Medical Officer, Dr B

An Accident and Medical Clinic

A Report by the

Health and Disability Commissioner

(Case 06HDC12322)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Mr A	Consumer/Complainant
Dr B	Provider/Medical officer
Ms C	Registered nurse
Dr D	Medical officer
Dr E	Medical officer
Dr F	Medical officer
Dr G	Clinical Services Manager, Accident and Medical Clinic Company
Dr H	General Manager, Accident and Medical Clinic Company
An Accident and Medical Clinic	Accident and Medical Clinic/Clinic
Accident and Medical Clinic Company	The Company

Complaint

On 18 August 2006, the Commissioner received a complaint from Mr A about medical treatment provided by Dr B. The following issues were identified for investigation:

- *The appropriateness of the treatment and care Dr B provided to Mr A on 6 August 2006.*

- *The appropriateness of the treatment and care that an Accident & Medical Clinic provided to Mr A on 6 August 2006.*

An investigation was commenced on 17 October 2006.

Information reviewed

Information from:

- Mr and Mrs A
- Dr B
- Ms C
- Clinical Director, Accident and Medical Clinic
- Dr G, Clinical Services Manager, Accident and Medical Clinic Company
- The Accident and Medical Clinic

Independent expert advice was obtained from Dr Stephen Adams, an accident and medical practitioner.

Information gathered during investigation

Background

The Accident and Medical Clinic

This is a very busy Accident and Medical Clinic close to a major shopping centre in a city. According to their website they treat approximately 75 patients per day and provide "comprehensive medical and nursing services for Accidents (including plastering) and Emergency Medical cases".

Dr B

Dr B had been a medical officer at the Accident and Medical Clinic since May 2006, having qualified as a doctor overseas. She had previous experience in emergency medicine (in her own country) from August 2003 until December 2005. While at the Accident and Medical Clinic she was clinically supervised by Dr D and Dr E. Dr H, the General Manager, stated that Dr B's orientation included "familiarisation with patient record systems and responsibilities of the doctor in keeping full and adequate records".

The New Zealand Medical Council's website gives information on the scope of practice of medical practitioners in New Zealand. The entry for Dr B states:

> "[Dr B] is permitted to practise medicine in the position of Medical Officer in Accident & Medical Practice at [the] Clinic under the supervision of Dr E between 26 September 2006 and 31 May 2007.
>
> The purpose of this registration is to enable [Dr B] to complete Council's requirements for registration within the general scope."

Chronology

On 6 August 2006, Mr A (aged 40 years) took Paramax tablets for a headache.[1] He stated:

> "Soon after [taking Paramax], my tongue started to swell. My wife drove me to [the clinic]. I walked into the clinic and my wife explained to the staff what had happened.
>
> She also explained to the doctor/s that I had previously experienced a similar incident when injected with Stemetil,[2] and that the doctor in that case gave me an antidote."

Registered Nurse (RN) Ms C was on duty. She stated:

> "At approximately 11.35am I overheard [Mr A] inform the receptionist he was experiencing an allergic reaction to some medication he had taken. I immediately took him and his partner to the [resuscitation room] and started a triage assessment. I left the room briefly and called [Dr B]. [Mr A] explained he had taken Paramax for a headache from his wife's prescription and was allergic to Maxolon. He was short of breath and his tongue was blue and swollen plus he was highly agitated. [Dr B] was in the room within minutes and immediately started her assessment."

In response to the provisional opinion, Mr A stated that the Paramax had been bought over the counter, and was not from his wife's prescription. He added that he was aware that he was allergic to Stemetil, but not Maxolon, and that if he had known that Paramax was related to Stemetil, he would not have taken it.

Dr B stated:

> "[Mr A] had a swollen and blue tongue, blue lips and had difficulty breathing. He could not lie flat on his back and I lifted the bed up to 45 degrees. As the clinic's pulse oximeter was out for repairs, I could not check [Mr A's] oxygen saturation. His respiratory rate was 20 [breaths] per minute, pulse rate 140 beats per minute (regular) and blood pressure was 180/90mmHg. His chest was clear. My assessment led me to believe that he was in the midst of an anaphylactic [allergic] reaction. I put up oxygen [via a] face mask at 8L/min with the help of [Ms C]."

[1] Paramax is prescribed to treat pain that is accompanied by nausea and vomiting. It contains the drugs paracetamol and Maxolon (metoclopramide hydrochloride).
[2] Stemetil (prochlorperazine): prescribed to treat nausea.

