A District Health Board

Dr B, Medical Practitioner

Mr C, Registered Nurse

A Report by the

Health and Disability Commissioner

(Case 03HDC04005)

Health and Disability Commissioner

Te Toihau Hauora, Hauātanga

Parties involved

Mr A	Consumer
Dr B	Provider/Medical Practitioner
Mr C	Provider/Registered Nurse
Dr D	Chief Medical Advisor, the District Health Board
Ms E	Operational Manager
Dr F	Director of Emergency Medicine
A District Health Board	Provider

Complaint

On 18 March 2003 the Commissioner received a complaint from Mr A about the medical and nursing care he received at the first public hospital. The complaint was summarised as follows:

Dr B

On 30 January 2002, Dr B did not provide services of an appropriate standard to Mr A. In particular, Dr B:

- *prescribed Maxolon despite Mr A's allergy which was recorded in his medical notes*
- *did not take remedial action in a timely manner to alleviate the adverse effects of Maxolon experienced by Mr A.*

On 30 January 2002, Dr B did not ensure Mr A made an informed choice and gave informed consent for provision of medical services. In particular, Dr B:

- *did not inform Mr A that she had prescribed Maxolon*
- *did not obtain Mr A's consent for the administration of Maxolon.*

Mr C

On 30 January 2002, Mr C did not provide services of an appropriate standard to Mr A. In particular, Mr C:

- *administered Maxolon to Mr A despite Mr A's allergy which was recorded in his medical notes*
- *did not take remedial action in a timely manner to alleviate the adverse effects of Maxolon experienced by Mr A.*

On 30 January 2002, Mr C did not provide Mr A with adequate information. In particular, Mr C:

- *did not inform Mr A that Maxolon was being administered until after the event.*

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

An investigation was commenced on 1 September 2003.

Information reviewed

- Letter of complaint from Mr A, dated 17 March 2003, and subsequent correspondence to Commissioner
- Letters responding to complaint from Dr D, Chief Medical Advisor, a District Health Board, dated 29 July 2003, 3 October 2003 and 15 March 2004, including notes of the DHB's internal investigation, from Ms E , Operational Manager for Surgical Services, and the Senior Medical Officer, Emergency Department
- Copies of the DHB's policies, including: "Management of and Documenting Allergies" (May 1997), "Management of and Documenting Allergies/Adverse Drug Reactions" (March 2002), "Drug Administration" (May 2000 and April 2002), "Prescription of Inpatient Medication" (March 2001 and March 2003), "Informed Consent for Treatment" (May 2001)"
- Clinical records for Mr A's admissions to the first public hospital on 29 November 2000, 29 January 2002, 18 June 2002, and 10 October 2002, and a second public hospital on 22 June 2001
- Copy of ACC Medical Misadventure Unit file, including reports of a general practitioner and Professor of Medicine, decision on claim dated 12 November 2002; review decision dated 15 January 2003; and reserved judgment of a District Court, 29 May 2003
- Responses from Dr B, dated 19 and 31 October 2003
- Responses to Commissioner's Provisional Opinion from Dr D, dated 1 April 2004 and 13 April 2004; and Dr F, Director Emergency Medicine, dated 1 April 2004
- Response to Commissioner's Provisional Opinion from Dr B, dated 15 June 2004, and further response via her legal representative, dated 24 June 2004
- Response to Commissioner's Provisional Opinion from Mr A, dated 29 April 2004.

Independent expert advice was obtained from Dr Geoffrey Hughes, Clinical Director, Emergency Department, Wellington Hospital.

Information gathered during investigation

Overview
Mr A presented at the Emergency Department (ED) at the first public hospital on 29 January 2002 complaining of abdominal pain and frequency/urgency in passing urine. Dr B prescribed Tilcotil for pain. Subsequently she prescribed further pain relief – tramadol – and Maxolon, an anti-emetic. At 2.10am Mr C administered to Mr A tramadol and Maxolon, in that order, without first confirming to him what drugs were being given. Mr A asked what the second drug was, and, when told it was Maxolon, informed Mr C that he had experienced an adverse reaction to that drug. Subsequently Mr A felt unwell, anxious and restless. He asked to be given diazepam because he knew from previous experience that this would counter the adverse effects of the Maxolon. At approximately 3.30am Dr B gave Mr A diazepam and his condition settled. Mr A complained that his informed consent to the administration of Maxolon was not sought by Dr B or Mr C; if it had been, he would have explained his situation and asked for alternative medication to be used or none at all. He also complained that Dr B did not administer diazepam in a timely manner.

Background
Dr B graduated from a University in England, in 2000 and is registered as a medical practitioner with the General Medical Council ("GMC") in the United Kingdom. In 2002 she held temporary registration in New Zealand and was employed by the District Health Public as a second-year house surgeon. She has since returned to the UK.

Mr C was employed by the District Health Board from 1 August 2001 until 28 February 2002 and during this period held an annual practising certificate with the Nursing Council of New Zealand. He left New Zealand shortly after these events occurred, and efforts to locate him in both Australia and the United Kingdom proved fruitless. The Commissioner has not obtained Mr C's response to Mr A's complaint.

Mr A had previously attended the first public hospital and a the second public hospital (both of which are administered by the District Health Board), and the first public hospital had his previous medical notes on file. These included notes for a visit to the ED on 29 November 2000 when the following information was recorded:

> "Medic alerts or allergies – *yes* – If yes, how do they affect you? – *Bactrim/Spectrim* [sic], *pethidine*, *LGL Syndrome*[1]. Past Medical history – *cardiac arrhythmia*."

A handwritten "[DHB] Medical Warning" on the cover of Mr A's medical file refers to "phenothiazine, Bactrim, Septrin, Maxolon, oral Voltaren, Vibramycin, sulphur drugs". It is not clear when this warning was attached to Mr A's records. However, when he was admitted to the second public hospital on 22 June 2001, as part of the routine admission

[1] Lown-Ganong-Levine syndrome is an abnormal heart rhythm. Symptoms may include rapid heartbeat, palpitations, lightheadedness, and shortness of breath.

procedure, his adverse drug reactions were noted and the following entered in the Treatment and Progress Notes:

> "DH [drug history] – Nil
>
> Allergies – Pethidine, Maxolon – both cause agitation;
> Vibramycin, Sulphur drugs.[2]"

On Mr A's inpatient front sheet a typed warning states: "AMRs [adverse medical reactions] exist for this patient." These are then listed and include allergy to phenothiazine, Bactrim, Septrin, Maxolon (metoclopramide), oral Voltaren, Vibramycin, sulphur drugs, pethidine, Stemetil, anti-emetics and "some antibiotics". The front sheet is undated, but includes reference to Mr A's "last admission" on 11 September 2002.

In addition to the warning on Mr A's physical file, on 18 October 2001 his AMRs/allergies had been entered on the DHB's electronic patient management system ("PMS Alpha"). Dr D, Chief Medical Advisor of the DHB, confirmed that Dr B had received training on how to use this system on 23 August 2001, and she had access to the system.

Mr A does not wear a medical alert bracelet to indicate that he experiences an adverse reaction to certain drugs, although he has done so in the past.

Neither Dr B nor Mr C saw Mr A's previous medical records, or checked PMS Alpha, during their assessment and treatment of him at the first public hospital on 29 and 30 January 2002.

Admission, 29–30 January 2002
Mr A self-referred to the first public hospital's ED on 29 January 2002, was triaged at 10.28pm, and first assessed at 10.31pm. His previous medical file was requested, although this request is not noted on the triage record nor confirmed elsewhere in the notes.

Mr C is named on the ED nursing progress notes as the "ED allocated nurse". While Mr C did not provide the Commissioner with information directly, the ED Charge Nurse at the first public hospital recalled that Mr C told her during the DHB's internal investigation that he had discussed Mr A's drug allergies with him when he was first seen. Such a discussion between Mr A and Mr C is not recorded contemporaneously in the nursing progress notes; the first entry states only "appears comfortable – await dr". On the triage form, the box marked "Medic alerts or allergies" is ticked "yes", but in relation to the printed question "if yes, how do they affect you?" no further information is recorded. Observations of Mr A

[2] During the hospital admission on 22-23 June 2001, Mr A received Stemetil and ten hours later, experienced feelings of anxiety and a tingling sensation in his hands. He received 5mg diazepam which calmed him. The "Medical Service Information on Leaving Hospital" form records that he "had possible reaction to IV Stemetil → Anxiety +".

were recorded as: blood pressure 132/83, pulse 69, respiratory rate 18, temperature 36.6ºC, oxygen saturation 98% and Glasgow Coma Score 15.

