideally and invariably placed in the left lateral or decubitus position prior to instillation. There are 3 reasons for this:
	 the most important reason is to prevent aspiration in the event of vomiting or regurgitation; it assists the flow into the stomach in the optimal anatomical
	direction;
	<i>3) having regard to the design of a laryngoscope, it facilitates intubation with an endotracheal tube should the need arise.</i>
	Aspiration of charcoal was one of the theories advanced for the presence of charcoal in [Master A's] lungs. As I have stated above, this was a complication that Dr [B] should reasonably have foreseen. By having [Master A] in the supine position throughout the instillation of charcoal via the nasogastric tube, Dr [B] failed to fulfill his duty of care to [Master A]. If aspiration was the cause of charcoal entering [Master A's] lungs leading to his death, then Dr [B] must be held to have been negligent.

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Opinion – Case 98HDC17069/VC, continued

Advice obtained by Mr and Mrs A continued

On the other hand, the other possibility is that charcoal entered the lungs directly via a nasogastric tube inserted into the trachea. The autopsy finding was that 50ml of charcoal were found in the stomach and duodenum (autopsy notes, p 4). The Pathologist stated that he was unaware at the time of autopsy that [Master A] had drunk some charcoal prior to the insertion of the nasogastric tube. As a result, his finding of aspiration being the cause of charcoal having entered the lungs was based on ignorance of this fact. Undoubtedly, this coloured his finding. He skirted this issue (was allowed to skirt this issue) at the inquest, claiming it would not have changed his finding as the volume of charcoal found in the stomach and the duodenum was, by volume, greater than that which had been ingested orally. Was he justified to be confident of this claim? There is no evidence that he analysed the 50ml of charcoal to establish whether it was pure, unadulterated charcoal or contained other substances, eg. gastric fluid. No-one knows what total volume of charcoal [Master A] swallowed prior to insertion of the nasogastric tube. We know, however, that Dr [B] instilled a total of 120ml of charcoal via the tube. So, where did the remaining 70ml go? The only possibility is the lungs, as the evidence is that [Master A] did not vomit. Therefore, even if we accept that the 50ml found in the stomach and duodenum was pure charcoal, then by volume, approx 58% entered the lungs and only approx 41% entered the stomach and duodenum. If, however, we take into account that part of the 50ml in the stomach and duodenum was from the unknown volume orally ingested, then it is clear that an even greater volume and percentage must have found its way into the lungs. So, using the Pathologist's own reasoning, it seems possible that this greater volume entered the lungs directly via a nasogastric tube inserted in the trachea.

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Opinion – Case 98HDC17069/VC, continued

Advice obtained by Mr and Mrs A continued

If the nasogastric tube had been inserted in the oesophagus, could 70ml or more of charcoal been aspirated? We know that [Master A] was fully conscious at the time of instillation of the charcoal. We know his swallowing was normal. This means his laryngeal reflex was intact. This is the involuntary mechanism that acts to protect the airway, i.e. the glottis from penetration by solids or fluids. It is probably the strongest protective reflex in the body's armamentarium. It may be compromised in a person with a depressed level of consciousness. It is possible that it may be breached in a person in the supine position with an overwhelming presence of fluid in the mouth and pharynx, restrained with no possibility of turning on to the side or sitting up and with these restraints causing significant alterations in the dynamics of dead space, lung compliance, intrapleural pressure and oesophageal pressure. It would be instructive to get an opinion from a Respiratory Physician about these dynamics and how they might have influenced or promoted aspiration, if indeed it occurred. ... It might also be useful to ask the Paediatric Cardiologist I recommended about the effects these dynamics might have had on the PDA.

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Opinion – Case 98HDC17069/VC, continued

Advice obtained by Mr and Mrs A continued

It must be emphasised, however, that it would take only a miniscule volume of fluid to provoke a paroxysmal cough in a desperate effort to expel even such a volume. [Master A] was a 14kg child, fully dressed, wrapped tightly in a cuddly and restrained in the supine position by 3 adults. Despite this, we know he was still struggling. It is not unreasonable to submit that, if he had aspirated a small volume of charcoal, his reaction to it might, in the circumstances, have gone unnoticed. It is, however, equally unreasonable to postulate that, during a 30sec period in which 120ml of charcoal was instilled via the NG tube and, assuming for the moment that the tube was in the stomach, he would've aspirated a minimum of 70ml of charcoal. Laryngospasm would have supervened at a far earlier stage. The rate of regurgitation of such a large volume within such a short space of time in a 14kg child would reasonably predict the mouth filling rapidly with charcoal, some of which would probably have spilt from the mouth and nose. The evidence does not mention this; nor does it mention it when he was handed to his father or taken to resus. The first time we hear of free charcoal being seen is when [...], the Anaesthetist, mentions in his statement that 'the laryngopharynx was full of charcoal mixture ...' (p 2). This was some 10min after the charcoal had been instilled via the nasogastric tube.

It would appear that the most likely cause for a large volume of charcoal to have entered the lungs was direct instillation via a nasogastric tube placed in the trachea. This occurred as a result of Dr [B's] failure to take reasonable precautions to ensure the tube was in the oesophagus and not the trachea, as I outlined above. Dr [B] should have reasonably foreseen this complication which led to the death of [Master A]. By not doing so, he failed in his duty of care and, therefore, acted negligently."

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Opinion – Case 98HDC17069/VC, continued

Independent Advice to Commissioner	The Commissioner sought advice from an independent emergency medicine specialist who responded to the Commissioner's questions as follows:
	Was the decision to administer the charcoal solution and to use a naso gastric tube appropriate? "In April 1998, the protocol used by Emergency Departments around New Zealand and internationally promoted by Poisons Centres, indicated the need for gastric decontamination using activated charcoal for potentially toxic ingestions of Paracetamol. As mentioned, current recognised authorities [as written in textbooks of Emergency Medicine and Toxicology] concurred with this approach.
	The dosage of activated charcoal recommended for children was 1-2 mg/kg of activated charcoal following a paracetamol overdose involving ingestions in the toxic range [ie. > 200mg/kg].
	Additionally, the norm required the clinical staff to assume that the child had ingested the maximum possible [the amount missing from the bottle] even though spillage may have been obvious by the parents/caregivers.
	Therefore, when the nursing and medical staff of [the Public] Hospital ED were told that [Mr and Mrs A] had a 500ml bottle of Pamol with a concentration of 250 mg/5ml and that 125ml was lost from the bottle, they were required, under the protocol, to assume that all of this was ingested by [Master A].
	As [Master A] weighed 14kg this equated to a potential ingestion of $6250mg \div 14 = 446 \text{ mg/kg}$. This was greatly in excess of the recommended potential 'toxic level' and as such indicated some degree of urgency to the staff to proceed immediately with gastric decontamination according to the protocol.
	In undertaking this approach, they considered both the size and recentness of the ingestion. [Master A's] ingestion of the Pamol had occurred most likely within 1 hour of his presentation to the ED, which was within the guidelines for this manoeuvre.

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Opinion – Case 98HDC17069/VC, continued

Independent
Advice to
Commissioner
continued

Textbooks of Emergency Medicine and the Poison Centres further advise that if the charcoal cannot be ingested orally, the recommendation 'should/may' be for the placement of a naso gastric tube through which the charcoal can be instilled directly into the stomach.

As indicated in the expert opinions obtained for the Coroner's inquest, many Emergency Physicians, both here and overseas (as well as the authors of textbooks such as Rosens) have questioned the invasiveness, the success, the evidence, and the risks associated with this recommendation.

In New Zealand, as mentioned, with the publication of the '[a children's hospital]' paper, the proposed major changes in the protocol from a Paediatric Accidental Ingestion of Paracetamol Elixir could be:

- An 'upping' of the level at which the antidote would be used (that is, instead of using >125mg/kg it is recommended that > 225mg/kg would be appropriate);
- The time for obtaining the serum paracetamol level would be changed from 4-hours to 2-hours;
- Discouraging/discontinuing the use of gastric decontamination with activated charcoal if more that 30 minutes had elapsed post ingestion. This is due to its lack of effectiveness in this population because of rapid absorption of the paracetamol elixir, as well as a lack of evidence overall for the effectiveness of this strategy as well as the availability of an effective and safe antidote."

Should Dr B have advised Mr and Mrs A that there was risk associated with this procedure?

'Doctors and nurses are required ... to inform patients/caregivers of the benefits and the harms associated with particular treatments and/or procedures.

Generally, this information is meant to include 'likely' benefits and harms.

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Opinion – Case 98HDC17069/VC, continued

Independent Advice to Commissioner <i>continued</i>	Dr [B], in his affidavit indicates that he did not discuss the reasons, the benefits or the potential harms associated with the use of either activated charcoal or the procedure of naso gastric intubation and charcoal instillation, with [Mr and Mrs A].
	Neither did he discuss the harms and potential management of a childhood accidental paracetamol poisoning with them.
	Often in Emergency situations, where time is at a premium, detailed informed consent of this magnitude is difficult, if not impossible, to undertake.
	There is a waiver in the Ministry of Health's Informed Consent Guidelines for Emergency situations where life or death may be imminent. However, it is difficult, in [Master A's] situation to justify such immediacy under this banner.
	It is known that clinical staff working in Emergency Departments often take a literal approach to treatment or management protocols, particularly when the dose thought to have been ingested is in the high toxic range. In [Master A's] case, urgency is definitely implied when the protocol is applied.
	It is also a well-known fact that health professionals often make decisions for patients/caregivers when providing therapeutic or diagnostic requirements for management of conditions.
	Often this is without involving the patients/caregivers in an informed discussion even though the patients/caregivers are most affected by these decisions. Clinicians often tell the patient what we plan to do/are doing, but frequently do not request consent to do so, often taking acquiescence as an acknowledgement by the patient/family that it is okay to proceed. There exists a body of medico-legal literature around the nature of this 'implied consent'. However, the issue has to do with 'informed' consent which is a different matter.

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Opinion – Case 98HDC17069/VC, continued

Independent Advice to Commissioner *continued* With regard to the issue of advising [Mr and Mrs A] of the potential hazards related to the nasogastric tube insertion and the possible aspiration of charcoal into the lungs of [Master A] becomes a matter of probability. All medical professionals working in Emergency Departments are aware of the possibility of aspiration of charcoal subsequent to nasogastric instillation of the formulation. This complication is described in the literature - but couched under terms of significant rarity. Many doctors and nurses have performed this manoeuvre frequently in their careers with this complication never arising. It is likely that as a consequence, the knowledge of the possibility of aspiration occurring is subconscious and therefore often not considered. Dr [B] confirmed this as the case from his perspective in his report.

As well, a prudent health professional takes as many steps as possible not to further increase the anxiety of parents who are already anxious. In this situation, the [A family] were not particularly anxious however, once informed that their son could die from the poisoning or might, in a very rare situation, suffer harm or die from the treatment, it is possible that they might have become anxious. The fact that Mr A had to move away from [Master A] during the insertion of the naso gastric tube as it 'distressed' him partially confirms this. However, raising a parent's anxiety level should not be seen as excusing the lack of information provided in such cases. However, a body of clinicians, undertaking this treatment, would have been unlikely to comment on the possibility of death by aspiration of the charcoal.

The answer to this point, is that [Dr B] should have advised [Mr and Mrs A] of the potential risks of the paracetamol ingestion, the available methods of managing the ingestion including charcoal gut decontamination, the risks associated with this strategy and the options available.