The clinical record completed by Dr B states "central cyanosis" and "[oxygen] saturation monitor not working". No record was made of shortness of breath or agitation.

In response to the provisional opinion, Dr H, General Manager, stated:

> "[The Company] has always required pulse oximeters to be a standard piece of equipment present in its clinics. This was the case at [the Clinic] on the day of August 6 2006 when [Mr A] was seen. However the pulse oximeter had been noted to be faulty earlier during that morning. As a result [the] (General Manager Nursing) had requested the backup pulse oximeter (located at [another] clinic) to be transported to [the Clinic]. Unfortunately it did not arrive at [the Clinic] till later in the same day."

Adrenaline — first dose
According to the clinical record, Dr B administered 1mg adrenaline[3,4] subcutaneously (SC) at 11.40am. Ms C witnessed the administration into Mr A's arm. However, in a subsequent letter dated 1 September 2006, Dr B stated that she administered only 0.5mg.

Hydrocortisone
Ms C said that the next drug to be administered was 200mg of hydrocortisone,[5] given intravenously (IV) by Dr B. The clinical record describes the dose and the route of the hydrocortisone, but the time of administration was not recorded.

Phenergan
Dr B stated that she "ordered … 25mg of Phenergan[6] IM [intramuscularly] to be given" after the first dose of adrenaline. However, Ms C said she saw Dr B administer 25mg Phenergan as a bolus IV dose after the second dose of adrenaline. The clinical record states that 25mg of Phenergan was given IV, but the time was not recorded.

Adrenaline — second dose
According to the clinical record, 1mg of adrenaline was given IV at 11.45am. Dr B subsequently stated that she gave 1ml of a diluted solution of 1mg (in 1ml) of adrenaline and 9ml of saline (made up by Ms C); by giving 1ml of the diluted 10ml solution, a dose of 0.1mg of adrenaline would have been given. Ms C witnessed this

[3] Adrenaline: prescribed for the treatment of allergic reactions. Also used in the management of cardiac arrest.
[4] The clinical record states: "Adrenaline 1/1000:L 1ml sc at 11h40, then 1ml IV at 11h45, then 1ml IV at 12h00." 1ml of 1/1000 adrenaline equates to a dose of 1mg of adrenaline.
[5] Hydrocortisone: a steroid given to treat the symptoms of an allergic response.
[6] Phenergan: prescribed to treat symptoms of allergic reaction, including conditions of the skin (such as itching) and breathing difficulties.

administration, and confirmed the dilution. She stated that the adrenaline was given as a "slow IV bolus", which took one to one and a half minutes to give. However, she did not note whether more than 1ml of this diluted solution was given, and she cannot recall what volume remained in the syringe when she discarded it. Dr B stated that she prescribed the second dose of adrenaline as there had been no improvement in Mr A's condition since the previous dose (given five minutes earlier). This lack of improvement was not recorded.

Dr B decided that Mr A should be admitted to hospital, and Ms C left the room to arrange an ambulance.

Adrenaline — third dose
Ms C stated that, at Dr B's request, she made up another syringe of 1mg (in 1ml) adrenaline diluted with 9ml of saline. Dr B stated that she administered 1ml of this solution, meaning 0.1mg of adrenaline would have been administered. Ms C did not witness the administration. According to the clinical record, 1mg of adrenaline was administered IV at 12.00pm.

Ms C stated that Mr A had stabilised by this stage, "and his cyanosis had decreased and his tongue appeared to be less swollen". She stated:

> "I then started another set of observations on the patient but was interrupted by the arrival of the ambulance officers. At this stage no … notes had been written so [Dr B] quickly wrote up the notes as I handed over [Mr A] to the waiting ambulance staff."

The transfer letter written by Dr B sets the clinical notes in the format of a headed letter. The only additional clinical information states: "Thank you for seeing [Mr A] who has anaphylaxis." The letter was signed "Kind regards … [Dr B]".

Mr A's blood pressure was found to be low on arrival in hospital, and he was admitted under the care of the cardiology team. The clinical summary written on his discharge from hospital on 9 August stated:

> "Primary Diagnosis
>
> — Myocardial infarction due to coronary artery spasm.
>
> …

> Raised TnT[7] and ECG changes probably caused by coronary artery spasm due to adrenaline administration 1mg x 3."

Related issues

Dr F

Mr and Mrs A said that Dr B consulted with another doctor during Mr A's treatment. They recall the doctor as a male of non-European extraction, and older than Dr B. Mr A and his wife recall that there was a discussion between Dr B and this other doctor about his care, in particular in relation to the administration of adrenaline and Phenergan. Mrs A believed that the doctor was a Dr F, as she had obtained a prescription from him in the past, and this was the name and the initial of the prescribing doctor on the bottle dispensed. According to information provided by the Clinic, Dr F was the only other doctor on duty when Mr A was admitted.