Dr B assessed Mr A at 12.30am on 30 January. She confirmed that when she did so, the medical records consisted only of the ED triage sheet, nursing documentation sheet ("Emergency Department Nursing Progress Notes", with "Medications/IV Fluids" chart), an observation chart, and medical "Treatment and Progress Notes". A printed label showing Mr A's full name, age, date of birth, sex, address, and GP appears on the top of each of these sheets, as provided to the Commissioner, with the exception of the triage sheet. The label also features a bar code, Mr A's hospital number, the ward he was in and the letters "AMR". While Dr B did not refer to this label or explain "AMR", when responding to the complaint, in response to my provisional opinion the Director of Emergency Medicine at the DHB, referred to a "non-specific medical alert abbreviation that appears on the patient label"; I believe these to be one and the same.

On the Treatment and Progress Notes, Dr B recorded that Mr A's pain was "10/10" in severity; his blood pressure remained at 132/83, pulse 69, respiratory rate 18, and his temperature had dropped slightly to 36ºC. Dr B stated that during her assessment of Mr A she took a detailed medical history, including a detailed drug history, and specifically asked if he was allergic to any medication. Dr B said:

> "He told me that he was not, but said 'Stemetil doesn't agree with me'. I documented what he said ad verbatim. I established that this was not an allergy. Despite my asking whether he had any other drug reactions or allergies, he did not mention that he had had any previous reaction to Maxolon."

Dr B recorded the following in the medical notes at 12.30am:

> "DH [drug history]: Nil. NKDA [No known drug allergies] "STEMETIL doesn't agree with me".

Dr B examined Mr A's cardiovascular and respiratory systems, and found them "unremarkable". She examined his abdomen, which was "soft but with suprapubic tenderness and voluntary guarding". No renal angle tenderness, masses, hernias, organomegaly or abdominal aortic aneurysm were found. She said: "Rectal examination was found to be normal, with normal tone, no masses, empty rectum and no prostatism or enlargement". Dr B ordered investigations (Dipstix urine, abdominal X-ray, full blood count and urea and electrolytes). She prescribed intravenous Tilcotil for pain, and IV fluids. She documented that she would review Mr A once she had the blood results and X-ray. Dr B's impression was that Mr A had renal colic.

At 12.54am, Mr C gave Mr A Tilcotil and set up a normal saline drip; bloods were taken and an X-ray performed. Mr C's entry for 1.02am states: "IV Tilcotil for pain relief + IVF [intravenous fluids] commenced".

At 1am, Dr B reviewed the X-ray and documented that there was faecal loading in the ascending loop of colon, and some dilated loops. She queried whether there was a renal stone (a condition Mr A told her he had experienced five years previously). At this time, Dr B spoke to the senior doctor, and it was planned that Mr A could go home if his pain settled, and that further tests might be arranged to confirm the presence of renal stones. Because Mr A's pain did not settle, Dr B prescribed further analgesia in the form of intravenous tramadol, and Maxolon, to prevent nausea. Mr A is adamant that at that time Dr B did not tell him what she had prescribed.

Dr B stated:

> "Whilst I do not (after a 20 month interval) remember exactly what I discussed with [Mr A] in relation to this treatment recommendation, it is my usual practice to advise a patient when prescribing analgesia that I am also prescribing a drug to minimise nausea."

The clinical records for 2am show that Mr A's blood pressure was 140/80, pulse 82, respiratory rate 14, and temperature 36.6°C.

At 2.10am, Mr C administered to Mr A 50mg tramadol and 10mg Maxolon intravenously. Mr C did not explain what drugs he was to give, before they were administered. As Mr A was expecting to receive one drug for pain relief, he was concerned to see a second medication added to his intravenous line. He therefore asked what the second drug was. Mr C told him it was Maxolon, and Mr A immediately said that he had previously suffered an adverse reaction to Maxolon. He told Mr C that he has a worse reaction to Maxolon than to Stemetil and that diazepam would counter the expected adverse reaction.

Mr A advised the Commissioner that the reaction he experiences if given Maxolon is known as akathisia, a condition that for him is characterised by restless overactivity, anxiety, and "a highly unpleasant bodily sensation that defies description". He also stated that at the time Maxolon was administered by Mr C, he had not in fact been feeling nauseous. He therefore questioned whether any anti-emetic had been necessary, and stated, "Given the choice, I would prefer nausea." Mr A is concerned that after telling Mr C of his reaction to Maxolon, Mr C did not check his previous medical records.

In a submission to the District Court,[3] Mr A stated that he would have expected the following conversation to have taken place before Mr C administered any IV medications to him:

[3] Mr A appealed against an independent reviewer's decision upholding ACC's decision to decline his claim for medical misadventure based on these events.

"[*Mr C]*
'I'm now going to give you tramadol for your pain and also some Maxolon, just in case the Tramadol causes nausea.'

[Mr A]
'No Maxolon. I've had severe reaction to Maxolon in the past. I'm happy with the tramadol and I'm prepared to take the risk of possible nausea. I've had no problems in the past with nausea and I've tolerated morphine without anti-nausea medication.'

[Mr C]
'Fine. I can't force you to have the Maxolon. I'll just note what you have told me in your notes.'"

Mr C recorded the following in Mr A' "Emergency Department Nursing Progress Notes" at 2.26am:

> "Tramadol 50mg + IV Maxolon for further pain. Now tells me is 'allergic' to Maxolon or 'gets a funny reaction/makes me anxious'. Now anxious and requesting diazepam. [Mr A] had earlier told me he was only allergic to Bactrim [an antibiotic]. D/w [discussed with] Dr who will see. [Patient's] pulse 80 + reg looks well."

Mr C told Dr B that Mr A believed he was having a reaction to the Maxolon. Dr B said:

> "At 02.30 I went to talk with [Mr A]. He told me that he was feeling agitated and that he always got agitated with Maxolon. He admitted to me that he did not inform me of this when I asked him about allergies to drugs during our initial consultation. His observations were stable. He demanded Valium from me to settle down his agitation. Whilst I acknowledged his concerns, I did not feel that Valium was indicated at that time. I was also concerned at prescribing him further medication unnecessarily. I therefore suggested that he tried to sleep whilst we awaited his blood results and see if he managed to settle. He was advised to try and inform medical staff accurately of his drug allergies in the future in order to avoid further similar episodes."

Dr B recorded the following in the Treatment and Progress Notes at 2.30am:

> "c/o [complaint of] … feeling agitated + that he always gets agitated with Maxolon. He admits that he didn't tell me that. He is currently suing a doctor for giving him Stemetil having told him that he couldn't tolerate it. I have suggested that he try to sleep whilst we await blood results. He is demanding Valium. I do not feel this is indicated presently. Pain settled."

Dr B did not record Mr A's temperature, pulse rate, respiratory rate or blood pressure at that time.

Mr A admitted that he initially failed to tell Dr B that Maxolon is one of the drugs to which he reacts badly, and explained this was because he was in severe pain when he first arrived in the ED. He noted that he also had "some degree of anxiety due … to previous negative experiences with doctors". He stated that these factors affected communication between them. Mr A objected to Dr B's note in his medical records that he "demanded" Valium (diazepam) on the basis that it was "emotive and misleading".

Mr A said:

> "[Dr B] initially refused to treat my reaction, and told me to sit down and stop making a nuisance of myself … I was left in a highly distressed state for 1½ to 2 hours before finally and reluctantly being given diazepam …"

Dr B recalled that Mr A wandered around the ED and at 3.30am was still feeling agitated. She recorded in the notes that "[Mr A] wants to speak to senior doctor. Situation resolved when offered diazepam". She did not record any observations of his vital signs. Dr B stated:

> "At this time I advised him not to take NSAIDS [non steroidal anti-inflammatory drugs] in view of his reduced kidney function. He was then given 5mg of diazepam by [Mr C] [at 3.30am]. He then slept."