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Opinion – Case 98HDC17069/VC, continued

Independent Advice to Commissioner *continued* It is important to stress at this point, that Dr [B] did not conduct his own targeted history or physical examination of [Master A]. That is, he did not undertake a targeted medical review of [Master A] prior to undertaking therapeutic management of the problem. Such an approach is occasionally justified in patients requiring critical rescue. However in this instance, there was adequate time for Dr [B] to perform his own examination.

Not doing his own examination precluded him informing the [A family] of the risks and benefits of both the intoxication as well as the management of the intoxication."

Was the correct amount of charcoal administered given the age and weight of Master A?

"[Master A] was weighed and the charcoal mixed according to the recommended guidelines provided both in the [Public] Hospital policy but also in the National Poisons Centre Policy. The correct dose of Activated Charcoal was given to [Master A] and within the appropriate timeframe."

Was the charcoal solution administered appropriately?

"All of the guidelines advise that if the patient will take the charcoal orally, this is the preferred method. Often diluting the charcoal slightly with water [makes it less viscous], with juice, coca-cola etc. [taste improvement], is recommended. This is not a requirement however. If the patient who requires activated charcoal refuses to take the solution orally, it is recommended that it be instilled using a nasogastric tube. The methodology for performing this procedure has been discussed earlier in this report. Notably, the deviations in the administration of the charcoal solution by the [Public Hospital] Emergency Department Clinical Staff included:

1. Dr [B] did not add the necessary '5 to 8cm' on to the externally measured tube to be inserted as recommended by Roberts in his Clinical Procedures in Emergency Medicine Textbook.

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Opinion – Case 98HDC17069/VC, continued

Independent Advice to Commissioner <i>continued</i>	2.	[Master A] was not encouraged to assist in the procedure by being offered water that would help direct the nasogastric tube into the oesophagus and stomach.
	3.	[Master A] was kept flat and horizontal when it is well recognised that placement should be head and shoulders up (at least thirty degrees) and left lateral position.
	4.	The nasogastric tube should have been strapped down to his nose and face to prevent shifting.
	5.	Instillation of the charcoal should have been slow and careful as it is a thick and viscous substance and a child's stomach is not very large."
	and I "Mar under Gene the c purpo out o in res well positi Many meas blood	it appropriate for Master A to be wrapped in a blanket held down during this procedure? ay of the Paediatric guidelines suggest that children rgoing these sorts of procedures should be restrained. rally the restraint uses a cuddly blanket and involves locking child's arms but not necessarily their torso. Again, the ose is to prevent the child from pulling the nasogastric tube r accidentally dislodging it. Having parents and staff assist straining the child is important but should involve verbal as as physical constraint. The nurse assisting should be in a ion to monitor the child and ensure that they are stable. w agencies would attach oximeter probes [instrument for uring the proportion of oxygenated haemoglobin in the l] to the child and monitor oxygen saturations although using levice depends on its availability."
	infor "As n	there any other issues arising from the supporting mation enclosed? mentioned earlier, there are a few major issues that have been hed on in this report.
	The d	

The first relates to the need for a medical practitioner, other than instances of crisis, to undertake his/her own history and physical examination of the patient before undertaking any therapeutic intervention.

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Opinion – Case 98HDC17069/VC, continued

Independent Advice to Commissioner	This was one of the issues raised by [Mr & Mrs A's lawyer] in his report related to [Master A's] demise.
<i>continued</i>	[Mr & Mrs A's lawyer] raised the possibility of the presence of a 'machinery-type' murmur due to [Master A's] patent ductus arteriosus [heart condition].
	He used this to raise some doubt as to whether Dr [B], in fact, heard 'instilled air' through the nasogastric tube when he listened over the epigastrium - was it due to the murmur of [Master A's] Patent Ductus?
	Dr [B] had not previously examined [Master A] and therefore would not have been able to distinguish between the two.
	It is therefore difficult to know whether Dr [B] might have been hearing the murmur and not the 'instilled air' that he believed he had heard.
	This is a question that will unfortunately remain unanswered and unresolved.
	The importance of doctors caring for patients to always review them historically and physically before undertaking therapeutic or diagnostic intervention underlies the problems in this issue.
	A lack of this basic but very important medical responsibility was not questioned by either Dr [B] or the nurses in [the Public Hospital] and thus leads one to suspect that the doctor not performing a basic history and physical examination is not out of the normal.
	The second issue raised has to do with the need for guidelines and protocols to be continuously updated thus remaining current and relevant to the care of individual patients.
	A component of this issue must be for the existence of effective mechanisms to ensure more rapid dissemination of new or different information especially from tertiary centres into smaller centres within New Zealand.

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Opinion – Case 98HDC17069/VC, continued

Independent Advice to Commissioner *continued* It is of concern that if [a children's hospital] had provided preliminary data on their study and its outcome within New Zealand indicating the need for some doubt as to the relevance of using activated charcoal gut decontamination in the case of child paracetamol intoxication, then Dr [B] may have reconsidered this approach and [Master A] might not have been subjected to a nasogastric intubation and instillation of activated charcoal.

A third issue has been both raised and reviewed by the Coroner who noted concerns regarding appropriate documentation, notekeeping and consistency of practice.

This is an issue that he dealt with very appropriately and I would recommend that the Health and Disability Commissioner support the Coroner's recommendations in this regard."

Conclusion:

"This particular complaint, from my perspective in advising the Health and Disability Commissioner, is predominantly about the performance of important basic medical care practices in order to ensure that patients receive care consistent with good clinical knowledge and good clinical skillsets.

In my opinion, Dr [B] and the nursing staff at [the Public Hospital] provided appropriate therapeutic management of young [Master A's] paracetamol elixir overdose in accordance with guidelines current at the time.

However, in my opinion Dr [B] failed to provide good medical practice in keeping with performing a targeted history and physical examination prior to undertaking care of a patient and in particular, care involving the performance of an invasive therapeutic intervention.

In my opinion, Dr [B] also failed to provide [Master A's] parents with appropriate information regarding the risks and benefits of the proposed therapeutic intervention and to outline the available management option.

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Opinion – Case 98HDC17069/VC, continued

Independent Advice to Commissioner <i>continued</i>	In my opinion Dr [B] also did not perform the procedure of nasogastric intubation and instillation of activated charcoal according to current good practice guidelines.
commucu	In so doing, he failed to ensure his patient's safety through performing the procedure while the patient was flat on his back and in a horizontal position.
	In my opinion he also failed to ensure that basic monitoring modalities were employed to enable provision of some overview of the patient's condition during the procedure.
	Further, in my opinion, by instilling the total dose of charcoal (approximately 100mls) in such a short time, he failed to provide appropriate duty of care to [Master A].
	In my opinion the nursing staff of [the Public Hospital] Emergency failed to support Dr [B] as a member of their health care team in not ensuring he independently took a full history of the event and examined the patient and recorded his findings.
	The nursing staff should have ensured that Dr [B] provided [Mr and Mrs A] with information on the balance of risk and benefit of the proposed intervention.
	The nursing staff are meant to advocate for the patient and family to ensure they are cared for appropriately and well.
	The nursing staff could have provided back-up support and information to the family regarding the procedure and an explanation of what the procedure entailed.
	The nursing staff could have provided backup support and information to the family regarding the procedure and an explanation of what this procedure entailed.
	They could have ensured that monitoring devices were attached to [Master A] such as an oximeter probe.
	Continued on next page

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Opinion – Case 98HDC17069/VC, continued

Independent Advice to Commissioner <i>continued</i>	In my opinion, the nursing staff should be aware of the correct positioning of a patient undergoing such a procedure and shoul know how to appropriately restrain a child of [Master A's] ag without causing major distress or placing the child in an unsag position.	
	[Master A's] death was accidental, it was unintentional but it did involve medical error.	
	Hopefully, improving on our processes, our interdependence and team work and by constant and continuous sharing of new evidence of what works best, we can reduce the incidence of errors and thus continuously improve our practice."	
Response to Provisional Opinion	In response to the Commissioner's provisional opinion, Ms G, Chief Executive Officer (CEO) of the Public Hospital, stated:	
Obmon	"I agree with the advice that the symptoms of possible intra- tracheal insertion of a nasogastric tube are 'excessive choking or gagging, or any coughing, change in voice'. [Master A] did not exhibit any of these.	

Continued on next page

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Opinion – Case 98HDC17069/VC, continued

Response to Provisional	
Opinion <i>continued</i>	There are other aspects of the medical advisor's advice which I do not agree with
	The advice states 'at this point the nursing staff and Dr [B] were permitted to go home', indicating that this occurred after [Master A] had been pronounced dead. This is not correct. All three of them left the hospital whilst the resuscitation was still going on.
	It also says 'they did not document the events of [Master A's] post nasogastric activated charcoal administration prior to leaving the Emergency department and did not inform Mr and Mrs A of [Master A's] death'. At the time the staff left the department [Master A] was still being resuscitated, and [Master A's] file was being used in the Resuscitation room. The staff could not speak to [Mr and Mrs A] about [Master A's] death as it was not yet certain that he would die.
	The staff who were extremely distressed by what had happened went home for support, with the high probability that the Police would want to speak to them very soon if [Master A] did die. The Police were short-staffed and decided not to interview the staff that day, so the staff were not called back to the department as quickly as anticipated, and the notes were not completed until the afternoon.
	The independent expert states 'if the charcoal cannot be ingested orally, the recommendation <u>should/may</u> be for the placement of a nasogastric tube'. The NPC protocol states 'for the few children refusing an oral dose, administration via a nasogastric tube <u>should be</u> undertaken'. The [children's hospital] protocol in use at that time is equally obligatory in its statement. Rosen's textbook of Emergency Medicine was quoted by the expert as 'if patients do not tolerate the unpleasant taste of charcoal or are uncooperative, <u>a nasogastric tube is used</u> for the administration'.

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Opinion – Case 98HDC17069/VC, continued

Response to Provisional Opinion *continued* There had been no national questioning of the procedure of nasogastric instillation of activated charcoal prior to this event. [The paediatrician/emergency physician expert witness at the Coroner's inquest] (Coroner's inquest cross-examination page 41, line 14) has indicated that it was as a direct result of this death, in addition to the research findings which became available in mid 1998, that doctors in New Zealand started questioning the need for nasogastric tube instillation of activated charcoal if oral administration could not be achieved. In spite of the medical community's increased knowledge since 1998, the fact remains that at the time of this death, the administration of activated charcoal via a nasogastric tube was the accepted course of action in this situation.

The paper from [the children's] hospital has just been published so is not relevant to the actions taken in early 1998. It is inappropriate to discuss what could be future changes to the national protocol in the section on 'was the decision to administer the charcoal solution and to use a nasogastric approach appropriate?' This debate needs to occur in the medical community.

It is not correct to state 'Dr [B] indicates he did not discuss the reasons, the benefits or the potential harms associated with either activated charcoal or the procedure of nasogastric intubation and charcoal instillation with [Mr and Mrs A]. Dr [B] states in the clinical record and under cross-examination at the Coroner's inquest (page 80, line 2) that he advised the parents prior to giving charcoal of the extreme toxicity of the dose of paracetamol taken, and the potential consequences of it. He talked about the need for it to be removed from [Master A's] system using activated charcoal. This is discussing the harm and potential management of paracetamol poisoning and the reasons and the benefits of using activated charcoal.