Ms C recalls that Dr F "came in several times to the room … to see whether we needed any assistance". She stated that Dr B and Dr F did discuss Mr A's care, but she cannot recall any details of the discussion.

However, Dr F does not recall being involved in Mr A's care. Dr B advised:

> "I was attending to [Mr A] in the resuscitation room when I asked the nurse to ask [Dr F] to help me with the resuscitation. I described [Mr A's] history to [Dr F] and explained the examination findings. He then helped me to administer the oxygen to [Mr A]. We did not discuss the adrenaline or Phenergan dose. [Dr F] then resumed his duties with other patients."

Internal investigation

As a result of [Mr A's] complaint, an internal investigation ("Sentinel Event Review #7") was performed by Dr G, Clinical Services Manager.

Dr G stated that she was provided with a statement from Ms C. However, this statement (unlike that supplied to my Office) did not state that Ms C witnessed the initial dose of 1mg adrenaline, and the IV administration of 25mg Phenergan. In the absence of Ms C's witnessed account, Dr G accepted Dr B's subsequent account that 0.5mg adrenaline had been given as a first dose, and that 25mg Phenergan had been given intramuscularly.

Ms C said that the statement that she initially provided to the internal investigation had been returned to her for further clarification. She then added the statements that she had witnessed the adrenaline and the Phenergan being given. She passed her

[7] TnT (Troponin T). A raised blood level of TnT indicates that there has been damage to the heart muscle.

second statement to her manager, expecting it to be made available to the internal investigation, and this was the statement provided to my Office.

In response to the provisional opinion, Dr H, General Manager stated:

> "An inquiry was held by the [Company's] Clinical Governance Board into why the clarified written statement by [Ms C] was not supplied to Dr G to use as part of the internal investigation. This appears to have been a simple error. [The Clinical Director] from [the Clinic] did not pass this second statement from Ms C to the [Clinical Governance Board] until much later in the investigation as he had supplied it to the investigator in question and simply believed he had already supplied it to the CGB. The inquiry recommended the implementation of a document checklist held by the CGB investigating doctor to record all documents pending for any inquiry. This checklist has been compiled and actioned."

Dr G's report was forwarded to Dr H.

The recommendations from the investigation were as follows:

> "**General:**
>
> 1. Ensure all doctors/nurses coming directly from another health system e.g. [from another country] to [the Accident and Medical Clinic Company], have completed an ACLS [advanced cardiac life support] update on or shortly after commencement of work at the [Clinic] setting.
>
> 2. Recommend all doctors/nurses coming in from another health system have completed an ACLS update within the year prior to their arrival in New Zealand.
>
> 3. Formulate recommendations for doctors when writing urgent referrals prior to transfer, to ensure accuracy of the record.
>
> **Specific:**
>
> 4. Organise … a 16 hr, 2 day ACLS update for [Dr B]: **Organised**
>
> 5. Review the [Clinic] Anaphylaxis Protocol with [Dr B]: **Pending**
>
> 6. Ensure regular meetings between supervisor and [Dr B]. In particular to discuss treatment protocols in the [Clinic] setting: **Organised**."

Cooperation with investigation
On 23 November 2006, Dr B was contacted to arrange an interview. She stated that she was leaving the country on Sunday 26 November 2006, advising that she would

not be returning for at least six months. Dr B was unable to arrange for legal representation to support her prior to her departure, but she provided an email address through which she could be contacted. No prior notice had been given to my Office that Dr B was leaving the country, including in the written response she sent on 17 November 2006.

Protocols
[The Clinic] provided a copy of the protocol used for the management of patients admitted with anaphylaxis. This protocol sets out the prescribing of adrenaline, and states that subcutaneous administration is "not recommended". In relation to the dose, the protocol states:

> "**IM:** …
>
> **Adults** 0.3–0.5mL (0.3–0.5mg) of 1:1000 solution; administer fraction of total dose (0.1–0.2mL) at site of antigenic exposure, if accessible, and 0.3mL into different extremity (thigh muscle is preferable); Max adult dose **0.3–0.5mg**.
>
> **IV: Note: Never give IV adrenaline bolus except in arrest situation; adrenaline infusion should be used only in severe anaphylaxis with a non-responsive hypotensive, refractory patient in a fully monitored situation.** … **Max dose IVI is 100ug."**

The protocol states in relation to the prescribing of Phenergan:

> "**Adult Dose**: 6.25–25mg slow IV (beware hypotension) … IV rate not to exceed 2mg/min."