Mr C recorded the following in the nursing notes at 4am:

> "Has now had 5mg diazepam + is settled. Had appeared very angry about not having diazepam earlier. Also has changed his story several times regarding what he is allergic to. I have suggested to [Mr A] that he make it quite clear to medical + nursing staff about his allergies. Now settled and sleeping."

Mr A disputes Mr C's comment that he "changed his story several times".

At 6.45am Mr A was reported to be pain free. Dr B recorded that his vital signs were "stable"; his temperature was 36.7ºC, blood pressure 100/55, and respiratory rate 14. These were the first full observations recorded since 2am.

At 8.40am, Mr A's blood pressure was 109/68; at 10.45am it was 120/65. The senior medical officer, diagnosed haemorrhoids with suspected renal colic/urinary tract infection and discharged Mr A to the care of his GP for further investigations.

Dr B summarised her response to Mr A's complaint as follows:

> "I aim always to respect my patients, and to offer them a good standard of care. I shall continue to take a detailed drug history when admitting a patient, to check current drug charts and notes for known allergies, and prescribe appropriately. I shall continue to prescribe alternative medication to one known to cause reactions in the patient. I will remain alert to possible reactions and aim to treat them appropriately. I shall also continue to inform patients of drugs which they should not take, and the

> reasons why. I believe that despite this unfortunate incident, I did at that time demonstrate reasonable clinical vigilance in this regard.
>
> I regret that [Mr A] feels that I abused his rights. Having to visit the Emergency Department is stressful in itself, and I regret that [Mr A] feels that I added to this. Whilst this complaint has made me reflect on my practice, I feel that I provided him with a reasonable standard of care according to good medical practice. I endeavoured to seek knowledge of previous drug reactions and to prescribe accordingly. I feel that my documentation is evidence that I listened to [Mr A], and that I sought to involve him in his own care. We also have a duty to minimise potential harm, and the time between [Mr A] expressing his concern at having a reaction to the Maxolon, and me treating him, served to avoid giving further potentially harmful medication."

Availability of previous medical records

Dr D stated that Mr A's previous medical file was requested by the ED on the night of 29 January 2002 and delivered "some time after midnight"; he did not confirm exactly when.

Dr B emphasised that the medical warning label on the front of Mr A's notes was not available to her at the time of these events. In response to my provisional opinion, she stated:

> "We received brief training on PMS but it was limited solely to how to access laboratory and other investigation results. I was given no training as to how to access drug allergies via this system, and indeed I was not even aware that such data was recorded on that system. PMS is a large data base with many functions in which not all staff were trained".

Dr D advised that he expected all clinical staff at the first public hospital to be aware of PMS Alpha and have access to it. However, his enquiries following these events revealed that "this system was not known to all clinical staff. Sometimes staff were educated by colleagues rather than by the staff of the IT Department and therefore at times that knowledge was incomplete". Dr D confirmed that all new clinical staff are now invited by the IT Department to attend computer systems training. In response to my provisional opinion he stated:

> "[T]he hospital patient management database was accessed only in cases of doubt or where a patient, for whatever reason, could not be expected to know their allergies. Of course, in this particular case, [Mr A] was *compos mentis* to discuss his side effects or allergies to medication and therefore there seemed to be no need to access the database. [Mr C] might also not have known about the PMS system as he did not receive formal computer training."

[The DHB's] policy – "Management of and Documenting Allergies" (issued May 1997, revised May 1999)

The DHB's policy on the management and documentation of allergies, in place in January 2002, stated:

> "STANDARD:
> Each prescriber shall be responsible for ascertaining the allergy status of any patient for whom they are prescribing medications. No medications should be charted on a medication chart unless the allergy section has been completed …
>
> METHOD:
> It is the responsibility of the first prescriber on each and every medication chart used, to clearly and legibly document a patient's allergy status. The minimum steps to establish the presence of an allergy are:
>
> 1. Check for medical alert bracelet/highlighted yellow ID bracelet
> 2. Check with the patient and/or caregiver if necessary
> 3. Check previous notes, admission sheet alerts and yellow or red stickers on the front cover of the medical notes.
>
> … The nurse taking the order must follow the minimum steps to establish the patient's allergy status prior to administration. If there is any uncertainty over the allergy status of the patient then the medication must not be administered and the prescriber is to be contacted.
>
> If there is conflicting information on medication charts or in the patient's notes with regard to allergy status then:
>
> 1. Prescribers need to follow the checking procedures outlined above to determine the patient's actual allergy status, annotating all medication charts accordingly and inform medical records of any change in allergy status …
>
> 2. Any other staff member finding conflicting information should immediately bring this to the attention of the medical staff responsible for the patient.
>
> **How to document allergies:**
>
> 1. *A patient has known or suspected allergies:* The name of each medication shall be documented on the medication chart, countersigned and dated.
>
> 2. *Appropriate history taking indicates that a patient has no known allergies:* The words 'No known allergies' shall be documented on the medication chart, countersigned and dated.

Nursing responsibility:
Except in an emergency no nurse may administer a medicine unless the allergy section of the relevant medication chart has been completed."

NDHB policy – "Informed Consent for Treatment" (issued May 2001)
This policy states:

"**RATIONALE:**
Health care delivery involves a partnership between the client/patient and the health professional. Informed consent based on informed choice is the basis of this partnership. Informed consent is the process whereby someone, who has the competence and the capacity to consent, having received sufficient information, makes a reasoned, unpressured choice to accept or decline a proposed therapy or procedure …

An unspecified general consent does not meet the requirements of informed consent …

METHOD:
1. **Verbal consent** is sufficient:
   For procedures/treatments where there is a limited level of risk and the person is conscious during the procedure and is able to call a halt to the procedure …
3. Every patient/client has the right to refuse services and withdraw consent to services …

7. **Information to be given:**
   Patients/clients have a right to information that any reasonable patient in that circumstance would expect to receive:
   (a) an explanation of his/her condition; and
   (b) an explanation of the options available, including an assessment of expected risks, side effects, benefits; …
8. **Responsibility for giving and obtaining consent**
   The primary responsibility for giving information and obtaining consent lies with the person responsible for the treatment/procedure; in situations where a team is involved, then this responsibility may be shared or delegated.
9. **Absence of coercion** … The patient has the right to decline or withdraw consent for treatment without fear of recrimination, penalty, or the withdrawal of physical or emotional support."

The DHB's internal investigation
As a result of Mr A's complaint, the DHB's Operational Manager for Surgical Services, undertook an internal investigation, following which an extensive training programme regarding allergies, drug reactions and documentation was given to staff. The DHB's Operational Manager wrote to Mr A on 15 October 2002 and stated:

> "I endorse your suggestion whereby the nurse talks the patient through what is happening as procedures are undertaken, and I will pass your comments on to the Charge Nurse of the Emergency Department.
>
> I apologise unreservedly for the fact that you did not receive the support and care from our service that you felt you needed. By communicating your distress, you have made it possible for our service to work at addressing the issues you have raised."

In a further letter to Mr A dated 17 December 2002, the Operational Manager advised that as a result of his concerns, the DHB staff would in future provide a more thorough triage assessment regarding patients' allergies/drug reactions with patients presenting to ED. The Operational Manager stated: "Patients will be asked to identify the drug reaction/side effect they suffer as a result of being given a particular drug and this will be clearly documented in the medical notes; and staff are expected to inform the patient of the drugs to be given prior to the actual administration."

Dr D advised that as a result of these events, "the issues re informed consent were reinforced" and that it is "common practice in the Emergency Department (as well as in the rest of the hospital) to give information and obtain informed consent re treatment". He also confirmed that the DHB's prescribing policy was to be upgraded to reflect changes in the patient management system software.

Accident Compensation Corporation

On 8 February 2002, Mr A submitted a medical misadventure claim to ACC in which he stated that as a result of being given Maxolon he suffered a personal injury, ie, an adverse reaction including anxiety and tachycardia. At that time he did not specifically claim that a medical error had occurred as a result of Dr B's or Mr C's failure to obtain his informed consent, although he subsequently raised this issue in letters to ACC. He claimed that "doctors failed to (initially) take measures to rectify the situation or monitor vital signs, despite being told immediately of the mistake by the nurse".