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Response to Provisional

Opinion

continued

A Public Hospital / Dr B / SN C / SN D / Master A

Opinion – Case 98HDC17069/VC, continued

The potential harms of activated charcoal are rare and minor by comparison with the toxic effects of paracetamol. In his affidavit to the Coroner (page 4, last sentence), Dr [B] states that he 'explained why we needed to insert a nasogastric tube'. He also said (Coroner's inquest cross-examination evidence, page 80, line 18) that inserting a nasogastric tube is quite a common procedure in hospitals for giving charcoal.

There is no dispute of the fact that [Master A] had ingested a potentially toxic amount of paracetamol. The national protocol states treatment with activated charcoal. No other options for treatment are mentioned in the NPC protocol. In order to be effective, the charcoal had to be given promptly. [The paediatrician/emergency physician expert witness at the Coroner's inquest] says 'as soon as possible after ingestion'. Given that it was one hour since the ingestion there was a degree of urgency.

Dr [B] and S/N [C] explained the administration of activated charcoal and the nasogastric procedure to Mr and Mrs [A]. The parents asked no further questions. Their consent was demonstrated by Mr [A] agreeing to assist with the procedure.

The matter not discussed with them was the extremely rare possibility of aspiration of the charcoal into the lungs. [The paediatrician/emergency physician expert witness at the Coroner's inquest] says 'charcoal itself is very, very rarely causing any problems'.

The medical advisor says 'this complication is described in the literature, but couched under terms of significant rarity'. She also says 'a body of clinicians would have been unlikely to comment on the possibility of death by aspiration of the charcoal'. It is inconsistent that she then criticises Dr [B] for not doing so.

It is incorrect to say 'Dr [B] did not conduct his own targeted history or physical examination of [Master A]. In his evidence to the Coroner, Dr [B] states 'I went in and introduced myself to [Master A's] parents and [Master A]. I confirmed from them the information given to me by the nurses, particularly regarding the quantity of Pamol consumed'. The information provided to him by the nurses included the fact that [Master A] had a patent ductus arteriosus (PDA).

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Opinion – Case 98HDC17069/VC, continued

Response to Provisional Opinion *continued* Dr [B] did assess [Master A's] physical condition whilst he was talking to [Mr and Mrs A]. He was able to observe [Master A's] general condition including his colour, breathing, muscle tone, and state of alertness. His ability to protect his airway had already been demonstrated during the attempts to persuade him to drink the charcoal. He could have listened to [Master A's] heart and discovered that he did not have a continuous murmur associated with his PDA. Nothing Dr [B] may have found by doing a full formal examination in addition to the assessment he did, would have changed the treatment required.

The medical advisor states 'not doing his own clinical examination precluded him (Dr [B]) informing [Mr and Mrs A] of the risks and benefits of both the intoxication as well as the management of the intoxication'. There is no cause and effect relationship. The significant effects of the poisoning were yet to occur, and nothing from the examination would have altered the information to be communicated about the management required.

The advice says 'Dr [B] did not add the necessary 5-8 cm on to the externally measured tube to be inserted as recommended by Roberts'. This is not information which has been previously mentioned by [the paediatrician/emergency physician expert witness at the Coroner's inquest] or in the usually quoted textbooks of Emergency Medicine. There are only 2 copies of Roberts and Hedges available at libraries in New Zealand so it is clearly not a widely used reference book. The NPC protocol (Nasogastric Intubation – Z405 – 22/4/98) describes the method for determining the length of tube required as 'The tube is measured against the patient from the corner of the mouth, over the ear, and down the xiphoid process'. No mention is made of having to add an extra 5-8cms.

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Opinion – Case 98HDC17069/VC, continued

Response to Provisional Opinion *continued* Another deviation in the administration of the charcoal solution is stated as '[Master A] was not encouraged to assist in the procedure by being offered water that would help direct the nasogastric tube into the oesophagus and stomach'. [Master A] had already refused to drink any more of the charcoal. It seems extremely unlikely he would have sipped water whilst the tube was being passed down his nose. In addition it is only mentioned as a suggestion under the protocols to ease the passage of the tube. It is not a requirement. The NPC protocol says 'it <u>may be useful</u> to allow the patient to sip water'.

The advice states '[Master A] was kept flat and horizontal when it is well recognised that placement should be head and shoulders up and left lateral position'. It is accepted that the protocols recommend that alert patients sit up for insertion of a nasogastric tube. This is to assist with the passage of the tube. In this case, it is unlikely that [Master A] would have co-operated with sitting up and the tube was able to be easily inserted without this position being adopted. The purpose of the left lateral position is to prevent aspiration of charcoal in patients who vomit or retch. The left lateral position was adopted part way through the instillation which would have permitted charcoal to flow out of the mouth had it been regurgitated at that time. The fact that no charcoal was present in the mouth when this position was adopted suggests that no aspiration had taken place up to that time.

The medical advice says, 'the nasogastric tube should have been strapped down to his nose and face to prevent shifting'. Strapping the tube to the nose is one method [of] securing it in place, however having a staff member continuously hold it in place is also acceptable.

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Opinion – Case 98HDC17069/VC, continued

Response to Provisional Opinion *continued* The statement 'instillation of the charcoal should have been slow and careful as it is a thick and viscous substance and a child's stomach is not very large' implies that the installation was not slow and careful. There is no evidence to support this opinion. The 100 mls (approximate) was administered in two stages with refilling of the syringe in between. The rate-determining step was the internal diameter of the 10F nasogastric tube, which was established at the Coroner's inquest as being 3mm. Administering a thick, viscous liquid through this small diameter has to be at a slow rate.

The process used to restrain [Master A] fits well with the description given in the advice. [Master A's] arms were restrained using a cuddly blanket to prevent him attempting to pull out the nasogastric tube. The nurse holding him, S/N [D], said that his hands were free to move under the blanket, and that he was still moving all the time. His father did assist with the procedure. Both Mr A and S/N [D] were talking to him during the procedure to reassure him. S/N [D] was monitoring him during the procedure and was clear that it was part of her role as a nurse to look for adverse reactions. Oximeters are commonly used in the Emergency department, primarily when nursing staff are not able to be with a patient continuously. In this situation the monitoring was best done by clinical observation.

The advice says, '[the medically qualified lawyer] raised the possibility of the presence of a machinery-type murmur due to [Master A's] patent ductus arteriosus'. It goes on 'he used this to raise some doubt as to whether Dr [B] heard instilled air through the nasogastric tube when he listened over the epigastrium, was it due to the murmur'.

The medical advisor then muses 'this is a question that will unfortunately remain unanswered and unresolved'. It can be easily answered and resolved as [Master A] did not have a 'machinery-type' murmur from his PDA.

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Opinion – Case 98HDC17069/VC, continued

Response to Provisional Opinion *continued* In addition, Dr [B] is clear that the noise he heard was from 'instilled air', and commented that he has always found the noises you hear to be different when you rapidly inject air into the stomach.

The medical advisor states 'a lack of this very basic but very important medical responsibility was not questioned by either Dr [B] or the nurses in [the Public Hospital] and thus leads one to suspect that the doctor not performing a basic history and physical examination is not out of the normal'. Firstly, it is not accepted that an appropriate history and physical assessment were not conducted. Secondly, there is no basis whatsoever for the medical advisor to make this statement. Unsubstantiated suspicion of this kind has no place in an opinion of this importance.

The question of protocols being continuously updated is raised. National consistency is maintained by this process being driven from the NPC rather than from the tertiary hospitals to the smaller centres.

It is stated 'Dr [B] failed to provide good medical practice in keeping with performing a targeted history and physical examination prior to undertaking care of the patient'. As outlined above this is incorrect ...

[As discussed above] it is not correct to say 'Dr [B] also failed to provide [Master A's] parents with appropriate information regarding the risks and benefits of the proposed therapeutic intervention and to outline the available management option' ...

•••

According to the nationally accepted protocols at the time, there was only one management option.

Dr [B] did perform the procedure of nasogastric intubation and instillation of activated charcoal according to current good practice guidelines.

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Opinion – Case 98HDC17069/VC, continued

Response to Provisional Opinion *continued* Dr [B] did take a targeted history and conduct an appropriate physical assessment. It is not the responsibility of nurses to ensure that the doctor records his findings. They were satisfied with the care provided to the family.

The comment 'the nursing staff should be aware of the correct positioning of the patient undergoing such a procedure and should know how to appropriately restrain a child of [Master A's] age without causing major distress or placing the child in an unsafe position', implies that [Master A] was subjected to major distress and placed in an unsafe position by the method of restraint used. There is no evidence to support this contention. The way [Master A] was restrained is standard practice and did not place him in any danger.

On the basis of the information detailed above, I do not agree with the opinion that '[Master A's] death ... did involve medical error'. This was a tragic situation where an internationally accepted practice was conducted in an appropriate manner, and unaccountably something went wrong which resulted in him aspirating and subsequently dying from this aspiration.

I do not agree with the finding that 'Dr [B] failed to perform the procedure of nasogastric intubation and instillation of activated charcoal according to current good practice guidelines'. ...

There was never any intention or attempt to conceal the fact that some of the notes were completed later that day rather than immediately after the event. It was an error not to record the actual time of documentation, but this fact was made known to the Police and the Coroner. Dr [B] was extremely distressed immediately after the resuscitation started and it was judged by the Charge Nurse that the notes would be more likely to be an accurate record of the events if they were completed once he had recovered from this initial shock. This was expected to be in the near future when he returned to the hospital to speak with the Police.

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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 – Case 98HDC17069/VC, continued

Response to Provisional Opinion *continued* As discussed [above], Dr [B] did perform a targeted history and an appropriate physical assessment. Therefore it is not correct to say he did not provide [Master A] with services of reasonable care and skill.

Mr and Mrs [A] did receive an explanation from Dr [B] prior to him leaving the hospital. Once the resuscitation team took over [Master A's] care, he went and spoke with Mr and Mrs [A] accompanied by [the] Charge Nurse [...]. She is quoted ... as saying 'Dr [B] indicated that he needed to go and inform the parents of what was happening'. He informed them of the gravity of the situation, and that he didn't understand what had gone wrong. He had given them as much explanation as he was able to at that stage.

As Dr [B] had no further involvement with [Master A's] care, the staff who had been involved with the resuscitation were the appropriate people to tell [Mr and Mrs A] that [Master A] had not been able to be resuscitated. [Two Public Hospital doctors] spoke with Mr and Mrs [A] after [Master A] had been pronounced dead and gave them whatever information they required at that point.

Once Dr [B] found out that [Master A] had died he offered to meet with Mr and Mrs [A]. This offer was first made via the social worker supporting the family, and then again by Dr [E] and C/N [...] when they met with [Mr and Mrs A] to answer their questions the day after the funeral. The family chose not to take up Dr [B's] offer for a meeting.

I do not believe that Dr [B] failed to provide a service consistent with Mr and Mrs [A's] needs.

Dr [B] did explain the potential risks of the paracetamol ingestion to Mr and Mrs [A] as detailed in the comments. According to the nationally accepted protocol there was only one management option recommended for an ingestion of this magnitude, that is, the administration of activated charcoal. The risk not discussed with [Mr and Mrs A] was that of aspiration of the charcoal into the lungs and it has been established that it was reasonable not to have done so given the rarity of its occurrence.