Independent advice to Commissioner

The following expert advice was obtained from Dr Stephen Adams:

> "I have been asked to provide an opinion to the Commissioner on case number 06/12322.
>
> I declare that I have read and agree to follow the 'Guidelines for Independent Advisors'.
>
> In preparing independent advice on this case, to my knowledge I have no personal or professional conflicts of interest.

My qualifications are BHB, MBChB (Auckland 1982), DipAnaes (UK), FAMPA. My training includes Registrar Positions in Anaesthesia, Emergency Medicine and General Practice. I am currently Senior Lecturer in Community Emergency Medicine at Auckland University. I work clinically for the Royal New Zealand Navy in Accident and Medical Practice and in Emergency Medicine at North Shore Hospital.

[Here, Dr Adams sets out the questions asked of him. As he repeats these questions in the body of his report, they have been omitted at this point for the sake of brevity.]

…

1. **Please comment generally on the care provided to [Mr A] by [Dr B]**
   Reading the supplied statements there are several differences between the accounts of the patient, the doctor's notes, the doctor's later recollections, the nurse and the later clinic investigation of what occurred in which some corrections to the notes were suggested. Where there are differences in the account I have used parentheses.

   While it is expected that in an emergency situation there may be differences of perception and errors/omissions in note/ record keeping I thought the variance in the original notes, later statements to the board of [the Company] and the nurse's statement over several issues of fact (adrenaline dose, Phenergan route of administration) to be of concern.

   According to the three accounts the patient presented with an abnormal tongue (swollen or blue or both) after taking Paramax which contains paracetamol and metoclopramide. The nurse's notes state that [Mr A] said he was having an allergic reaction, and that he knew he was allergic to metoclopramide. [Mr A's] letter says he had a similar reaction in the past to Stemetil (prochlorperazine) for which he was given an antidote.

   His HR [heart rate] was noted to be 140, his blood pressure 180/90.

   He was (or was not) in respiratory distress.

   There was no skin rash or wheeze.

   The initial diagnosis was anaphylaxis.

   No differential was noted at this time but might have included angio-oedema (isolated swelling of the tongue and throat) and an acute tongue dystonia both of which may look like early anaphylaxis.

He was given one dose of adrenaline (0.5 or 1.0 mg) subcutaneously and two doses (0.1 to 1mg each) intravenously, then 25mg promethazine (intravenously or intramuscularly) and 200mg hydrocortisone intravenously.

There was a single further observation of 'heart rate 120, respiratory rate 16, no wheeze and cardiovascularly stable' before he was transferred to [hospital] by ambulance.

At the time of arrival there he became hypotensive. Nonspecific inferolateral ECG changes, an elevation of serial Troponin T levels and an echocardiogram showing abnormalities of ventricular function led to a diagnosis of myocardial infarction. Coronary angiography showed a small diagonal branch with ostial stenosis.

Serum tryptase and a complement screen were taken to investigate the cause of the presumed drug reaction that initiated this encounter. The results of these are not available to me. Other documents that might have been useful in formulating this opinion are the referral letter to the Medical Registrar and the original notes of the admitting Medical Registrar.

Based in these accounts [Mr A] had prompt treatment for what was considered at the time a medical emergency although the patient's recollection suggests the severity was not as great as that perceived by the clinic staff and that in particular he did not experience respiratory distress.

The initial diagnosis was reasonable although in [Mr A's] letter he said he had been given an antidote in the past and later that there was no need for adrenaline — it is not clear if he knew or imparted the second piece of information at the time.[8] If so it should have raised the possibility of other diagnoses including angio-oedema (isolated tongue/mouth swelling) or an acute dystonia (muscular spasm) of the tongue, both of which may present in this way and mimic anaphylaxis (Ref 5).

There are no generally accepted clinical criteria conclusively diagnosing or excluding early anaphylaxis although any combination of rash, hypotension, airway obstruction asthma and gastrointestinal symptoms raises a strong probability (Ref 6). In the absence of hypotension or rash the decision to give adrenaline should have been made on either respiratory obstruction (which he

[8] Commissioner's note: Mr A stated in response to the provisional opinion:

> "[Regarding] your query ... that in my letter I stated there was no need for adrenaline — no, that was just me being wise after the event. I certainly did not say that at the time."

was perceived by the clinic staff to have) or concern that he was about to have a full anaphylactic reaction. Current guidelines and reviews continue to stress the importance of early use of adrenaline (Ref 1, 2, 6).