ACC sought the advice of two experts, a general practitioner and Professor of Medicine. The general practitioner stated:

> "During the course of his treatment [Mr A] was given, amongst other medications, an intravenous injection of Maxolon. [Mr A] asserts that he was given this injection despite telling staff that he gets a funny reaction to it. The medical records do not support his statement that he told them of this funny reaction. [Mr A] claims high blood pressure, anxiety and tachycardia as a result of the injection. All recordings in his medical records from the hospital and his general practitioner are of a normal blood pressure and pulse rate.
>
> Maxolon is a drug widely used for treatment of nausea and vomiting. It is well known to have side-effects …

> I have seen no evidence in the copies of medical records I have in front of me of a raised blood pressure or tachycardia. Agitation is not easily measured but I am in no doubt that [Mr A] was agitated that night until he had the tablet of Diazepam. He had an injection of Tilcotil at 0054 hours 30th January 2002. He then had the injection of Maxolon and Tramadol at 0210 hours 30 January 2002. I mention the Tramadol as some of its side effects are similar to Maxolon and also Tilcotil can also cause some restlessness and sleep disturbance. All the symptoms of anxiety appear to have resolved by the time he left the Department on the morning of 30th January 2002. I cannot identify a personal injury here."

The Professor of Medicine advised:

> "Akathisia is well described with the use of metoclopramide [Maxolon]. It can certainly occur at normal doses although it is often related to high doses. This seems to be the reaction that [Mr A] had. It had obviously gone by the time he left hospital. With regard to medical error I can find no evidence for the same as [Mr A] did not advise the doctor that he was unable to tolerate metoclopramide until after he had been given the drug. Therefore this claim should be declined."

Both of ACC's experts concluded that there was no evidence of medical error on the part of the providers involved in Mr A's care, and that his claim did not meet the criteria for medical mishap. On 12 November 2002 ACC declined Mr A's claim and advised:

> "With all claims, there must be an established direct link between the actions of the health professional and your personal injury. The injury claimed 'increased pulse, increased blood pressure, shaking, anxiety and extreme restlessness.' The claim is not consistent with the findings of the Medical Misadventure investigation. All recordings of pulse and blood pressure are within normal limits. … It is not possible to establish a clear causal link between the prescribing of Maxolon and the anxiety you experienced. The pain you were experiencing and side effects from the other medications (Tilcotil and Tramadol) could also cause anxiety. …
>
> For a claim to be considered as a medical error there must be a failure of a registered health professional to observe a standard of care and skill reasonably to be expected in the circumstances. … [ACC's expert advisors] and ACC agree that there is no evidence of [Dr B] failing to observe a standard of care and skill reasonably to be expected in the circumstances. The clinical notes supplied by [the first public hospital] Emergency Department have an entry by [Dr B] for 0230 hours recording that you were feeling agitated and always get agitated with Maxolon. However she has also written 'he admits that he didn't tell me about that'. There is also an entry from [Mr C], '[Mr A] had earlier told me he was only allergic to Bactrim'. There is no evidence to support your allegation that medical or nursing staff were aware of your inability to tolerate Maxolon until after you had received the medication. There is no evidence of medical error. ...

> For a claim to be considered as a medical mishap, the adverse consequence of your treatment must be both rare and severe. … [ACC's general practitioner expert advisor] states that 'reactions to Maxolon (and Tramadol and Tilcotil) are not rare [do not occur in less than 1% of patients] … The reaction to Maxolon did not hospitalise you for 14 days or cause significant disability for 28 days. This claim does not meet the criterion of [rarity or] severity."

On 14 January 2003 Mr A applied for a review of ACC's decision. The following day, an independent reviewer upheld ACC's decision stating that there was no evidence that Mr A had suffered personal injury in terms of the relevant ACC legislation (the adverse reaction was of short duration and there was no adverse outcome), or that there was a causal connection with the standard of care provided by Dr B or Mr C.

Mr A appealed to the District Court and submitted that his akathisia amounted to a mental injury – and therefore a personal injury – that had been caused by medical error, ie, a registered health professional's negligent failure to obtain his informed consent to treatment, and failure to provide diazepam in a timely manner. In a judgment issued on 29 May 2003, the Judge dismissed Mr A's appeal and stated:

> "I think that it was not unreasonable to have acted on the inference that after [Mr A] indicated that he had an adverse reaction to one particular drug that the people responsible for his care did not disclose or tell him of the other drugs that would be involved in the medical procedures to be used. … I do not think that [Mr A] has discharged the burden of proof of showing that he was not treated with the expedition for which he argued. Hindsight reasoning is not enough. [Dr B] and the nurses may well have thought his condition would settle.
>
> If I am wrong in these conclusions I do not think that [Mr A] has suffered a personal injury by accident that was caused by any medical error. There is no medical evidence of personal injury. It is hard to see how a transient anxiety condition that does not appear to have any lasting effect could qualify as an injury within the embrace of the legislation."

Mr A sought leave to appeal to the High Court. ACC advised the Commissioner that Mr A's appeal case was "withdrawn/refused in December 2003".

General Medical Council, United Kingdom

In letters to the Commissioner dated 14 October 2003 and 29 April 2004 Mr A expressed concern that his care at the first public hospital may have been compromised because Dr B trained and registered in the United Kingdom and may not have been aware of providers' obligations in New Zealand in terms of obtaining informed consent prior to treatment. He asked: "Is British law in relation to informed consent the same as NZ law? Does the DHB have any policy with regard to the orientation of overseas trained medical staff that it employs?"

In response to my provisional opinion, Dr B stated:

> "At induction and orientation at [the first public hospital] we were told that there was a Code of Rights,[4] but were not issued with a copy. Had this been done I would still have interpreted my actions as conforming with 'informed consent'. I believe that my standard of care in relation to informed consent meets UK standards, and had no reason to believe that it would not conform with New Zealand standards. If there is a difference in these standards, this point needs to be clarified to the large number of UK doctors that provide services in New Zealand."

The GMC's publication *Good Medical Practice* (May 2001 edition) describes the principles of good medical practice and standards of competence, care and conduct expected of doctors registered with the GMC and working in the UK. In relation to obtaining informed consent, it states:

> "Obtaining consent
>
> 17. You must respect the right of patients to be fully involved in decisions about their care. Wherever possible, you must be satisfied, before you provide treatment or investigate a patient's condition, that the patient has understood what is proposed and why, any significant risks or side effects associated with it, and has given consent. You must follow the guidance in our booklet *Seeking Patients' Consent: The Ethical Considerations.* …
>
> Good Communication
>
> 21. Good communication between patients and doctors is essential to effective care and relationships of trust. Good communication involves:
>
> - listening to patients and respecting their views and beliefs;
> - giving patients the information they ask for or need about their condition, its treatment and prognosis, in a way they can understand, including, for any drug you prescribe, information about any serious side effects and, where appropriate, dosage; …"

Seeking Patients' Consent: The Ethical Considerations (November 1998) includes the following guidelines:

> "1. … Patients must be given sufficient information, in a way that they can understand, to enable them to exercise their right to make informed decisions about their care.

[4] The Code of Health and Disability Services Consumers' Rights 1996.

2. This right is protected in law, and you are expected to be aware of the legal principles set by relevant case law in this area …

3. Effective communication is the key to enabling patients to make informed decisions …

13. Obtaining informed consent cannot be an isolated event. It involves a continuing dialogue between you and your patients which keeps them abreast of changes in their condition and the treatment or investigation you propose. Whenever possible, you should discuss treatment options at a time when the patient is best able to understand and retain the information. To be sure that your patient understands, you should give clear explanations and give the patient time to ask questions…"

Independent advice to Commissioner

The following expert advice was obtained from Dr Geoffrey Hughes:

"**Introduction**

I, Dr Geoffrey Hughes, am employed as a clinical director to the emergency department at Wellington Hospital, Capital Coast Health. A copy of a recent curriculum vitae is held by the Health and Disability Commissioner (HDC).