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Opinion – Case 98HDC17069/VC, continued

Response to Provisional Opinion continued	I do not consider that S/N's [C] and [D] failed to provide Mr and Mrs [A] with information about the risks of paracetamol ingestion and the benefit of activated charcoal administration as I have detailed above There is no evidence to conclude that [Master A] was not restrained safely whilst the nasogastric tube was being inserted,
	nor that he was caused 'major distress' during this procedure. He was able (and did) move under the blanket, and S/N [D] could observe his chest movements with breathing, but he was not able to attempt to pull the tube out.
	The completion of the clinical records which was done by the nurses that afternoon consisted of S/N [C] signing the A & E form he had completed that morning, which he was not able to sign at the time as the notes were in use in the resuscitation room. S/N [D] wrote a paragraph about noticing [Master A's] colour change and lack of breathing when she handed him back to his father.
	The main purpose of writing notes is to document accurately what has occurred. There is no question that by not signing his notes until the afternoon S/N [C] failed to comply with this requirement. Similarly, there has been no comment from [Mr and Mrs A] that S/N [D] did not accurately describe the events which occurred after the nasogastric tube was removed. It is correct that there is no annotation that this paragraph was written in the afternoon, but this information was supplied to the Police and the Coroner.
	In a situation like this, the nursing responsibility for communicating with the family is usually assumed by the Charge Nurse, as it was in this case. C/N [] accompanied Dr [B] to speak with Mr and Mrs [A], and later [two Public Hospital doctors] when they informed them of [Master A's] death. She also went with Dr [E] to visit [Mr and Mrs A] at their house the day after the funeral. Dr [E] offered verbally and in her letter of 25 th April to [Mr and Mrs A] that any of the staff involved would be prepared to meet with the family. Mr and Mrs [A] chose not to take up this offer.

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Opinion – Case 98HDC17069/VC, continued

Response to Provisional Opinion	I believe that Nurses [C] and [D] had met their professional responsibilities to [Mr and Mrs A] before they left the hospital.
continued	[The Public Hospital] disagrees with the finding that it did not have appropriate policies and procedures in place which complied with professional standards. The protocol for gastrointestinal decontamination (children) was entirely congruent with the current nationally accepted protocol for the management of paracetamol poisoning promulgated by the NPC, and the evidence is that they were correctly implemented.
	The staff were clear about the usual procedure for restraining children and followed this procedure in this case.
	The standard process for continuous clinical monitoring was followed. This is the basis of good clinical care and as such is not documented separately.
	The expectation of the organisation is that clinical notes will be accurate, comprehensive and completed in a timely manner. The competing priority of these three requirements in this case resulted in some of the notes being written several hours after the event. This is not unusual in any hospital, nor did it affect the care received by [Master A].
	The policy on documentation in the clinical record has been updated to emphasise the expectation that significant events should be recorded as close as possible to the time of the event."

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Opinion – Case 98HDC17069/VC, continued

Response to Provisional Opinion continued	In response to the Commissioner's provisional opinion, Dr B stated: <u>"Pulse Oxymeters</u>		
	<u>-1 uise</u> 1.	Pulse oxymetry is not something I use during a procedure on a struggling infant. A pulse oxymeter probe clips on to a digit of the patient being monitored, and any movement causes the machine to sound an alarm indicating that an erroneous measure is being displayed. In short, it would not give valuable information but instead would give misleading information and therefore is not normally used in these circumstances.	
	2.	There were four machines in the department at that time, but they are just not effective in this setting. None of them was used.	
	Observ	rations	
	3.	I observed [Master A] closely during the insertion of the nasogastric tube. I was standing more or less over him at the end of the bed, which he was lying across the end of. While inserting the tube I observed that he was struggling, and breathing like any other child that I performed the same procedure on. I was talking to him during the procedure trying to sound encouraging etc. I noticed no abnormal sounds or coughing to suggest that the tube was in the trachea. I noticed no unusual colouring, movement or lack of movement.	
	4.	As the charcoal was being instilled via the tube there was no coughing or any appearance of charcoal around his	

As the charcoal was being institled via the tube there was no coughing or any appearance of charcoal around his mouth or nose. The first charcoal did not appear until after we arrived in the resusc room. A two year old's air tubes have a volume of about 30 mls."

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Opinion – Case 98HDC17069/VC, continued

Response to Provisional Opinion <i>Continued</i>	Dr B also provided advice he had received from an emergency medicine specialist in response to the Commissioner's provisional opinion. In his advice the emergency medicine specialist stated: <i>"With regard to technical matters of the health/medical management in this case as referred to in the provisional opinion:-</i>
	 There is no question that the decision to proceed with activated charcoal via a nasogastric (N-G) tube at that time was most appropriate and the only option medically acceptable (NPC guidelines). In fact had Dr [B] not proceeded with this course and the child suffered liver damage he would have been culpable. The current evidence against this practice is not solid and suggestion in the opinion that the [children's hospital] data, had it been released earlier and incomplete, may have changed Dr [B's] therapy is extremely ill founded and dangerous. This type of research data must never be released prematurely either incomplete or before proper peer review. Even today there is not unity within the emergency medical fraternity as to the correct path to proceed with regard to Paracetamol elixir poisonings. The restraining of a child in a cuddly blanket is a standard and accepted practice. No further comment is required. Under such circumstances although the sitting or semi upright position is much preferred, it is often difficult and in many situations (such as with a wriggling child) one resorts to the lying the child supine or left lateral position (as described in the expert opinion). The comment 'that placement should be head and shoulder up AND left lateral position obviates or precludes the other. The comment on measurement of the tube to 'add 5 to 8cm' takes no consideration of how Dr [B] measured the tube and is therefore unjustified. The quote from Roberts text only refers to when the length is measured using the parameters described

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by Roberts. No reference to how Dr [B] measured the tube

appears in any of the Coroner's or H&DC documents.

Opinion – Case 98HDC17069/VC, continued

Response to Provisional Opinion *Continued*

- Comments re diluting the charcoal with water are non scientific and this increases the volume so increasing the risk of vomiting and is not standard practice. Similarly the adding of juice or coca cola in practice is thought not to work as it is adsorbed onto the charcoal. Although this method is frequently used, it is not scientific nor standard practice.
- Although strapping of the N-G tube is common practice if the tube is to be left in place, it is not usually the practice in such short procedures when the tube is continuously held by hand.
- Offering water to a struggling 2 year old, to help passage of the N-G tube, is somewhat impractical and I would not consider this option in such a case.
- Comment on the speed of installation of the charcoal is non scientific and I believe inappropriate, as it is the volume not the speed of installation which is the issue for the 'child's stomach which is not very large'. Secondly it is almost impossible to instil such a thick viscous substance (such as activated charcoal) 'too fast' through a 10F N-G tube, even with a syringe.
- References to 'monitoring' are in principle correct but use of a pulse oximeter is neither routine nor reliable in a struggling, restrained child as the probe will not give any consistent or reliable reading sufficient to justify its use. However, visual monitoring is essential and the nurse must be in a position to observe the child's breathing and colour. There is no evidence in either this report or the Coroner's report that this was not done though without clarification some doubt must exist.
- Comments regarding confusion of a patent ductus for the bubbling of the instilled air into the stomach, only brings into question the Coroner's report, not Dr [B's] performance and is not relevant in this report into Dr [B's] or nurses [C] and [D's] performance.

Continued on next page

Opinion

A Public Hospital / Dr B / SN C / SN D / Master A

Opinion – Case 98HDC17069/VC, continued

Response to Several references are made through the opinion and report to **Provisional** Dr [B's] not taking a personal targeted history and physical examination. Although ideal, in reality this is a relatively Continued minor issue as the decision regarding treatment is based solely on the history. The history was very clear and consistent from all sources that there was no need to question it. Dr [B] was in the room with the parents and [Master A] before and during the N-G tube insertion and there is recorded verbal communication between Dr [B] and the parents. I regard this as fulfilling some of this requirement. Although far from optimal in its execution it has little or no relevance to the outcome. In regard to giving appropriate information on the proposed therapeutic intervention I believe some of this was given in the above and the nurses' communication with the parents.

> As to therapeutic 'options', I do not believe under the NPC guidelines, that there were any other than that carried out and as stated above Dr [B] would have been culpable had an attempt to give the charcoal not been carried out and the child suffered liver damage from the Paracetamol ingestion.

> I therefore find that most of the conclusions drawn in the H&DC [provisional] report are questionable. I support one statement ... in that 'Dr [B] and the nursing staff at [the Public Hospital] provided appropriate therapeutic management of young [Master A's] Paracetamol overdose in accordance with guidelines at the time'. All other conclusions are in question or refer to the ideal. I believe most of this has occurred by taking the expert opinion out of context.

> Ι do acknowledge serious shortcomings in Dr [B's] communication before and after the event, and his failure to make adequate documented notes as soon after the event as practically possible. His going home after this is fully understandable, and I speak from experience that he would have been unfit to continue duty. However this does not excuse the non completion of notes nor the needed communication with the A family, recognising that Dr [B] may have needed some peer support to do so. I believe Dr [B's] nursing and medical colleagues should have helped in this."

> > *Continued on next page*

Opinion – Case 98HDC17069/VC, continued

Response to Provisional Opinion continued	Mr F, a legal advisor for the New Zealand Nurses Organisation, responded to the Commissioner's provisional opinion on behalf of staff nurses C and D and stated: <u>"No source for the 'Best practice'</u>	
	The expert sets out 'best practice' for the insertion of the nasogastric-tube. He or she expects the nurses to be familiar with this 'best practice'. However, no source is listed. No reference is made to the complications children present. Reliance cannot be placed on the 'best practice' as a result.	
	Expert inconsistent	
	The expert states:	
	a body of clinicians, undertaking this treatment, would have been unlikely to comment on the possibility of death by aspiration of the charcoal.	
	This is a <u>Bolam</u> reasonable practice. It is inconsistent for the expert to later state that the hospital staff should have provided this information to [Mr and Mrs A].	
	The expert also states that the use of the cuddly blanket to restrain [Master A] was appropriate. However, he or she then goes on to state that the nurses should have known how to appropriately restrain a child of [Master A's] age. The expert suggests that the child's arms should be locked but not necessarily their torso. With respect, it is difficult to envisage how this could be achieved	

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and the expert gives no practical advice.

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Opinion – Case 98HDC17069/VC, continued

Response to Provisional Opinion *continued*

Use of an oximeter

The expert suggests that an oximeter should have been used. There is no evidence that one was available. I am instructed that, at the time of the incident, there was an oximeter in the resuscitation room for emergency use. However, it would be unusual for one to be used for this procedure. By the time that an oximeter showed a decrease in oxygen saturation, inserting charcoal into the lung would have done irrevocable damage.

Monitoring the treatment by the doctor

The expert states that the nurses should have monitored the treatment provided by Dr [B] and advocated more for the patient. This places an onerous expectation on the nurses to have the same level of knowledge of acceptable practice as the doctor. The nurses feel that they did advocate for the patient by providing prompt and appropriate treatment.

If the expert is correct then health professionals would be obliged to interfere in the therapeutic relationship between the lead carer and the patient. To do so would undermine the patient's confidence in the lead carer.

Urgency of the treatment

It is submitted that the expert is inconsistent in the issue of the urgency of the treatment. The expert states:

`... it is difficult, in [Master A's] situation to justify such immediacy under this banner.'

The expert then contradicts his or her own references. Rosen states that:

'If a patient has ingested only APAP and presents to the ED within 1 hour of ingestion, activated charcoal (AC) with a cathartic may be administered.'