The progression of the treatment versus the response is not recorded in the notes and it is difficult to say if the second and third doses were justified. Continuing adrenaline after the first dose is based entirely on response and it is difficult to comment on this without that information. The literature is less clear cut on recommending use of intravenous adrenaline but there is agreement on a higher risk of cardiac adverse effects including myocardial infarction with intravenous adrenaline and this risk is further amplified with bolus (single-shot) administration (Ref 1, 6).

Referral to hospital via ambulance was appropriate and done expeditiously.

Summary:
The diagnosis of anaphylaxis was not unreasonable with the bare facts but there are some parts of the history which along with the lack of signs in other systems should have led to consideration of other diagnoses. However given the importance in treating anaphylaxis early an urgent response was required if it could not be excluded.

2. Route of administration of Adrenaline:

Current recommendations for administration of adrenaline in anaphylaxis are for an initial intramuscular (IM) dose of up to 0.5mg (NZ Resuscitation Council, [Company] Anaphylaxis Protocol).

Subcutaneous administration (SC) has been used for anaphylaxis however the slow and variable uptake found in trials on non anaphylactic subjects means the IM route is preferred in local practice although the subcutaneous route has been included as a valid route in overseas guidelines and reviews as recently as 2006 (Massachusetts Emergency Services Treatment Protocols — Ref 3).

Intravenous adrenaline (in small doses) is generally reserved for use where intramuscular adrenaline has failed or as an infusion in prolonged reactions.

As double blinded randomized trials of anaphylaxis treatment are rare and difficult to perform most recommendations on adrenaline route/dose come from small non randomized trials and expert opinion.

Summary:
I think the use of subcutaneous adrenaline does also fall below the accepted local standard and would be moderately disapproved of by peers although this route is still accepted elsewhere.

3. Total Dose of adrenaline

Of the three possible scenarios:

0.5 mg SC, 0.1mg IV, 0.1mg IV in the space of 30 minutes

is the safest by virtue of the lowest dose.

Notwithstanding the issues around subcutaneous administration, IV adrenaline given slowly (over about a minute) is listed in the NZRC guidelines as an option for anaphylaxis which does not respond to the initial dose to be undertaken with continuous ECG monitoring.

1.0mg SC, 0.1mg IV, 0.1mg IV in the space of 30 minutes

Given the uncertain but slow absorption of subcutaneous adrenaline this is likely to be not very different to the first scenario — once again provided IV doses are given over 1 minute each.

1.0mg SC, 1mg IV, 1mg IV in the space of 30 mins

The total dose is in the order of the maximum given in anaphylaxis according to NZRC guidelines — an upper limit of infusion of 0.1 to 0.2mg per minute, used in ECG monitored patients who have failed to respond to lower doses and who are not maintaining a blood pressure of 80 mm Hg. There are no guidelines I could find that would subscribe to 1mg IV bolus doses other than in cardiac arrest and the literature repeats the risk of arrhythmias, myocardial ischemia, infarction or arrest from IV dosing.

Overall, if the need for adrenaline was established and given the timeline for the two IV injections — 15 minutes apart and assuming some absorption of the SC dose the two 0.1mg IV doses would be within limits while two 1.0mg doses would be excessive.

Summary:
Intravenous adrenaline of the order of 0.1mg given intravenously would be acceptable if over about a minute[9] and given for failure of response to the previous dose, however bolus dosing at this level is hazardous and larger doses more so and as such represents clearly substandard care.

Again it is not clear from notes whether the response to initial dose was or was not inadequate.

4. Intravenous promethazine (Phenergan)

The use of this drug in anaphylaxis is primarily for urticaria (skin rash) and itching which were not present in this case but there is some support for its use for airway swelling.

However given the concern that he had an allergic reaction to prochlorperazine (which is also a chemical of the phenothiazine group) and metoclopramide, administration of this drug may have been unwise.

Current recommendations (Ref 4, 5) for intravenous promethazine are that it is given no more rapidly than 25mg/ minute as a diluted solution. The [Company] protocol specifies a maximum of 2mg/min which is safe but would require nearly 15 minutes to administer. Transient hypotension would be the side effect of most concern here but reduced level of consciousness and agitation have also been reported.

Summary:
The use of promethazine was probably contraindicated and certainly should not be given as an IV bolus which is clearly stated in the information sheets. Again there is dispute as to whether it was given IV or IM.