I have been asked by him to provide an opinion on this case, in particular to advise him whether [Dr B] provided an appropriate standard of care to [Mr A] at [the first public hospital].

I have read the supporting information provided by the HDC (see below) at length. I will not repeat all the details as they are well covered in that supporting information.

Background from the HDC

[Mr A] attended the Emergency Department at [the first public hospital] late on the evening of 29 January 2002 and was assessed by [Dr B]. [Mr A] received Maxolon in conjunction with Tramadol to treat his pain. [Mr A] had in the past experienced an adverse reaction to Maxolon. His symptoms included the sensations of anxiety and restless over-activity. He knew that diazepam would counter this reaction. As soon as he realised that he had received Maxolon, [Mr A] informed [Dr B] of his reaction and requested diazepam to alleviate the distressing symptoms. The doctor decided that diazepam was not indicated at this time (which was 2.30am).

An hour later (3.30am) [Mr A] was still in a distressed state and asked for the senior doctor. The situation was resolved when [Dr B] prescribed diazepam to [Mr A].

Complaint

On 30 January 2002, [Dr B] did not provide services of an appropriate standard to [Mr A]. In particular, [Dr B]:

- *Did not take remedial action in a timely manner to alleviate the adverse effects of Maxolon experienced by [Mr A].*

Supporting Information

- [Mr A's] letter of complaint to the Commissioner, 2 pages (pages 1–2) marked 'A'
- The Commissioner's notification letter to [Dr B], 2 pages (pages 3–4) marked 'B'
- [Dr B's] response to the Commissioner, 4 pages (pages 5–8) marked 'C'
- [Mr A's] medical records, 8 pages (pages 9–16) marked 'D'

Expert Advice Required

To advise the Commissioner whether, in [my] opinion, [Dr B's] decision to delay prescribing diazepam to treat [Mr A's] distressing symptoms was reasonable in the circumstances.

- What standards apply in this case?
- Did [Dr B's] care reach those standards?
- Please comment on any other matter which in your opinion should be brought to the Commissioner's attention.

Opinion on key issues

1. The notes and records completed by [Dr B] are of an acceptable standard.

2. In particular she recorded a drug history and she records that Stemetil 'does not agree' with the patient. No further details of this 'disagreement' are noted. The recording of a patient's drug history is normal and standard practice.

3. 'Does not agree' is a vague and imprecise phrase. It can be interpreted in one of several ways. It may mean that the patient experiences known side effects from a drug; experiences the desired effect of the drug; experiences an idiosyncratic reaction to it or may actually experience a true allergy.

4. True drug allergy can manifest like other allergies, e.g. to peanuts. In rare cases drug allergy can lead to severe anaphylaxis and even death. Experiencing the side effects of a drug is not the same as being allergic to it. It is prudent for a doctor to define further terms such as 'does not agree' when considering prescribing drugs.

5. All drugs produce side effects. Not all patients experience the side effects of a drug. Some patients tolerate side effects better than others. With some drugs all patients

will experience side effects if they are given enough of it. Some side effects with some drugs indicate the drug is achieving its desired clinical effect.

6. Drug side effects can be treated with nothing (allowing the effects to wear off with time), with a specific antidote or reversal agent (another drug) or with a non specific drug to ameliorate symptoms until the side effects wear off. The decision as to how best treat any drug side effects is a judgement based on the nature of the primary drug, the nature and severity of the side effects and the nature of the antidote, if indeed one is available, as well as the nature of the illness being treated.

7. Very commonly in clinical practice side effects are not treated. Patients are able to tolerate them quite well (coupled with an adequate explanation as to their nature) or the side effects are less of a concern than the fact that the drug is achieving its desired effect, or there is no antidote available. Another option is to stop the drug and review whether it is needed or not. An alternative drug may be available.

8. Stemetil (trade name Stemetil but true name = prochlorperazine) and Maxolon (trade name Maxolon but true name = metoclopramide) are different drugs but they have some overlapping properties and side effects. Their properties include an anti-nausea/vomiting effect, the most common reason for their prescription.

9. Side-effects which can occur with both of them include something known as (amongst other things) an 'extrapyramidal reaction'. These reactions are not allergic in nature but are due to the way the drug interacts with a receptor in the nervous system. To a lay person the differentiation between a side effect and an allergic reaction may seem pedantic but biologically and pharmacologically it is crucially important.

10. Extrapyramidal side effects are also seen, for example, in patients taking certain drugs (neuroleptics) used for treatment of psychiatric disease. At the severe end of the spectrum the extrapyramidal side effects can be extremely unpleasant with very severe and unusual body movements and posturing. These can also be called 'drug induced movement disorders'. For the severe or debilitating form of extrapyramidal side effects specific drugs or antidotes are available. These can be given orally or intravenously.

11. The symptoms [Mr A] describes in his letter may fall under the category of an extrapyramidal reaction, but at the more benign end of the spectrum of such side effects. Akathisia refers to an irresistible and unpleasant sensation of motor restlessness, and the inability to sit or stand still, all of which may be mistaken for mental or psychological problems. Akathisia remits if the offending drug is withdrawn. It may be helped (but not always) with a non specific drug such as a benzodiazepine, of which diazepam is an example. It may be difficult to diagnose and may not be recognised by health professionals, especially in emergency departments. To quote the Oxford Textbook of Medicine (Vol 3 page 1067 4th edition), these

drug induced side effects 'pose a repeated diagnostic problem in emergency departments'.

12. The medical records were not available in the middle of the night that [Mr A] attended the hospital.

13. Their lack of availability is of some concern although it is quite a common problem in hospital practice if the hospital uses a traditional 'hard copy' medical record with a folder system stored in a central archive. Notes can be unavailable for many reasons relevant to hospital activity. Even with the best tracking systems used to trace hard copy records they can still be unavailable. As health systems change to electronic medical records this anomaly will become less common. Change to a 'paperless' (electronic) medical record is a complex and costly business which does not and cannot happen overnight.

14. Having said this I am not convinced that availability of the notes on this particular night will have materially changed what happened. If the notes had been available it is difficult to say with any certainty that a different sequence of events will have occurred.

15. What do the hospital notes actually state about [Mr A's] reactions to drugs? What detail do they describe? What level of authority or expertise does the author of the note have? Is this note clearly visible? What hazard/warning system is used to highlight this risk?

16. Of interest is a note (0400hrs) that the patient 'changed his story several times regarding what he was allergic to'. There suggests some inconsistency in what [Mr A] was telling the staff. This will have caused some confusion or uncertainty to the health professionals.

17. The time taken to give diazepam is eighty (80) minutes after the Maxolon was given. All in all this is, in my opinion, within reasonable limits. There is no specific standard I am aware of to measure this against, but as mentioned above it is ultimately down to the clinical judgement of the health professionals involved, coupled with individual experience and/or seniority.

18. The side effects [Mr A] complained about were relatively ill defined at this stage. There was certainly no indication of a life threatening emergency, whereby an antidote needed to be given immediately. There was some uncertainty as to exactly what drug or drugs the patient was allergic to or disagreed with him. [Mr A] initially only mentioned Stemetil. The hospital records were not available.

19. Health professionals in this situation need to be convinced that the indications for giving a drug such as diazepam are fully justified. If not there is a risk of compounding a problem. If the patient experiences serious adverse effects then these are normally readily apparent and antidotes or life saving measures can be started at

once. If the symptoms are vague or non specific and not life threatening then care is needed before prescribing additional drugs. Due caution and reflection is mandatory.

20. Another thing which can go through the mind of a health professional in a situation like this is to consider whether the patient is showing 'drug seeking behaviour'. Diazepam for example, is a drug of dependence and people attending emergency departments who are dependent on it manifest a range of different means to try and gain access to it. I am not in any way saying that this is the case here but it is a factor that also needs to be considered in situations where patients demand a named drug which is known to cause dependence.

21. The need for senior input depends on the nature of the situation, as mentioned earlier.

22. I believe the time taken to give the diazepam to Mr A is acceptable.

Conclusion

Overall I believe the staff, in particular [Dr B], have provided care to [Mr A] that is well within acceptable limits. Apart from my criticism of not detailing further the nature of the comment that 'Stemetil does not agree with me' I have no concerns about the quality of the care he was given."