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Opinion – Case 98HDC17069/VC, continued

Response to Provisional	Ellenhorn states:
Opinion continued	'For the patient who presents more than 1 hour after a pure paracetamol overdose, it is unlikely that gastrointestinal decontamination will be useful.'
	The expert refers to a [children's] Hospital paper:
	'The use of enteral charcoal is unlikely to enhance paracetamol elimination unless it is given within an hour of ingestion.'
	Furthermore, the Poisons Centre Treatment Guideline (and the [Public] Hospital Protocol) state[s]:
	<i>` administer single dose activated charcoal if paracetamol liquid or tablets ingested within 2 or 4 hours respectively.'</i>
	The Coroner found that [Master A] presented at the hospital less than 1 hour after the ingestion.
	There was, clearly, urgency. The hospital staff were conscious of the need to administer the charcoal as quickly as possible. Despite the urgency, the staff did provide information to [Mr and Mrs A].
	It is submitted that the expert judges the urgency of the situation, not according to the state of knowledge at the time of the incident, but according to the current view that the use of charcoal 30 minutes after ingestion may be ineffective.

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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 – Case 98HDC17069/VC, continued

Comments on the Provisional Report

Informed consent

...

I am instructed that, when [SN C] gave Mrs [A] the charcoal preparation so she may get [Master A] to ingest as much as possible, he advised her that [Master A] had a potentially toxic dose of Pamol, what the charcoal tasted like, how it worked and why [Master A] needed it. He also said that a tube might need to be inserted if [Master A] did not drink the charcoal mixture. He did not go into this in detail because he did not anticipate that the tube would need to be used and because he did not want to alarm [Mr and Mrs A].

Later, when [SN C] advised [Mr and Mrs A] about the intended procedure (what it entailed, the expected benefits and risks) he did not raise the risk of death because the risk is so low. It was for this reason that he was shocked when it occurred. I am further instructed that [Mr and Mrs A] told him that not only did they wish to be present but Mr [A] also wanted to assist. [Mr and Mrs A] did not question the procedure. Therefore, [SN C] believed that he had [Mr and Mrs A's] fully informed consent.

[SN D] also spent some time talking to the family.

Leaving the hospital

I am instructed that, when [SN C] and [SN D] left the resuscitation room, and went home, the resuscitation was still in progress. They were told by Staff Nurse [...] to leave the resuscitation room and went to [the] Charge Nurse['s] [...] office. [SN C] asked if it would be alright to go home. Both were told that they should go home but they may be contacted by phone. They were told that they might present a risk to the other patients if they remained on duty in their distressed state. They were informed that [the Charge Nurse] would supervise the care of [Mr and Mrs A].

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Response to Provisional Opinion *continued*

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 – Case 98HDC17069/VC, continued

Response to Provisional Opinion *continued*

Completing the clinical records

[SN C] did not 'complete the clinical records' when he returned to the hospital in the afternoon. I am instructed that he signed his name to the notes he made at the time, without adding anything further. He wrote his notes while [Master A] was drinking the charcoal and while the equipment for the nasogastric tube procedure was being set up.

I am instructed that when [SN D] returned to the hospital in the afternoon, she asked [the Charge Nurse] whether she needed to make an entry in the notes. [The Charge Nurse] advised her that this would not be necessary, as [SN C] had written the notes and because she had only been assisting. However, [SN D] felt she needed to record what happened after the nasogastric tube procedure to make the notes complete. These notes were written before the debriefing occurred.

Both nurses were only 5 minutes away from the hospital and contactable at all times. No one from the Police or the hospital contacted them.

There is an insinuation that the notes were 'concocted'. The Coroner found that the notes were of an acceptable medical standard.

Dr B's examination of Master A

The nurses were not present when Dr [B] assessed [Master A] and advised [Mr and Mrs A]. [SN C] walked in half way through and then left again. He had no reason to believe that Dr [B's] examination was not done adequately. In fact, [SN C] was led to believe that [Mr and Mrs A] knew about the procedure because Mr [A] wished to assist.

The nasogastric tube procedure

I am instructed that [SN C] does not recall Dr [B] measuring the nasogastric tube inappropriately.

Continued on next page

Opinion – Case 98HDC17069/VC, continued

Response to
Provisional
Opinion
continued

[SN C] was reluctant to give [Master A] water to drink during the procedure. [Master A] was already distressed by what the staff had given him to drink. [SN C] perceived that [Master A] had lost his trust in what the staff had given him to drink and would not take anything he may give to [Master A]. He did not want to upset [Master A] any further.

Furthermore, the expert states that the patient may be given water to sip to ease the passage of the tube, only if the patient is cooperative. [Master A] was, clearly, uncooperative.

The procedure was carried out in accordance with the hospital's protocols. Reassurance was given to [Master A] during the procedure. The blanket was loose enough to see the chest rising. Indeed at one stage, [Master A] was able to free an arm.

It appeared to the nurses that the administration of the charcoal via the nasogastric tube was given over a slow and controlled period.

I am instructed that, during the procedure, the nurses closely observed [Master A's] colour and breathing. Not until the procedure had been completed did the nurses observe that there was a problem.

Alleged breaches of the Code

The nurses are adamant that they provided [Mr and Mrs A] with all the relevant and necessary information. It is only with the benefit of hindsight that it is possible to say that their care was a breach of Rights 6(1)(b), 6(2) and 7(1) of the Code. Can it truly be said that, if faced with a choice between proceeding with the insertion of the nasogastric tube, knowing there was a small risk of death, and risking liver damage through the over dose of paracetamol, [Mr and Mrs A] would have chosen the latter?

²⁸ September 2000

Opinion – Case 98HDC17069/VC, continued

Response to Provisional Opinion <i>continued</i>	The breach of Right 4(2) is assessed against 'current good practice guidelines'. Current practice is, with respect, irrelevant. What is relevant is the practice in April 1998.
	There is no suggestion that the failure to complete the notes before the nurses went home resulted in inadequate information being recorded or, worse, the falsification of the records. Would not the nurses have been criticised more if they had attempted to complete their notes, to the extent required by the expert or you, in a distressed state and they had omitted important information?
	In relation to Right 4(3), if you place yourself in the position of [Mr and Mrs A] at the time of the incident, would you prefer to have someone who was calm provide you with an explanation or someone who was distressed and unable to clearly set out all that went on?"

Opinion – Case 98HDC17069/VC, continued

Further	After reviewing the responses to the provisional opinion, the	;
Advice to	Commissioner sought advice from an independent nursing advisor. The	•
Commissioner	nursing advisor stated:	

"1. Admission

[Master A] was taken to Emergency Dept @ [the Public] Hospital with accidental ingestion of Pamol, on 21 April 1998, 8am approx. S/N [C] met [Master A] and his parents, commenced his assessment of [Master A] and was assisted by S/N [D]. S/N [D] noted the recordings in the admission chart and realised that information relating to allergies and existing medical conditions was missing so she rectified this by asking Mr & Mrs [A] for the information. S/N [C] then referred [Master A] to Dr [B] for treatment. Both nurses, in my opinion, met NZ Nursing Council standards in relation to communication relevant information of and consultation/referral to prescribing practitioner (NCNZ 1999:4.1-4.5) at admission.

2. Charcoal Administration

Dr [B] prescribed charcoal in line with the National Poisons Centre and [the Public] Hospital criteria at that time. S/N [C] measured the prescribed dose into a drinking cup whilst Dr [B] was explaining to the parents why we were going to administer charcoal and what we might need to do (AIP statement: 19/22). S/N [C] gave the charcoal mixture to Mr [A] and states (23) that he had already talked to the family about using charcoal and the possible need for a nasogastric tube. [Master A] declined to drink sufficient charcoal mixture so S/N [C] reported this to Dr [B] and it was decided to insert a nasogastric tube to deliver the remaining charcoal mixture.

²⁸ September 2000

Opinion – Case 98HDC17069/VC, continued

Further Advice to Commissioner *continued*

- S/N [C] prepared the trolley for the procedure and S/N [D] talked to the family. Both nurses and Mr [A] assisted with holding [Master A] so he could not interfere with the procedure or harm himself. [Master A] was laid on a cuddly and wrapped so his arms couldn't escape and dislodge the tube. The cuddly was firm enough to carry out the procedure but loose enough for Dr [B] to put his hand and stethoscope down and for [Master A] to get one hand out. In my opinion S/N [C] and [D] met professional standards of care when restraining [Master A] as they recognised contextual factors (such as his age) and administered/monitored the prescribed intervention/treatment within a framework of current nursing knowledge (NCNZ, 1999).
 - S/N [D] notes (written submission: 18) that both Dr [B] and S/N [C] explained the procedure at different times during the setting up period. Mr [A] assisted to hold [Master A] during the early part of the procedure until he became distressed and S/N [D] spent time reassuring him. Mr [A's] willingness to assist with the procedure and the nurse's reassurance when he felt unable to continue indicate that appropriate information was supplied, consent had been given and the nurses acted appropriately as client advocates. As written consent forms are not required for the insertion of a nasogastric tube, nurses can assume consent if there are no further questions or requests for further information. The evidence has established that the risk associated with the procedure was deemed to be minimal at the time compared to the risk of [Master A] not receiving the charcoal so it is my opinion that the nurses gave sufficient information to [Mr and Mrs A].

²⁸ September 2000

Opinion – Case 98HDC17069/VC, continued

Further Advice to Commissioner *continued* There is a body of opinion in the nursing literature that states that it is not the nurse's responsibility to ensure consent for procedures to be carried out by another professional. ... It is my opinion therefore that both S/N [C] and [D] met required professional standards for communication, consent and advocacy (NCNZ, 1999).

• HDC provisional report notes that 'all present indicated that Dr [B] was satisfied that the tube was in the stomach' and that whilst the tube was inserted with [Master A] in the horizontal position, he was placed in the recovery position during the procedure. S/N [C] and [D] both clinically observed [Master A] closely during the procedure and neither they nor Dr [B] observed anything untoward during the procedure. In my opinion the use of an oximeter would not have alerted the staff to the aspiration of the charcoal until after the event and as [Master A] was being closely observed was not necessary. In my opinion both nurses met professional standards for assessment, monitoring and safe practice (NCNZ, 1999).

²⁸ September 2000

Opinion – Case 98HDC17069/VC, continued

Further Advice to Commissioner *continued*

3. Resuscitation Procedures

Following removal of the nasogastric tube [Master A] was • noted to be not breathing and blue around his lips. Emergency procedures were initiated and the hospital resuscitation team and paediatrician then took over the care of [Master A]. S/N [C] and [D] left the resuscitation room and both went home with the consent of their charge nurse who had taken over communication/information processes for the family. [The] Charge Nurse [...] had ensured that another member of the nursing staff and a social worker supported Mr and Mrs [A] and Dr [B] had discussed the gravity of the situation with the parents. In my opinion S/N [C] and [D] had met their professional responsibilities to the [A] family prior to leaving the hospital as they were no longer treating [Master A], the resuscitation was still in progress and [the Charge Nurse] had assumed responsibility for the ongoing communication process. It is also my opinion that the nurses and Dr [B] initiated and carried out the preliminary emergency procedures in a competent and efficient manner until the resuscitation team and paediatrician arrived. This met the competencies required by Nursing Council that nurses act appropriately when faced with unexpected client responses and determine action to manage emergency situations (NCNZ 1999: 5).

²⁸ September 2000

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Opinion – Case 98HDC17069/VC, continued

Further Advice to Commissioner *continued*

5. Clinical Records

The clinical records were noted by the Coroner to be of an expected standard but he commented that the notes were not completed in a timely fashion. The purpose of the clinical notes is to provide an accurate record of what has occurred. It is reasonable to assume that notes written at the time of the events will be more reliable than notes written later S/N [C] did not sign his notes until the afternoon. S/N [D] wrote her notes describing what had happened following the removal of the nasogastric tube later in the afternoon and did not annotate this in those notes. None of the evidence I have seen has indicated that the nurses notes were not truthful but the delay in both signing and writing them did not, in my opinion, expected performance criteria meet for accurate documentation as detailed by Nursing Council of NZ (NCNZ, 1999: 9.6-9.8).