5. Clinical observations

It is unfortunate that there was no pulse oximeter as this would have given an objective measure of cyanosis (lack of oxygen in the blood).

It is not stated whether [Mr A] was connected to an ECG monitor continuously or whether he had serial electrocardiograms made but the former is advisable in a resuscitation situation or when adrenaline is administered provides instant feedback on heart rate and may alert to cardiac ischaemia.

[9] Commissioner's note: Ms C stated that the first IV dose of adrenaline was given by Dr B over one to one and a half minutes.

Sequential recordings of blood pressure, heart rate, colour and respiratory rate should have been made and recorded as a measure of progress. It is difficult to say how many times but it would have been reasonable to try for 5 minute intervals while treatment was continuing. I think there should have been at least three more sets of recordings, after each administration of adrenaline as a record of response.

Summary:
Inadequate clinical recordings during administration of drugs with quite profound effects on the cardiovascular system.

6. [Company] Protocol for management of patients with anaphylaxis:

I thought this quite a good protocol and makes the important point that delay in administration of adrenaline is one of the most frequent errors in treatment. It also states that symptoms in one system may predominate and that angio-odema alone may result in airways obstruction.

In general I concur with its recommendations although I would be less prohibitive of use of intravenous adrenaline.

The promethazine regimen uses a very slow administration and the adult maximum (50mg/day) is actually less than the paediatric maximum (25mg/8hr) which is contradictory.

7. Supervision / oversight of [Dr B]

The outline of orientation for [Dr B] at the [other] clinic was documented and seems comprehensive while the orientation to [this] clinic was not so clearly documented but also seems adequate if the clinic protocols and procedures were largely identical. Oversight is provided by a vocationally registered Accident and Medical Doctor — at one point [Dr D] who described the supervision but later [Dr E] for whom there is not a statement. The Medical Council has quite clear requirements in terms of supervision expected which would be a condition of [Dr B's] registration.

8. Other comments

As mentioned before it is difficult to give a clear cut opinion on the standards of this patient's management because of discrepancies between the accounts of the patient and staff over issues as basic as the nature of the presenting complaint and more so with the varying account of drug doses and routes of administration.

To this extent I think the records of the treatment administered and the response were significantly below the accepted standard, as was IV bolus dosing of adrenaline and administration of promethazine. The use of subcutaneous adrenaline is also regarded as substandard but as noted this is not a universal view.

Secondly a lot of the treatment recommendations are not based on good randomised trials as these are difficult to do in this condition so the guidelines referred to have a less than perfect evidence base.

Appendices/References

1. NZRC Anaphylaxis Guidelines 2000
2. [The Company] Treatment Protocols — Anaphylaxis
3. Massachusetts Prehospital treatment Protocols 2006 (http://www.mass.gov/Eeohhs2/docs/dph/emergency_services/treatment_protocol_prehospital.pdf)
4. Medsafe Prescribing Information Phenergan
5. Promethazine Injection NZ Healthcare Pharmacists Notes on Injectable Drugs 9th ed 1999
6. Anaphylaxis: Diagnosis and Management Brown SGA, Gold MS Med J Aust 4 Sept 2006 Vol 185 No 1 P 283–289
7. Epinephrine absorption in Adults IM vs SC injection Simons EF et al J Allergy Clin Immunol. 2001 Nov 108 v5 p871–3”

Response to provisional opinion

In response to my provisional opinion, Dr B stated:

“I am deeply sorry that [Mr A] suffered myocardial injury after I had given him adrenaline in good faith during resuscitation on 6 August 2006. I administered the adrenaline subcutaneously and then intravenously based on my learning of ACLS (advanced cardiovascular life support) in 2002. I was taught to assess my patient’s condition. If the diagnosis of anaphylaxis was made, I would have to do the following (amongst other ACLS actions):

— ensure that an adequate airway was established.

— ensure adequate breathing, to administer oxygen by the appropriate methods (face mask, ambu-bag or via endotracheal tube or nasotracheal tube).

— ensure adequate circulation and put up a high-flow intravenous line.

— administer any appropriate resuscitation drugs. In the case of anaphylaxis, I was taught to start with adrenaline subcutaneously and then intravenously at 0.5mg/kg. This is the dose of adrenaline that I am certain I administered to [Mr A], not the amount that I recorded erroneously.

I also monitored [Mr A] by ECG which I attached to the relevant clinical notes.

I did make the error in writing my notes as I mentioned in my letter dated 31 October 2006. I did this while hastily transcribing the notes for the ambulance staff.