Response to Commissioner's provisional opinion

Mr A

In response to my provisional opinion, Mr A stated:

> "I told [Dr B] that while I didn't have drug allergies as such, I had a history of adverse reactions to several drugs including antibiotics. [Dr B] fails to acknowledge the fact I was in severe pain. I have had a previous history of kidney stones and it is acknowledged the resultant pain is severe. I have since had a diagnosis of raised serum uric acid and mild gout in the L big toe which explains my predisposition to the development of kidney stones. Both [Dr B] and [Mr C] seem to give the impression that I was deliberately vague and obstructive and possibly untruthful …
>
> At no times did I 'demand' Valium. I requested valium. I may have even begged. The use of the word 'demand' implies aggression. The fact that I requested to speak to a senior doctor suggests that I was acting reasonably and exercising my right to a more senior opinion. What is interesting here is that up to that point [Dr B] was adamant that I would not get any valium and it was only the possibility that her handling of my case might be reviewed by a more senior doctor that changed her mind. In my opinion

her interpretation of my request for valium as a demand is indicative of professional egotism reminiscent of doctors' 'I know best' attitudes of an era long past …

One question that arises is, if [Dr B] had any intention to prescribe an anti-emetic once I had volunteered that I had a reaction to stemetil (an anti-emetic), why didn't she enquire, 'how about Maxolon?'

… [Dr B] states that it is her 'usual practice' to advise a patient when prescribing analgesia that I am also prescribing a drug to minimise nausea. FACT. In the first instance the drug Tilcotil, an analgesic, was administered without an anti-emetic. There is no evidence … that I was informed that a different analgesic Tramadol in conjunction with Maxolon would be used.

Another question in relation to the fact of the reaction to Maxolon is: why [weren't] my reported symptoms compared to the symptoms of akathesia a known and relatively common adverse reaction to Maxolon as documented in New Ethicals. Lack of knowledge as to the side effects of medicines prescribed also raises questions of substandard professional care.

Informed consent is more often than not obtained informally. 'I am now going to do this, give you this.' Allowing the patient the opportunity to say 'no' or 'why'. This wasn't done here. In this case the patient's impaired communication due to severe pain has been conveniently and with the benefit of time to think, interpreted as the patient being difficult and obstructive and untruthful. Why would anyone purposely give false information to compromise the quality of his or her treatment?"

Dr B

In a letter dated 15 June 2004 in response to my provisional opinion, Dr B stated:

"I believe that we have to trust what our patients tell us. I had no reason to doubt [Mr A's] account of his allergies or to suspect that it was incomplete. Upon direct questioning as to allergies, he did not inform me of a Maxolon allergy. I therefore maintain that I prescribed in a reasonable and safe manner based on the information available to me.

The side effects of Maxolon which are material to this case are very uncommon and I do not feel that they are routinely explained to patients given this medication. Guidelines indicate a need to discuss 'commonly occurring or serious side-effects'. On mentioning that I was about to prescribe an anti-nausea medication, [Mr A] did not mention an adverse reaction to Maxolon. I think it likely given his experience with this drug that [Mr A] was aware that Maxolon was an anti-nausea drug.

I do not believe that it is standard practice to use the specific names of each and every drug given in a one off dose, as they are not normally familiar to patients. An example of this would be anaesthesia where I believe it would be most unusual to state to a

patient the name of each drug to be utilised. Furthermore, had I called Maxolon 'metoclopromide', [Mr A] may still not have made any further comment."

The District Health Board

Dr F, Director of Emergency Medicine, the DHB stated:

"I am concerned primarily with the findings of a breach of the Code on behalf of [Dr B] and [Mr C] with respect to the issue of prescribing Maxolon despite [Mr A's] allergy recorded in his notes. [Dr B] and [Mr C] were faced with a patient with acute abdominal pain requiring urgent analgesia. The patient gave a very clear history of an allergy to Stemetil and no other known allergies. In an alert and competent patient such a statement is a reasonable basis upon which to proceed with the administration of medication. The Stemetil allergy would have satisfied any curiosity aroused by a tick appearing in the medic alert or allergy box, as well as a non-specific medical alert abbreviation that appears on the patient label. I think it is only reasonable to expect the doctor or the nurse to have gone to the patient management system for further information if they thought the patient was either giving incomplete information or unable to give information at all. To the contrary, this patient gave a very clear history of which medication he was allergic to. I would have taken him at his word.

I think it is worth noting that the patient management system is now no longer in use by doctors in the hospital and instead a transition patient information system is in place which is also due for replacement. The current system available to medical staff carries no information about patient allergies. [The DHB's] prescribing policy needs to be updated to reflect this change …

With regard to the opinion regarding breach of requirement for information and consent, I think it is important to note that [Dr B] and [Mr C] acted in good faith to administer analgesia and an anti-nausea medication in a speedy and humane manner. A clear indication was given of what the medication was for. At that point there was no suspicion of allergies beyond the initial clearly stated intolerance to Stemetil. An extensive discussion of the side effects from the medicines that were delivered is not appropriate in an Emergency Department setting as in most cases the side effects are rare. The benefit in almost all cases weighs on the side of speed delivery when compared to the small risk of an adverse reaction without a pre-stated allergy.

On a more difficult issue I think it is important to note that there seemed to be inconsistencies in the statements made by the patient at the time of his visit to the Emergency Department, which at best would have proved confusing to those trying to care for his urgent medical problem. This patient has a history of similar behaviour at other [DHB] facilities. I would expect the patient to have a duty to provide reasonable information as well as to accept reasonable advice from his caregivers without excessive demands. Surely his behaviour has contributed to the conflict arising out of this situation and this should be reflected in the Commissioner's opinion."

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. …

4) Every consumer has the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer …

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; and…

e) Any other information required by legal, professional, ethical, and other relevant standards; …

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.

Opinion: Breach – Dr B and Mr C

Prescribing and administering Maxolon
Under Rights 4(1) and 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code) Mr A had the right to have services provided by Dr B and Mr C with reasonable care and skill, and that complied with relevant standards, including the DHB's internal policy on management and documentation of allergies.

The policy in place in January 2002 placed primary responsibility for ascertaining Mr A's allergy status on the prescribing doctor. The minimum steps required of Dr B to establish Mr A's allergy status were: checking for a medical alert bracelet, checking directly with Mr A, and checking his previous notes. The policy was clear that no medications were to be charted until these minimum steps had been followed and information as to Mr A's known or suspected allergies, or confirmed "no known allergies", had been recorded on the medication chart, countersigned, and dated. The policy also stated, "Except in an emergency no nurse may administer a medicine unless the allergy section of the relevant medication chart has been completed". Prior to the administration of any medication to Mr A, Mr C was required to follow the same minimum steps as Dr B, to confirm Mr A's allergy status and ensure no conflicting information had been provided.

During the triage assessment, Mr A answered "yes" to the question "medic alerts or allergies?" It is not clear whether he was asked or gave an answer to the next question printed on the triage form − "if yes how do they affect you?" − because a response has not been entered on the form. At some time, Mr A mentioned to Mr C that he had an adverse reaction to Bactrim. From Mr C's account to the ED Charge Nurse it appears that he discussed Mr A's drug history with him at an early stage in the admission process, and received "varying" responses. However, Mr C's entries in the records are insufficiently detailed to show what Mr A actually told him, or when. This was poor practice in terms of Right 4(2) of the Code and the DHB's policy.

The information that Mr A gave to Dr B at 12.30am appears to have differed from that given to Mr C. Mr A specifically mentioned Stemetil when questioned by Dr B. I agree with the advice of my expert, Dr Hughes, that as Stemetil and Maxolon have some overlapping properties and side effects, including akathisia, it would have been prudent for Dr B to have enquired further of Mr A as to what he meant when he said Stemetil did not "agree" with him, and to have recorded in the notes the detail of his response. I consider that this was the type of information required to be entered on the medication chart in accordance with the DHB's policy.