6. SUMMARY

- In my opinion S/N [C] and [D] met professional standards of nursing practice in the assessment, admission and referral of [Master A] at the time of admission.
- In my opinion S/N [C] and [D] met professional standards of nursing practice in the restraint, assessment and monitoring of [Master A] whilst he was receiving charcoal via the nasogastric tube.
- In my opinion S/N [C] and [D] met professional standards of nursing practice in the information and support they gave to Mr and Mrs [A].
- In my opinion S/N [C] and [D] had met professional standards of nursing practice when they left [the Public] Hospital with the resuscitation still in progress as the responsibility for communication with the [A] family was with the resuscitation team and Charge Nurse.
- In my opinion S/N [C] and [D] met professional standards of nursing practice when they responded rapidly and appropriately to the emergency situation.

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Opinion – Case 98HDC17069/VC, continued

Further Advice to Commissioner *Continued*

• In my opinion S/N [C] and [D] did not meet professional standards of nursing practice when S/N [C] did not sign his notes for eight hours (approx.) after the events and S/N [D] did not write hers or annotate that they had been written eight hours (approx.) after the events."

Further advice was obtained from the Commissioner's independent advisor on emergency medicine, who was asked to review her original advice in light of the responses to the provisional opinion.

The emergency medicine advisor stated:

"[I have now referred to the following relevant Position Statement:]

Summary of the Position Statement: Single-Dose Activated Charcoal¹ published by the American Academy of Clinical Toxicology and the European Association of Poisons Centres and Clinical Toxicologists in 1997.

'Introduction:

- Overall, the mortality from acute poisoning is less than one percent. The challenge for clinicians managing poisoned patients is to identify promptly those who are most at risk of developing serious complications and who might potentially benefit, therefore, from gastrointestinal decontamination.
- Single-dose activated charcoal therapy involves the oral administration or instillation by nasogastric tube of an aqueous preparation of activated charcoal after the ingestion of a poison.

 ¹ American Academy of Clinical Toxicology; European Association of Poisons Centres and Clinical Toxicologists. Position Statement: Single-Dose Activated Charcoal. Clinical Toxicology, 35(7), 721-741 (1997).
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Opinion – Case 98HDC17069/VC, continued

Further Advice to	Rationale:
Advice to Commissioner Continued	• Activated charcoal comes in direct contact with and absorbs poisons in the gastrointestinal tract, decreasing the extent of absorption of the poison, thereby reducing or preventing systemic toxicity.
	In Vitro [test tube laboratory] Studies
	• Scores of compounds, including many drugs, have been shown to be absorbed to activated charcoal by varying degrees. ²
	Animal Studies
	• The administration of activated charcoal in animal studies has produced variable reduction in marker absorption. ²
	Volunteer Studies:
	• The results of 115 comparisons with 45 drugs indicate considerable variation in the absolute amount of charcoal used (0.5-100g) and the time of administration (up to 240 minutes after ingestion).
	• In these studies, when activated charcoal was administered 30 minutes or less following drug administration, the mean bioavailability was reduced by 69.1%. When activated charcoal was administered at 60 minutes following drug administration, the mean reduction in bioavailability was 34.4%.
	• In 40 studies involving 26 drugs, using at least 50g of activated charcoal, the mean reduction in drug absorption was 88.6% when charcoal was administered up to 30 minutes after dosing; mean reduction at 60 minutes was 37.3%.

Continued on next page

² Cooney DO. Activated Charcoal in Medicinal Applications. New York: Marcel Dekker, 1995.

Opinion – Case 98HDC17069/VC, continued

Further Advice to Commissioner <i>Continued</i>	 Clinical Studies There are no satisfactorily designed clinical studies assessing benefit from single-dose activated charcoal.
Commu	 One study³ of symptomatic patients who received activated charcoal and some form of gastric evacuation (gastric lavage, ipecac, gastric aspiration) showed that patients receiving gastric aspiration and activated charcoal were less likely to be admitted to an intensive care unit.
	Indications:
	• Based on volunteer studies, activated charcoal is more likely to produce benefit if administered within 1 hour of poison ingestion.

- The administration of activated charcoal may be considered if a patient has ingested a potentially toxic amount of poison up to 1 hour following ingestion.
- Activated charcoal may be considered more than 1 hour after ingestion, but there are insufficient data to support to exclude its use.

Dosage Regimen:

- The optimal dose of activated charcoal for poisoned patients is unknown, though available data imply a dose-response relationship that favours larger doses.
- Data derived from animal and human volunteer studies have little relevance to the clinical situation because these experimental studies were performed in fasting animal and human subjects who ingested a known quantity of drug.

³ Merigian KS, Woodward M, Hedges JR et al. Prospective evaluation of gastric emptying in the self-poisoned patient. Am J Emerg Med 1990;8:479-483.

²⁸ September 2000

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Opinion – Case 98HDC17069/VC, continued

Further Advice to Commissioner <i>Continued</i>	 The United Stated Pharmacopoeia (USP DI, 1997) recommends the following oral dosage regimen. Children up to one year of age: 1g/kg Children 1 to 12 years of age: 25 to 50g Adolescents and adults 25 to 100g
	• Constipation has not been observed after the administration of a single dose of activated charcoal.
	Contraindications:
	• An unprotected airway.
	• A gastrointestinal tract not anatomically intact.

• When activated charcoal therapy may increase the risk and severity of aspiration (e.g. hydrocarbons with a high aspiration potential).

Complications:

Few serious adverse effects or complications from the use of single-dose activated charcoal have been reported in poisoned patients.

Following administration of aqueous activated charcoal, vomiting occurs infrequently. However, the incidence of vomiting appears to be greater when activated charcoal is administered with sorbitol.'

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Opinion – Case 98HDC17069/VC, continued

Further Advice to Commissioner *continued* One case report⁴ quoted and outlined by the authors of the position statement, similar to [Master A], was recorded as follows: '... An alert 8-month-old girl received ipecac syrup followed by activated charcoal 9g in 35ml of water via a nasogastric tube. She vomited charcoal, became cyanotic, and cardiorespiratory resuscitation was initiated. Direct laryngoscopy revealed a trachea occluded with charcoal. After an eleven-day hospital course, she was sent home with normal chest radiographs and physical examination.'

Following careful consideration of the above quoted position statement, the Commissioner's Provisional Report and the additional information provided by [Master A's] family, the staff of [the Public Hospital] including the review by [Dr B's independent expert], I wish to underline and amend some aspects of my previous advice to the Commissioner as follows:

- 1. The clinical staff of [the Public] Hospital provided appropriate therapeutic management of young [Master A's] paracetamol elixir accidental overdose in accordance with guidelines provided by the National Poisons Centre and by [the Public] Hospital. As noted in the position statement, both the criteria outlined in the introduction were met by the clinical staff.
- 2. Dr [B] did discuss the rationale for providing a singledose of activated charcoal to the [A] family after failed attempts to have [Master A] ingest the slurry orally. This discussion was witnessed and corroborated by staff members.

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⁴ Pollack MM, Dunbar BS, Holbrook PR, Fields Al. Aspiration of activated charcoal and gastric contents. Ann Emerg Med 1981; 10:528-529.

²⁸ September 2000

Opinion – Case 98HDC17069/VC, continued

Further Advice to Commissioner continued	3.	 Dr [B] undertook a visual assessment of [Master A] but did not undertake a physical examination. In his report, [Dr B's independent expert] advises that there was urgency required given: The size of the potential overdose – very much in the high toxic range. [Note: the standard of the time required doctors and nurses to consider the total amount of paracetamol missing from the bottle to have been ingested unless the ingestion was witnessed]. The rapidly approaching timeframe for efficacy of the activated charcoal in binding to paracetamol in the gastrointestinal tract [i.e. most efficacious the soonest, and within 60 minutes, following the time of the ingestion].
	4.	 Dr [B] undertook a physical assessment of [Master A] in keeping with the urgency of the timeframe and according to recent guidelines set out for Australasian Emergency Physicians⁵ [note this is a textbook of adult EM medicine but these guidelines would apply to Paediatric cases]: Identify any immediate threats to life and the need for intervention [no immediate threat to life, but required immediate nasogastric instillation of activated charcoal to reduce potential serious toxicity]; Establish a baseline clinical status [vital signs, history of ingestion, clinical assessment of child in the ED]; Corroborate the history [Parents further queried by Dr [B] regarding volume of Pamol in the bottle and amount missing – corroborated nursing and Poisons Centre estimation according to principles as outlined by the Poisons Centre];

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⁵ Cameron P, Jelinel G, Kelly A-M, Murray L, Heyworth J, editors Textbook of Adult Emergency Medicine. Churchill-Livingstone 2000;page 660-61.

²⁸ September 2000

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Opinion – Case 98HDC17069/VC, continued

Further Advice to Commissioner *Continued*

- Identify intoxication syndromes [known Paracetamol ingestion];
- Identify possible alternative diagnoses [known witnessed Paracetamol ingestion];
- Identify any complications of the poisoning [hepatic failure; multiple organs system failure; potentially lethal].
- 5. After a review of 'current practice' regarding insertion of nasogastric tubes in New Zealand, there is evidence of marked variation around the country. Therefore, there is no current New Zealand standard applicable to the performance of this invasive intervention. Therefore, Dr [B] cannot be said to have performed below the current standard as he:
 - Chose an appropriate sized tube for the size of [Master A];
 - *Measured the tube to ensure the length would reach into [Master A's] stomach;*
 - Considered the ease of passage of the tube and noted the absence of cough etc;
 - Attempted to aspirate the tube for gastric contents;
 - When unable to aspirate gastric contents, placed a stethoscope over [Master A's] stomach and listened while he instilled a bolus of air, satisfying him that the tube was in the correct position.
- 6. There is a wide variation amongst New Zealand Emergency Departments regarding physiological monitoring requirements during the performance of invasive interventions. Therefore there is no current standard in New Zealand Emergency Departments. Dr [B] therefore did not breach a standard of care in this regard.

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Opinion – Case 98HDC17069/VC, continued

Further7.There is written disagreement regarding the time taken for
the instillation of the 100 mls of aqueous activated
charcoal. Additionally, [Dr B's independent expert]
reports that it is not physically possible to instill a viscous
substance of this nature rapidly through a 10F nasogastric
tube. In addition, the nursing staff corroborate that the
slurry was given via the nasogastric tube over a 'slow and
controlled period'. Therefore Dr [B] cannot be said to
have breached a standard in this regard.

8. Nursing staff have indicated that they did discuss the rationale for providing oral aqueous activated charcoal to [Master A] as well as its unpalatable nature, with [Mr and Mrs A]. Staff Nurse [C] also indicated that they should encourage [Master A] to take it orally as the only other option was for instillation via nasogastric tube. They noted that [Mr and Mrs A] assisted the nursing staff in attempting this administration. Therefore the nursing staff cannot be said to have breached a standard in this regard.