I do note that I should have considered angio-oedema as a differential diagnosis and that [Mr A] had previously had a similar reaction which was treated with medication (which he refers to as an 'antidote'). I was aware that [Mr A] had had a similar reaction prior to this one as his partner told me this while I was getting a history from her. Even with a differential diagnosis of angio-oedema my primary concern was to address what appeared to be an allergic reaction and administer adrenaline promptly.

I would like to return to New Zealand to practise and will undertake ACLS refresher training by end May 2007. I am happy to provide confirmation of this. I do not believe that a full competency review (as you have recommended) is reasonable. I have not had any incidents other than the present case. I recognise the importance of being familiar with the specific protocols in place wherever I practice. I have certainly reviewed my practice in light of this case and have read the expert advice that was obtained. In future, if I encounter a patient who has had an allergic reaction I will consider the differential diagnosis of angio-oedema and not administer adrenaline in this diagnosis. I will also make sure that I transcribe my notes accurately.

I offer [Mr A] my sincerest apologies."

Code of Health and Disability Services Consumers' Rights

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

Right 4
Right to Services of an Appropriate Standard

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

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

Other relevant standards

Good Medical Practice — A guide for doctors (Medical Council of New Zealand, October 2004):

"**Domains of Competence**

Medical Care

Good clinical care

…

3. In providing care you must:

…

- Keep clear, accurate, and contemporaneous patient records that report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed."

Opinion: Breach — Dr B

Introduction

Under Rights 4(1) and (2) of the Code of Health and Disability Services Consumers' Rights (the Code), when Mr A presented at the Accident and Medical Clinic, he was entitled to have services provided with reasonable care and skill, and in compliance with professional standards. Dr B was responsible for the care Mr A received during the period from his admission to the clinic until his transfer to hospital by ambulance. For the reasons given below, Dr B did not provide an appropriate standard of care, and failed to comply with professional standards.

Management of care

According to my independent expert, Dr Stephen Adams, Dr B correctly diagnosed that Mr A was suffering from an allergic reaction to a drug he had taken, Maxolon, which was a compound of a tablet he had taken for a headache. Having made that

diagnosis, Dr B was required to manage Mr A's care appropriately. In my view, she failed to do so.

Adrenaline
Dr B stated that the first dose of adrenaline given was 0.5mg, yet Ms C witnessed that 1mg was given, and this is supported by the clinical record. On the balance of probability, I conclude that Dr B's recollection is inaccurate, and that she administered 1mg of adrenaline.

Dr B stated that the second and third doses of adrenaline were 0.1mg. Although this is not entirely consistent with the clinical record, I note that Ms C witnessed the administration of the first IV dose, and was also involved in the diluting of the second and third doses. The clinical record states that "1ml" was given on the second and third dosages, and 1ml would equate (with the diluted solution of 9 ml saline and 1ml/1mg adrenaline) to a dose of 0.1mg. In the absence of clear evidence to the contrary, I conclude that the second and third doses of adrenaline were probably of 0.1mg. Thus a total of 1.2mg adrenaline was probably administered by Dr B.

Dr Adams advised that a total dose of 1.2mg of adrenaline was appropriate, according to the New Zealand Resuscitation Council, provided that there was continuous ECG monitoring of the patient. However, there is no evidence that Mr A was on a cardiac monitor. An ECG was said to have been performed, but has not been supplied to my Office.

The first dose of adrenaline was given subcutaneously by Dr B. This is contrary to the Clinic's anaphylaxis protocol, which states that such a route is not recommended. Dr Adams advised:

> "[The] use of subcutaneous adrenaline does … fall below the accepted local standard and would be moderately disapproved of by peers although this route is still accepted elsewhere."

Phenergan
Dr B stated that she "ordered … 25mg Phenergan IM to be given". This is contrary to Ms C's recollection, which is supported by the clinical record. Ms C stated that this dose was given IV by Dr B. On the balance of probability, I conclude that Dr B administered 25mg Phenergan IV, and that her recollection is, again, inaccurate. I also accept Ms C's evidence that the drug was given not as a slow rate (as set out in the protocol), but as a bolus administration.

Dr Adams advised that Phenergan is of the same drug group (phenothiazine) as prochlorperazine, a drug to which Mr A had previously exhibited an allergy. I therefore endorse Dr Adams' view that the use of Phenergan was "probably contraindicated and certainly should not be given as an IV bolus".