Mr A says that communication was difficult because he was in significant pain and feeling anxious, and was not fully coherent or able to properly explain his history. He admits he did not mention Maxolon to either provider when they asked him about his reactions to medication. However, by contrast, Dr B stated that Mr A was fully coherent and gave her a clear history. I find it difficult to reconcile this with the further recollections of both Dr B and Mr C that Mr A's responses to questions about his drug history were varied and

changed several times. The clinical records are insufficient to resolve these conflicts between the parties' accounts. Clearly, however, if Mr A gave varying information this should have been recorded, discussed, and checked; whether or not his responses were clear and coherent, the medication chart should have been completed and countersigned with Mr A' s allergy status specifically recorded. Had these steps been taken, it is probable that Dr B and Mr C would have identified a conflict in the information they had received.

Furthermore, had the request for Mr A's previous medical records been pursued, or PMS Alpha accessed and checked, Dr B and Mr C would more likely than not have realised that there was also a conflict between the information Mr A had given them, and what had previously been entered on his medical file. Dr Hughes commented that the availability of Mr A's previous notes may not have "materially changed what happened". I agree this is possible − the "[District Health Board's] Medical Warning" and front-sheet are undated and therefore I cannot be certain that "Maxolon" had been recorded on them before 30 January 2002. However, as the second public hospital notes of 22 June 2001 contained information confirming that Maxolon caused Mr A to become agitated, and his AMRs had been entered on PMS in October 2001, I consider it likely that in January 2002 the warning label would have included reference to Maxolon. Accordingly, had Dr B or Mr C seen this information, they would have recognised that Maxolon presented difficulties for this patient and that the possibility of prescribing or administering it should be discussed with him. Of particular concern in respect of these issues are Dr B's concession that she was unaware how to access information regarding a patient's AMRs on the computer system, the DHB's advice that Mr C received no training on the system at all, and Dr D's statement that the previous records were delivered to the ED "sometime after midnight".

The Director of Emergency Medicine suggested that Mr A's advice to Dr B regarding Stemetil, Mr C's tick in the "allergies" box on the triage sheet, and "AMR" on the patient label were sufficient to allow Dr B to have taken Mr A "at his word". He stated that "it is only reasonable to expect the doctor or the nurse to have gone to the patient management system for further information if they thought the patient was either giving incomplete information or unable to give information at all". The difficulties with this argument are that neither Mr C nor Dr B appears to have noticed or fully recognised the significance of "AMR" on Mr A's pre-printed patient label; Dr B's verbatim note of Mr A's advice gave an insufficiently clear clinical picture of his actual AMR status; and Dr B and Mr C failed to recognise that their patient had given different information to each of them about his AMRs. Moreover, the requirement to check Mr A's previous records was one of the three minimum steps required to establish Mr A's allergy status, and was not subject to conditions or qualification.

I accept that communication between Mr A and those caring for him in the early hours of 30 January 2002 was difficult, and that because he gave conflicting information to his providers, a degree of confusion arose. I acknowledge that Dr B and Mr C acted in good faith when providing services to Mr A, and agree with the comment that Mr A had a degree of responsibility to provide reasonable information to his providers, to assist them to make

appropriate clinical decisions for him. I note that Mr A did not wear a medical alert bracelet; had he done so this may have provided some assistance in confirming his AMR status.

However, in terms of the Code, the test is whether Dr B and Mr C acted reasonably in the circumstances. In accordance with the DHB's policy it was Dr B's responsibility to confirm Mr A's allergy status. As the allocated ED nurse, Mr C was required to follow the same minimum steps as Dr B, and cross-reference the information Mr A had provided. In my opinion, both Dr B and Mr C failed to act with reasonable care and skill so as to sufficiently discharge these responsibilities and did not fully comply with the DHB's policy. Therefore, they breached Rights 4(1) and 4(2) of the Code.

Informed consent

Informed consent is not a "one off" event, but a process, involving open, honest, and effective communication (Right 5); and the provision of information that a reasonable patient, in that patient's circumstances, needs to make an informed choice or give informed consent (Right 6(2)). Subject to specific exceptions, services may be provided only if the patient has made an informed choice and given informed consent (Right 7(1)). It is important to note that in terms of this process, Mr A's implicit refusal of Stemetil (to Dr B) and Bactrim (to Mr C), on the basis of their anticipated adverse effects, did not constitute his implied acceptance of all other alternative options for pain relief and nausea control.

The DHB's policy on "Informed Consent for Treatment" in place in January 2002 reflected these statutory requirements, noting that "an unspecified general consent does not meet the requirements of informed consent" and that "Informed consent based on informed choice is the basis of [the provider/patient] partnership. Informed consent is the process whereby someone, who has the competence and the capacity to consent, having received sufficient information, makes a reasoned, unpressured choice to accept or decline a proposed therapy or procedure …" The policy gave primary responsibility for giving information and obtaining consent to Dr B, but noted that responsibility may be shared in a "team care" environment.

Mr A expressed concern that Dr B and Mr C, who both trained in England, may have been unaware of their obligations to obtain their patient's informed consent when working in New Zealand. I do not believe this to have been the case. In England, established principles of good medical and nursing practice set out clear guidelines on informed consent. While they are not codifed by statute, as is the case here, the requirements are the same, ie, a continuing dialogue between doctor/nurse and patient, involving effective communication, sufficient information that a patient can understand, and a patient's informed choice. I have no reason to believe that Dr B and Mr C were unaware of their obligations in this respect and that they did not recognise their responsibility to apply the same principles to their work in New Zealand. While it is concerning that Dr B says she had not read the Code before starting work in New Zealand, this does not absolve her from responsibility for complying with it.

Dr B advised that her "usual practice" when prescribing analgesia is to advise the patient that she is also prescribing an anti-emetic. In her initial response she stated that she could not recall, given the distance in time, whether she advised Mr A that she was going to prescribe him tramadol with Maxolon. However, in response to my provisional opinion, she said that "on mentioning that I was about to prescribe an anti-nausea medication, Mr A did not mention an adverse reaction to Maxolon". On balance, for the reasons I set out below, I consider that Dr B did not tell Mr A that she was going to prescribe Maxolon.

When Dr B prescribed Tilcotil for Mr A, she had prescribed it without a parallel anti-emetic. When further pain relief was considered necessary it would have been prudent for Dr B to have asked Mr A whether the Tilcotil had made him nauseous, to have informed him that because his pain had not settled, she intended to prescribe further but different pain relief, and that as a precaution she proposed to prescribe Maxolon to counter nausea. There is no evidence that she did so. Dr B did not record in the notes any discussion she had with Mr A regarding her prescription of tramadol and Maxolon, and I do not agree with her assertion that her documentation is "evidence" that she listened to Mr A and sought to involve him in his own care. In contrast, Mr A stated that at 2.10am he expected to receive only one drug, for pain relief, but was surprised to see Mr C administer a second drug, without explanation.

I accept that in a busy ED it is impracticable for doctors to engage in an "extensive discussion of the side effects" of the medicines prescribed for each patient, and I acknowledge the Director of Emergency Medicine's advice that Dr B and Mr C acted in good faith to administer analgesia and anti-nausea medication to Mr A in a "speedy and humane" manner. However, whether Dr B and Mr C should have discussed possible side effects of the drugs charted for Mr A is not, in fact, the issue in this case. Rather, it is that Mr A was not given the minimum information to which he was entitled – what drugs were proposed or why – before they were administered through his IV line. In this respect, Mr A's submission to the District Court regarding the conversation he would have expected to have occurred before medication was prescribed or administered is correct; it would have taken little time at all for Dr B and Mr C to have informed Mr A, "I am going to give you Tramadol for your pain, and some Maxolon, in case the Tramadol causes nausea". In terms of paragraph 7 of the DHB's policy on the method for obtaining informed consent, Rights 6(1)(a) and (e), and Right 6(2) of the Code, this was information that Mr A was entitled to receive in order to make an informed choice whether to receive either drug.

In the continued absence of Mr A's previous medical records, initiating such a discussion would also have allowed a further opportunity to clarify Mr A's drug history and allergy status and check his tolerance for specific anti-emetic drugs. However, contrary to Dr B's own usual practice, the DHB's policy on informed consent, and Right 6(2) of the Code, she failed to do so. In my opinion Dr B therefore breached Rights 4(2), 6(2) and 7(1) of the Code. Similarly, because Mr C failed to inform Mr A that Maxolon was about to be administered, he breached Rights 4(2) and 6(1)(a) and (e) of the Code.