- 9. There is no current New Zealand standard regarding the application of a 'cuddly restraint' to a child in order to undertake a invasive intervention such as nasogastric intubation. Additionally, the nursing staff indicate they were able to visualise [Master A's] chest moving and at one point, he was able to free an arm. As a consequence, the nursing staff cannot be said to have breached a standard in this regard.
- 10. Dr [B] did request the child be turned onto his left side during the instillation of the activated charcoal via the nasogastric tube. There is a discrepancy as to the timing of this manoeuvre. The standard, as agreed by [Dr B's independent expert] in his submission, requires that the patient be either upright or in the left lateral position during an instillation of this type.

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Opinion – Case 98HDC17069/VC, continued

Further Advice to Commissioner *continued*

- 11. Dr [B], the nursing staff, [the Public Hospital] and [Mr and Mrs A] have all agreed that Dr [B] and the nurses left the hospital during the active resuscitation efforts for [Master A] and prior to his death. However, there is a duty of care required by all clinical staff involved in the care of a patient to ensure that the events, information and interventions that were undertaken under their authority have all been fully and duly recorded. In this regard, they must ensure that if they do not write the 'record of events' themselves, that someone is authorised to do so in their This did not take place. The enormity of the place. circumstance these clinicians found themselves in having a child deteriorate to the point of respiratory/cardiac collapse is appreciated. However, the standard of care in New Zealand does require this level of documentation. As registered health professionals this is a required standard. Further, Mr [A] has recorded that he alerted the nursing staff to the fact that [Master A] had turned blue around the mouth and white in the face and did not appear to be breathing – not Staff Nurse [D]. Given the events of the time, who called the alert is of lesser importance than the rapidity of response to the alert. In this regard, Staff Nurse [D] carried out a rapid, appropriate and immediate response.
 - 12. [The Public Hospital] advise that Dr [B] did address [Mr and Mrs A], prior to leaving the hospital during [Master A's] resuscitation attempt. This is corroborated by [the] Charge Nurse [...], who accompanied him and noted that 'he informed them of the gravity of the situation, and that he didn't understand what had gone wrong. He had given them as much explanation as he was able to at that stage'. Therefore, it cannot be said that Dr [B] breached the standard required in this regard.

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Opinion – Case 98HDC17069/VC, continued

Further Advice to Commissioner <i>continued</i>	13.	The nursing staff consulted the policy provided by [the Public Hospital] regarding the management of Paracetamol elixir ingestion in a child. This policy followed the existing guidelines of the New Zealand Poison's Centre of the time. Therefore, [the Public Hospital] met the existing standard of the time.
	14.	There is no current policy standard in New Zealand requiring explicit guidelines, protocols or intervention standards nationally or locally, with regard to:
		• The technique for placement of nasogastric tubes or other significant invasive interventions;
		• The technique for restraining of children, or other patients, clients who require it;
		• The credentialing of clinical personnel in the performance of these techniques;
		• The nature of, and type of information suitable to adequately inform, but not to frighten or threaten, families or patients with regard to prognosis and options for management;
		• The agency, group, health professionals, responsible for updating emergency medicine medical and nursing practitioners throughout the country; the timing of the updating; and the form of the updating, for the management of acute poisoning and many other common problems/conditions;
		• The standard and nature of clinical documentation required in Emergency Department attendances;
		• The standard and nature of clinical history and physical assessment required for patients presenting requiring urgent intervention need/rescue;

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Opinion – Case 98HDC17069/VC, continued

Further Advice to Commissioner *continued*

- The standard and content of clinical documentation required in Emergency Department attendances;
- The standard, nature of, and appropriateness of information required to be provided by clinicians to family/whanau/patients in order to obtain consent for procedural interventions;
- The standard for available current textbooks, on-line evidence-based information, instruction, algorithms and current periodicals that all Emergency Departments should be able to locally access to provide the 'decision-thinking and making' support required by medical and nursing practitioners in order to provide evidence-based acceptable standards of care.

Conclusion

The development of a provisional report by the Health and Disability Commissioner in this case enabled further either unavailable or unconsidered necessary information to be reviewed. This material provided assistance in uncovering the nature of the circumstances involved in the presentation, treatment and subsequent death of [Master A].

What is most obvious at this point is the paucity of approved, nationally consistent and evidence-based acceptable standards for provision of care to patients/family/whanau within Emergency Departments in New Zealand.

As has become obvious in this further report, the only standard that could be considered in possible breach was the delayed documentation of events. Additionally, the positioning of [Master A] during the instillation of the charcoal is questionable as to the actual timing of this manoeuvre.

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Opinion – Case 98HDC17069/VC, continued

Further Advice to Commissioner *continued* From the documentation perspective, given the circumstances and the reasons for the delay and given the fact that no major errors of record resulted, it is difficult to be firm on this point. There are certainly times, in every Emergency Department medical and nursing career, where the timely completion of notes takes second place to the immediacy of the problems at hand.

At this point, I believe it is essential to raise the issue of 'who takes responsibility for ensuring that clinicians have access to evidence-based knowledge regarding the most appropriate therapeutic management for particular conditions when it becomes available or when standard practice is questioned as appropriate?'

As noted at the beginning of this report – the position statement on single-dose activated charcoal was published by two major standards-setting international organisations in 1997. Whilst the content of the statement is available piece-meal in other formats, the existence of it - and intent of the information provided, was not known to myself until just recently (May 2000).

This statement indicates that provision of single-dose activated charcoal later than one hour may be of only minimal if any benefit to patients following acute poisonous ingestions. Yet, the Poisons Centre's guidelines continued to indicate the provision of this therapeutic agent 2 to 4 hours post ingestion as the standard. Knowing that the agent is highly unlikely to be of significant benefit more than one hour post toxic ingestion, particularly of a substance such as Paracetamol, may bring an element of reconsideration to undertake an invasive procedure into a clinician's deliberation. It also introduces options for patients and families as there is a very good available antidote.

Information such as provided in the Position Statement, is acceptable from an evidence-based evaluation and should be influencing Poisons Centres and Emergency Department health professionals much sooner that the almost three years it has taken to date to filter down.

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Opinion – Case 98HDC17069/VC, continued

Further Advice to Commissioner *continued* As a result, I would strongly advise the Commissioner to be proactive in raising this issue regarding ensuring access to nationally consistent standards. The Commissioner could consider approaching Government, the Policy Agency and District Health Boards to ensure that there is some organisation or individual accountable for the development, dissemination and introduction of national standards. Hopefully such advice would ensure the adoption of a rational framework for the future to enable appropriate and rapid availability of evidence-based standards for assessment, diagnosis and therapeutic management of acute emergency department patients.

By this means, we can begin to eliminate potential and real 'flaws' in the system of Emergency Medical Care provided to patients in New Zealand.

As noted in a recent book and report by the Institute of Medicine in the United States: 'To Err is Human', we need supportive systems to assist teams of qualified and competent health professionals in order to begin to reduce the incidence of human errors in the delivery of health care to patients/families/whanau."

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Opinion – Case 98HDC17069/VC, continued

Code of Health and Disability Services	The following Rights in the Code of Health and Disability Services Consumers' Rights are applicable to this complaint:
Consumers'	RIGHT 4
Rights	Right to Services of an Appropriate Standard
	 Every consumer has the right to have services provided with reasonable care and skill. Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.

3) Every consumer has the right to have services provided in a manner consistent with his or her needs.

RIGHT 6

Right to be Fully Informed

- 1) Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including ...
 - b) An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; ...
- 2) Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent.

RIGHT 7

Right to Make an Informed Choice and Give Informed Consent

1) Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.

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Opinion – Case 98HDC17069/VC, continued

Other Standards	'Cole's Medical Practice in New Zealand' – The Medical Council of New Zealand
	Privacy Matters: The Medical Record (p 88)
	"[N]ever add a late comment, or record an event out of time without making a note that this is the case; while there may be a good reason to do it, it can be interpreted as deceitful."
	'Nasogastric Intubation (Document Z405)' – National Poisons Centre
	 Preparation Child The parent(s) or caregiver should have the procedure fully explained, especially if they are to assist or remain in the room during the procedure. The child must be firmly held or wrapped in a sheet to keep their arms/hands out of the way. Prior to attempting tube placement the length of tube required should be determined. The tube is measured against the patient from the corner of the mouth, over the ear, and down to the xiphoid process. It is useful to mark the correct length with a piece of tape.
	Patient Position Tube placement in children is best undertaken with the child sitting or semi-reclined (30-45° angle) with the head supported.
	Technique The lubricated tip of the tube is placed into the nose and gently passed via

The lubricated tip of the tube is placed into the nose and gently passed via the nasopharynx to the oesophagus. It may be useful to allow the patient to swallow water to assist the passage of the tube into the oesophagus. The tube should be passed quickly into the stomach up to the desired length. The correct placement of the tube should be ascertained by checking the pH of a small amount of aspirate. Alternatively a small amount of air (2mls) may be introduced via the tube while listening to the stomach with a stethoscope. Gastric placement is confirmed if gurgling is heard. Children should be closely observed for the onset of cyanosis, gagging, vomiting etc. Secure the tube to the nose with adhesive tape."

²⁸ September 2000

Opinion – Case 98HDC17069/VC, continued

Opinion:	Right 4 (2)
Breach	Patient position for nasogastric intubation
Dr B	The relevant guideline entitled 'Nasogastric Intubation' (document Z405,
	dated 26 September 1997) supplied by the National Poisons Centre to the
	Public Hospital and used as a basis for the Public Hospital's protocol
	'Gastrointestinal Decontamination (Children)", in operation from October
	1996, states under the heading 'Patient Position', that "tube placement is
	best undertaken with the child sitting or semi-reclined (30-45° angle) with
	the head supported".

Dr B administered the charcoal, via a nasogastric tube, to Master A while he was in a supine position. This was a clear breach of the guideline used as a basis for the protocol in place at the Public Hospital at the relevant time. I note that the Coroner stated that "[*i*]t seems possible that the nature of the treatment itself, and the unnatural presence of a tube in his oesophagus and at the entry to his stomach could have been factors in the loss of stomach contents into his oesophagus and the draining of the stomach contents into his larynx" (para 57, quoted at p 13, above).

Mr and Mrs A's expert stated that "[b]y having [Master A] in a supine position throughout the installation of charcoal via the nasogastric tube, Dr [B] failed to fulfil his duty of care to [Master A]" (p 29, above). Although, after much deliberation, I have not found that Dr B failed to exercise reasonable care and skill in treating Master A (and therefore did not breach Right 4(1)), in my opinion Dr B did breach Right 4(2) by his failure to comply with a relevant standard.

I note that my independent adviser on emergency medicine, in the original advice, stated that "[Master A] was kept flat and horizontal when it is well recognised that placement should be head and shoulders up (as least thirty degrees) [or] left lateral position" (p 38; above, correction added). In the further advice provided after reviewing the responses to the provisional opinion, my independent adviser maintained that "The positioning of [Master A] during the installation of the charcoal is questionable" (p 80, above).

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Dr B

A Public Hospital / Dr B / SN C / SN D / Master A

Opinion – Case 98HDC17069/VC, continued

Opinion: It is no answer to say, as the Public Hospital did in its response to my Breach provisional opinion, that "It is unlikely that [Master A] would have cooperated with sitting up" (p 47, above). The gist of the defence provided on behalf of Dr B and the Public Hospital, in relation to the decision to continued administer charcoal, and the method of nasogastric intubation adopted, was that this complied with accepted practice in New Zealand at the relevant time. It is inconsistent with that line of defence to seek to excuse non compliance with the recommended National Poisons Centre 'Patient Position' guideline used as a basis for the relevant protocol in operation at the Public Hospital in April 1998.

For these reasons, in my opinion Dr B breached Right 4(2).