Clinical observations
Dr Adams advised that "at least three more sets of recordings, after each administration of adrenaline" should have been performed. In his view there had been "inadequate clinical recordings during [the] administration of drugs with quite profound effects on the cardiovascular system". Although Dr B was working with a registered nurse, it was the doctor's responsibility to ensure that adequate clinical observations were performed to monitor the effectiveness of the treatment.

Documentation
As noted above, Dr B erroneously recorded that a total of 3mg of adrenaline was given, and this was information that was communicated to the hospital in the transfer letter. It is essential that the administration of medicines is accurately recorded to ensure safe continuity of care.

Dr Adams advised that it was not possible for him to judge whether the second and third doses of adrenaline were justified, as the "progression of the treatment versus the response is not recorded in the notes".

Although I accept that Dr B was rushed, the accurate recording of Mr A's condition, as well as the treatment provided and his response, was important information that should have been documented. Mr A had settled by the time the ambulance had arrived, and there was sufficient time to ensure that the documentation was accurate.

Summary
Dr B failed to provide Mr A services with reasonable care and skill in a number of areas. She inappropriately administered the first dose of adrenaline subcutaneously, administered further doses of adrenaline without continuous cardiac monitoring, inappropriately prescribed and administered Phenergan, and failed to ensure that adequate clinical observations were performed. She also failed to comply with professional standards promulgated by the Medical Council, as she did not "keep clear, accurate, and contemporaneous patient records that report the relevant clinical findings, the decisions made … and any drugs or other treatment prescribed". Accordingly, Dr B breached Rights 4(1) and 4(2) of the Code.

I am concerned that Dr B has made subsequent statements that are contradicted by both the contemporaneous clinical record (that she typed herself) and an eye-witness, Ms C.

No Breach — Accident and Medical Clinic

Vicarious liability
In addition to any direct liability for a breach of the Code, an employing authority may be vicariously liable under section 72(2) of the Health and Disability Commissioner Act 1994 for any breach of the Code by an employee. Section 72(5) affords a defence for an employing authority if it took such steps as reasonably practicable to prevent the relevant conduct.

Dr B was an employee of the Clinic. According to Dr Adams, the protocols in place, and the supervision provided to Dr B, were generally acceptable. There were clear policies and guidelines for the management of anaphylaxis, with which Dr B should have been familiar.

In my opinion, the Clinic took reasonable steps to prevent the relevant conduct and is not vicariously liable for Dr B's breaches of the Code.

Other matters

Internal investigation
The management of the Company undertook an internal investigation once they became aware of Mr A's complaint. I am concerned that Dr G, who had been tasked to perform the investigation, was not provided with two key items of evidence: that Ms C had witnessed both the initial administration of 1mg adrenaline and that 25mg Phenergan was given intravenously, corroborating the clinical record, and thus contradicting Dr B's subsequent claims. These were important and relevant facts from an eye-witness that corroborated the clinical record, and their absence from Dr G's analysis detracts from the quality of her investigation and the resulting recommendations.

Dr H stated in response to the provisional opinion that the omission was a "simple" human error, and processes have now been amended to prevent a similar event occurring.

Dr F
Mr and Mrs A have a clear recollection of Dr B consulting another doctor about Mr A's care. Mrs A identified this doctor as Dr F from a previous consultation with him, and Dr F was the only other doctor on duty when Mr A was being treated by Dr B. Ms C recalls that Dr F came into the room "several times", and that discussion between Drs F and B took place about Mr A's care. However, Dr F does not recall this consultation, and Dr B stated that his only involvement was to help her "administer oxygen to [Mr A]", a duty Dr B previously stated she had done "with the help of [Ms C]".

I find it implausible that Dr B, as a junior doctor, would not have discussed the administration of adrenaline and Phenergan with her senior colleague, Dr F (which is what Mr and Mrs A recall), and I am concerned that Dr B has stated that Dr F's only involvement was to administer oxygen.

Cooperation with investigation
I am also concerned that Dr B did not advise my Office that she was leaving the country when she knew she was the subject of an investigation. It was fortuitous that she was contacted three days prior to her departure. Unfortunately, by then there was insufficient time to arrange an interview. I note that Dr B has responded to subsequent queries by email.

Phenergan
In response to my expert's view that the dosage of Phenergan for adults and children was "contradictory" in the anaphylaxis protocol, the Company has amended the protocol.

Follow-up actions

- A copy of this report will be sent to the New Zealand Medical Council with a recommendation that, if Dr B returns to practise in New Zealand, her competence be reviewed.

- A copy of this report with details identifying the parties removed, except the name of Dr B, will be sent to the Accident and Medical Practitioners Association.

- A copy of this report, with details identifying the parties removed, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.