No breach – Dr B, Mr C

Remedial action to counter the effects of Maxolon
Under Right 4(4) of the Code Mr A had the right to have services provided in a manner that minimised potential harm, and optimised his quality of life. Mr A complained that neither Mr C nor Dr B took remedial action in a timely manner to alleviate his anxiety following the administration of Maxolon.

At 2.10am, as soon as Mr C told Mr A that he had administered Maxolon, Mr A stated that in the past Maxolon had made him anxious and agitated to the extent that diazepam had been required to alleviate his condition. This information was conveyed by Mr C to Dr B and recorded in the nursing progress notes. I am satisfied that Mr C's actions in this regard were appropriate, as it was not for him to make a clinical decision whether diazepam was warranted.

Dr B spoke to Mr A at 2.30am, and formed the impression that diazepam was not indicated at that time. She acknowledged Mr A's anxiety, but was concerned not to prescribe him further medication unnecessarily. She advised: "We … have a duty to minimise potential harm, and the time between [Mr A] expressing his concern at having a reaction to the Maxolon, and me treating him, served to avoid giving further potentially harmful medication." This approach was endorsed by my expert, Dr Hughes, who stated:

> "There was certainly no indication of a life threatening emergency, whereby an antidote needed to be given immediately … Health professionals in this situation need to be convinced that the indications for giving a drug such as diazepam are fully justified. If not there is a risk of compounding a problem. If the patient experiences serious adverse effects then these are normally readily apparent and antidotes or life saving measures can be started at once. If the symptoms are vague or non specific and not life threatening then care is needed before prescribing additional drugs. Due caution and reflection is mandatory."

In relation to Dr Hughes' further comment that another matter to be considered by health professionals in such situations is whether the patient is showing "drug seeking behaviour", I should make clear that neither Dr Hughes nor the Commissioner suggests that this was the case with Mr A. There is also no evidence that this was one of the factors Dr B took into account when declining diazepam for Mr A.

It is evident from both Dr B's and Mr A's accounts that he became restless and agitated. I agree with the assumption of my advisor, Dr Hughes, that Mr A most likely experienced akathisia as a result of receiving the Maxolon. Dr Hughes advised that akathisia presents certain difficulties to emergency department medicine, because it is not always recognised by those providing care and it is difficult to diagnose. I acknowledge that there were other factors that potentially contributed to Mr A's restless and agitated state, including the effects of Tilcotil and tramadol, his unsettled abdominal pain, his anxiety at being in ED and

his distress in perceiving that he was not being taken seriously when he had previously had negative experiences in hospital.

However, in such circumstances it would have been wise for Dr B to have explained to Mr A her reasons for withholding diazepam at 2.30am. Further, it would have been appropriate for full observations to have been taken and recorded between 2.10am and 3.30am, and 3.30am and 4am when Mr A settled and fell asleep. While Mr C took Mr A's pulse shortly before 2.30am (it was recorded as 80 and regular), I am somewhat concerned that no observations were taken within the above time periods. Accordingly, while there is no evidence in the medical records that Mr A experienced tachycardia and high blood pressure after receiving Maxolon, nor is there definitive evidence that he did not. Had Dr B and Mr C taken these steps, Mr A's perception that his symptoms were not being addressed and he was perceived as a "nuisance" may have been minimised.

On balance, I am satisfied that it was appropriate for Dr B to adopt a "wait and see" approach to Mr A's condition. While a wait of 80 minutes for diazepam undoubtedly felt like an inordinate length of time to Mr A, I consider it was not clinically inappropriate or likely to cause him further potential harm. I place no weight on Mr A's assertion that the only reason Dr B agreed to give Mr A diazepam at 3.30am was her concern that her actions would be reviewed by a more senior doctor. Rather, I accept Dr Hughes' advice that Dr B's decision was "within reasonable limits" and as a matter of clinical judgement was reasonable in the circumstances. Accordingly, in relation to these matters I am satisfied that neither Mr C nor Dr B breached the Code.

Opinion: Breach – The District Health Board

Vicarious liability
Under section 72(2) of the Health and Disability Commissioner Act 1994, employers are responsible for ensuring that their employees comply with the Code. Pursuant to section 72(5) of the Act, it is a defence for an employing authority to prove that it took such steps as were reasonably practicable to prevent the acts or omissions leading to an employee's breach of the Code.

I am concerned that while the DHB had systems and policies in place for management and documentation of allergies and obtaining informed consent, these were insufficient and had been inadequately advised to ED staff, to prevent Dr B and Mr C from breaching the Code. Moreover, the absence of a system to ensure speedy delivery or transfer of a patient's previous medical records from within the first public hospital to the ED, inadequate staff training on PMS Alpha, and Dr B's comment that the DHB had not provided her with a copy of the Code during her induction, are cause for concern.

Mr A had arrived in ED at 10.31pm, and his previous medical records were requested. However, neither the DHB nor Dr B can confirm whether the records became available or

when; Dr D has only said that they were delivered "some time after midnight". Checking a patient's previous notes, admission sheet alerts and stickers on the front cover of the medical notes was one of the three minimum steps required of staff to establish Mr A's allergy/AMR status. PMS Alpha was not specifically included in that check list, despite being implemented at a public hospital in the same year that the policy took effect. In my view, it should have been included at the time or in 1999 when the policy was updated.

While Dr D expected all clinical staff at the first public hospital to be aware of PMS Alpha and have access to it, it is clear that the system was not in fact known to all clinical staff and at times their knowledge of how to use it was incomplete owing to insufficient or inappropriate training. According to Dr B, her training on PMS was limited to accessing laboratory results and had not included locating AMR warnings. Dr D conceded that Mr C "might also not have known about the PMS system as he did not receive formal computer training".

In my opinion, the DHB's systems were inadequate to ensure that its own policies, and the Code, were complied with by staff. Accordingly, the DHB is vicariously liable for Dr B's and Mr C's breaches of the Code.

Actions taken

As a result of Mr A's complaint, the DHB carried out an internal investigation following which an extensive training programme regarding allergies, drug reactions and documentation was given to staff, and issues regarding informed consent were reinforced. Ms E, the DHB's Operational Manager for Surgical Services, confirmed directly to Mr A that having addressed the issues he had raised, the DHB would ensure that in future a more thorough triage assessment regarding patients' allergies/drug reactions will take place with patients presenting to ED, and staff will be expected to inform the patient of the drugs to be given prior to the actual administration.

As Mr A had suggested, staff would be encouraged to "talk the patient through what is happening as procedures are undertaken". The DHB also updated its policies on "Management of and Documenting Allergies/Adverse Drug Reactions" (March 2002), "Drug Administration" (April 2002) and "Prescription of Inpatient Medication" (March 2003). I commend the DHB on these actions and acknowledge that a gracious and sincere apology was extended to Mr A at that time.

Dr F advised that PMS Alpha is now no longer in use. He highlighted the need for the District Health Board to update its prescribing policy in light of the transition system for management of patient records and the pending introduction of a further new system. I encourage the DHB to attend to these matters.

Follow-up actions

I recommend that Dr B take the following actions:

- Provide a written apology to Mr A for her breaches of the Code. This should be sent to my Office and will be forwarded to Mr A.

- Review her practice in light of this report, in relation to providing information to patients and obtaining their informed consent.

I recommend that the District Health Board take the following actions:

- Provide a written apology to Mr A for the breaches of the Code by its staff. This should be sent to my office and I shall forward it to Mr A.

- Continue to review and update its policies for management and documenting of allergies.

- Confirm that a new system for management of patient records has been implemented and that the Board's policies appropriately correspond to the way this system is utilised.

- Ensure that its induction and training programmes for all staff, including foreign-trained staff in particular, include reference to the Code and providers' obligations under it. I encourage the DHB to provide copies of the Code to all new employees.

Further actions

- A copy of this report will be sent to the New Zealand Medical and Nursing Councils, the General Medical Council in the United Kingdom, and ACC.

- 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.