Record Keeping

Dr B failed to complete his notes as soon as was practicable after Master A's death. Instead Dr B left the Public Hospital and went home before returning to complete the notes. These notes have no annotation to indicate that they were recorded out of time. This is a breach of the guidelines published by the Medical Council of New Zealand in 'Cole's Medical Practice in New Zealand'. In my opinion, in failing to comply with professional standards, Dr B breached Right 4(2).

Rights 6(1)(b), 6(2) and 7(1)

Having carefully reviewed all the evidence and considered the independent advice I received, I have concluded that Dr B breached Rights 6(1)(b), 6(2) and 7(1) of the Code. In my opinion reasonable parents in Mr and Mrs A's situation would expect to receive information about the potential risks of the paracetamol ingestion, the risks associated with nasogastric tube insertion, and any other options available.

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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 – Case 98HDC17069/VC, continued

Opinion:	Dr B did not inform Mr and Mrs A of the potentially life threatening
Breach	complication of charcoal entering the lungs and failed to allow them a
Dr B	reasonable opportunity to consider the risks and benefits of the procedure.
continued	In Dr B's own words at the Coroner's inquest:
	-

"... in retrospect I wish I had balanced the risk of the procedure with the risk from paracetamol accidental ingestion and really helped them to make the decision. I guess I was driven by the way we treat paracetamol poisoning from a variety of sources. I meant medical information."

At the heart of the Code of Rights is the statement in Right 6(1)(b) that a consumer has the right to receive the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including an assessment of the expected risks. The standard for disclosure is patient-centred; what a reasonable consumer in a similar situation would expect.

I note that my independent advisor on emergency medicine stated (p 36, above) that "[a]ll medical professionals working in Emergency Departments are aware of the possibility of aspiration of charcoal subsequent to nasogastric installation of the formulation". Although my adviser subsequently stated that "a body of clinicians, undertaking this treatment, would have been unlikely to comment on the possibility of death by aspiration", conforming with the practice of even a responsible body of medical opinion (the Bolam test) will not necessarily satisfy the information disclosure requirements of Right 6(1). As noted by Elias J in B v Medical Council (HC 11/96, Auckland, 8 July 1996), in the context of medical disciplinary proceedings, "[i]n the case of adequacy of communication to the patient, however, wider consideration are relevant".

I note that even Dr B's independent expert acknowledged "serious shortcomings in Dr [B's] communication <u>before</u> and after the event" (p 57, above; underlining added).

Continued on next page

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Dr B

A Public Hospital / Dr B / SN C / SN D / Master A

Opinion – Case 98HDC17069/VC, continued

Opinion: I accept that Dr B was faced with a difficult and potentially life-Breach threatening situation. However, there was sufficient time to explain not only the rationale for charcoal treatment, but also the associated risks, and the option of waiting until four hours post-ingestion of the Paracetamol, to continued check the blood Paracetamol level and commence N-Acetyl Cysteine if necessary. Mr and Mrs A were deprived of the opportunity to weigh the options and make their own decision. It is no answer to say that they may well have asked Dr B to proceed to administer the charcoal even if they had known of the associated risks.

> In my opinion Mr and Mrs A were given insufficient information to make an informed choice and to give their informed consent to the administration of charcoal, and therefore Dr B breached Right 6(1)(b), Right 6(2) and Right 7(1) of the Code.

²⁸ September 2000

Opinion – Case 98HDC17069/VC, continued

Opinion: No Breach Dr B In my opinion Dr B did not breach Right 4(2) or Right 4(3) of the Code of Health and Disability Services Consumers' Rights in the following respects:

Right 4(2)

Subject to my comments above in relation to Master A's supine position, I accept that Dr B made a decision to administer charcoal via a nasogastric tube, and inserted the tube, in accordance with guidelines which he understood to be safe and effective. After reviewing the statements provided in response to my provisional opinion my independent advisor on emergency medicine conducted a review of nationally and internationally recognised good practice guidelines. My advisor found that Dr B's administration of charcoal, installation of the nasogastric tube, and monitoring of the treatment complied with current New Zealand practice but did not comply with internationally recognised good practice guidelines. Although the National Poisons Centre had developed guidelines that were consistent with international good practice, they had not been widely disseminated.

While Dr B's insertion of the nasogastric tube was flawed and may have contributed to Master A's death, it is not appropriate to blame Dr B for the method he used to insert it, subject to my comments above in relation to Master A's supine position. I accept that, with this exception, the services Dr B provided to Master A complied with professional standards in New Zealand at the time, and did not breach Right 4(2).

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Opinion – Case 98HDC17069/VC, continued

Opinion: No Breach Dr B *continued* Dr B failed to perform a targeted history and physical examination prior to undertaking care of Master A and, in particular, care involving the performance of an invasive therapeutic intervention. However, my advisor on emergency medicine informs me that, in situations where a patient requires urgent care, failure to conduct a targeted history and physical examination may be excused. In this situation I accept that the potential size of the overdose and the short timeframe to ensure efficacy of the treatment indicated urgency to Dr B. Dr B undertook a brief physical assessment of Master A which included identifying any immediate threats to life, establishing a baseline clinical status, corroborating the patient's history, identifying intoxication syndromes and identifying possible complications. I accept the advice of my advisor that Dr B's examination of Master A complied with professional standards and did not breach Right 4(2).

Right 4(3)

In my opinion Mr and Mrs A were entitled to an explanation of what had occurred once things went wrong. Dr B spoke to Mr and Mrs A in the company of the charge nurse while the resuscitation team attempted to resuscitate Master A. At this time Dr B explained the gravity of the situation and stated he did not know what had gone wrong. While this explanation was short, I accept that Dr B provided Mr and Mrs A with as much information as he was able at the time. Therefore, in my opinion, Dr B provided a service in a manner consistent with Mr and Mrs A's needs and did not breach Right 4(3).

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Opinion – Case 98HDC17069/VC, continued

Actions: Dr B I recommend that Dr B:

- Apologise in writing to Mr and Mrs A for breaching the Code of Health and Disability Services Consumers' Rights. This letter should be sent to this office and I will forward it on.
- In future informs and involves consumers in the decision making process prior to providing treatment, including describing the expected risks, side effects and benefits of each option and obtaining the consumer's informed consent prior to the provision of a health service.
- In future completes his notes relating to treatment as soon as possible after the treatment has been provided.

²⁸ September 2000

Opinion – Case 98HDC17069/VC, continued

Opinion: Breach SN C and SN D	SN C and SN D failed to complete their notes as soon as was practicable after Master A's death. Instead they left the Public Hospital and went home before returning approximately eight hours later. At this time SN C signed the notes he had written that morning and SN D completed her notes. These notes have no annotation to indicate that they were recorded or signed out of time. It is reasonable to expect that notes are recorded at the same time or shortly after the events they record. My advisor informed me that SN C did not meet professional standards of nursing practice by failing to sign his notes until eight hours after Master A's death and SN D did not meet professional standards of nursing practice by failing to write her notes at the time of events, or annotate that they were not contemporaneous. I accept the advice of my nursing advisor. In my opinion SN C's and SN D's failure to record their involvement in Master A's treatment breached professional standards and therefore breached
	Right 4(2).

Rights 6(1)(b), 6(2) and 7(1)

No Breach SN C and SN D Nursing staff have a legal duty under the Code to ensure consumers are supplied with information regarding a procedure and what it entails. Guidelines provided by the National Poisons Centre indicated that the recommended course of treatment for paracetamol overdose was providing a dose of activated charcoal. The guidelines did not mention alternative treatments. SN C discussed the administration of activated charcoal with the A family during the set-up period. SN D spent time reassuring Mr A as he became distressed during the early part of the procedure.

In my opinion, responsibility for disclosure of the risks of charcoal treatment to Mr and Mrs A lay with Dr B, as the medical officer overseeing Master A's care, and not with SN C and SN D. I accept the advice of my independent nursing advisor that "... *it is not the nurse's responsibility to ensure consent for procedures to be carried out by another professional*" (p 67, above).

Therefore, in my opinion SN C and SN D did not breach Right 6(1)(b), Right 6(2) or Right 7(1).

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Opinion:

Opinion – Case 98HDC17069/VC, continued

Right 4(2)
I accept the advice of my independent nursing advisor that SN C and SN D met professional standards of nursing in the restraint, assessment and monitoring of Master A while he was receiving charcoal via the nasogastric tube. The restraint technique used by SN C and SN D was in line with current New Zealand practice. While it appears that this practice is flawed and may have contributed to Master A's death, it is not appropriate to blame the nurses for its use. SN C and SN D adhered to a practice that they understood to be safe and effective.
Therefore, in my opinion, SN C and SN D complied with professional standards and did not breach Right $4(2)$.
Right 4(3)
Once the resuscitation team took over the care of Master A, SN C and SN D left the hospital and went home. In my opinion Mr and Mrs A were entitled to an explanation of what had occurred. Dr B spoke to Mr and Mrs A in the company of the charge nurse while the resuscitation team attempted to resuscitate Master A. I accept that before leaving SN C and SN D obtained the consent of the charge nurse who took on the responsibility of communicating with the family. Therefore, in my opinion, SN C and SN D provided a service in a manner consistent with Mr and Mrs A's needs and did not breach Right 4(3).
I recommend that SN C and SN D:In future complete their notes relating to treatment as soon as possible after the treatment has been provided.

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Opinion – Case 98HDC17069/VC, continued

Opinion:	Right 4(2)
No Breach	Direct Liability
The Public	Subject to my comments above in relation to Master A's supine position,
Hospital	while the policies and procedures in use at the Public Hospital have
	subsequently been shown to be inadequate, I accept that they complied
	with accepted practice in New Zealand in April 1998. While that practice
	was flawed and may have contributed to Master A's death, it is not
	appropriate to blame the Public Hospital for following it. The Public
	Hospital adopted a protocol that it understood to be safe and effective.
	Therefore, in my opinion, the Public Hospital complied with relevant
	standards and did not breach Right 4(2).

Rights 4(2), 6(1)(b), 6(2) and 7(1)

Vicarious Liability

Employers are vicariously liable under section 72 of the Health and Disability Commissioner Act 1994 for ensuring that the Code is complied with. Under section 72(5) it is a defence for an employing authority to prove that it took such steps as were reasonably practicable to prevent the employee from doing or omitting to do the thing which breached the Code.

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Opinion – Case 98HDC17069/VC, continued

Opinion: No Breach The Public Hospital <i>continued</i>	I accept that the Public Hospital had taken such steps as were reasonably practicable to ensure that all health professionals it employed were aware of, and complied with, their duties in relation to information disclosure and consent, and record keeping. Accordingly, in my opinion the Public Hospital is not vicariously liable for Dr B's breach of Rights 6(1)(b), 6(2) and 7(1), nor for Dr B's, SN C's and SN D's breach of Right 4(2).
Actions: The Public Hospital	 I recommend that the Public Hospital: Apologise in writing to Mr and Mrs A for breaching the Code of Health and Disability Services Consumers' Rights. This letter should be sent to this office and I will forward it on. Reviews its protocols on gastrointestinal decontamination and nasogastric tube intubation and ensure that all relevant staff receive training in relation to the protocols.
Other Actions	I endorse my emergency medicine specialist's recommendations in relation to the need to develop and disseminate nationally consistent evidence-based standards for the assessment, diagnosis and therapeutic management of Emergency Department patients. A copy of this report will be sent to the National Poisons Centre, the Director-General of Health, the Nursing Council of New Zealand and the Medical Council of New Zealand.

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