Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Complaint

A man who had had an aortic valve replacement in February 2005 presented to his GP in September 2005 with signs of an acute chest infection. The GP took a blood culture, commenced antibiotics and referred him to hospital with provisional diagnoses of pneumonia and/or endocarditis.

In hospital, chest X-rays confirmed pneumonia and, as he had no clinical signs of endocarditis, his antibiotics were continued, and he improved, despite the blood culture growing *Staphylococcus aureus*. He was discharged from hospital only to return four days later with acute bacterial endocarditis, and subsequently died. The Commissioner's investigation (and lesson from this case) concerned the prophylactic treatment of bacterial infections in patients following valve replacement.

30 May 2006

Dear Mrs A

Complaint: Dr B & a public hospital
Our ref: 05/18414

Thank you for your response to my provisional decision.

You have asked a number of questions, which I have carefully considered and will address in the course of explaining my final decision below.

But first I need to tell you, that, having further reviewed the information from Dr B, a District Health Board and ACC, the report from ACC's cardiology advisor, Dr Phillip Matsis, and your response to my provisional decision, I have not been persuaded to alter my provisional decision. In accordance with section 38(1) of the Health and Disability Commissioner Act 1994, I have decided to take no further action on your complaint because having regard to all the circumstances further action is unnecessary. My reasons (which until page 5 paragraph 4 are unchanged) are as follows:

Investigation
The following issue was identified for investigation:

- *The appropriateness and adequacy of diagnosis, investigation and treatment Dr B provided to Mr A at a public hospital between 28 and 30 September 2005.*

Information gathered
Mr A had an aortic valve (tissue valve) replacement in February 2005.

On 28 September 2005, your husband's general practitioner, Dr C referred him to a provincial hospital. Mr A had been experiencing high temperatures, which you had been unable to reduce with paracetamol and cool sponging. Dr C listened to your husband's chest, noted poor air entry into the lungs and recorded low oxygen levels. He began antibiotics.

When Mr A presented at the provincial hospital, blood was taken for culture and he was transferred to the public hospital. The provisional diagnoses were pneumonia or endocarditis (infection of the lining of the heart).

At 10.30pm Mr A was seen by the medical registrar at the public hospital. He was admitted to the ward, two further blood cultures were ordered, and he was commenced on intravenous Augmentin, an antibiotic. Although the medical staff suspected your husband could have a heart infection, there appears to have been no clinical evidence of it at the time. There was also no evidence of heart failure. The chest X-ray was consistent with a diagnosis of pneumonia.

At 9.20am on 29 September, Dr B saw Mr A for the first time. Although Mr A reported feeling a little better, the consolidation at the base of his lungs and fever remained. Dr B could hear a heart murmur, but this had been recorded previously and remained unchanged. As there were no clinical signs of endocarditis, Dr B still believed the diagnosis was pneumonia and he continued the intravenous antibiotic.

Discharge
Dr B saw your husband again on 30 September. By then he was aware that your husband's first blood culture grew *Staphlococcus aureus*, a bacterial infection. But Mr A's temperature and respiratory rate had returned to normal, his chest was clear and he had no signs of infection in or around the heart. Nevertheless, Dr B returned to see your husband again before he was discharged that afternoon. Dr B said that the presenting symptoms, clinical findings, and chest X-ray confirmed the diagnosis was pneumonia, but because endocarditis had not been excluded, he arranged to see Mr A in the outpatient department five days later. Mr A was prescribed oral antibiotics and discharged from the public hospital.

However, over the next few days, your husband's condition deteriorated and on 4 October he returned to the public hospital, with fever, sweats and lethargy. His ECG recorded heart block. Mr A was diagnosed with endocarditis and intravenous flucloxacillin was commenced.

On 5 October Dr B saw Mr A, and ordered an urgent ECHO cardiogram. Dr B said that the ECHO "showed a suspicion of a lesion in association with the aortic valve". Your husband was transferred to CCU and then to a city hospital for further management. Tragically, Mr A died in the city hospital a short time later.

The DHB investigation
The Clinical Director of the Department of Medicine at the public hospital, Dr E, was notified of your husband's transfer to the Department of Medicine at the city hospital

and initiated an investigation the following day. On 11 October, Dr E received a letter from Dr D, the city cardiologist who treated your husband. Dr D was concerned about what appeared to be "the lack of appropriate action taken once the blood cultures grew *Staphylococcus aureus*, with regard to both the initial diagnosis and, more importantly, the appropriate parenteral antibiotic treatment".

On 26 October a special meeting of the public hospital Medical Services Mortality and Morbidity Group was called, to discuss the quality of Mr A's care. Following that, Dr E contacted you to arrange to meet to discuss the findings of their investigation.

Meeting
On 16 November you and your son met Dr E and Dr B at the provincial hospital. Dr E also arranged for an advocate and general practitioner to attend. You had prepared a number of questions which Drs E and B attempted to answer. Dr E followed up the meeting with a written report of the investigation.

You were concerned that your husband was discharged from the public hospital on 30 September in an effort to reduce the weekend workload, and Dr E assured you that was not the case. Dr B acknowledged that he did not act on the results of the blood cultures appropriately and that he had made the wrong diagnosis. He did not order a scan because your husband was responding to antibiotics, and this had seemed to confirm his diagnosis of pneumonia. Dr B apologised to you for his error, "which he deeply regretted", and subsequently provided a written apology. However, you remain of the view that Dr B "completely ignored ALL the indications of Endocarditis".

ACC advice
On 8 February 2006 ACC accepted your treatment injury claim on the basis of a delay in adequate treatment. The ACC advisor, Dr Phillip Matsis said that, because of the aggressive nature of the organism, the history of aortic valve replacement and the high risk of mortality, a diagnosis of endocarditis should have been presumed and treated aggressively. Mr A should have received intravenous antibiotics for four to six weeks; an echocardiogram (or serial echocardiograms) should have been performed to confirm the diagnosis; and tertiary services should have been consulted about the most appropriate treatment.

Systemic issues
Since your husband's death, cardiologists, physicians and microbiologists at the public hospital and two tertiary hospitals have been involved in developing new guidelines for the treatment of patients presenting with *Staphylococcus aureus* at hospitals in the region.

In addition to this, the DHB intends to audit all cases of *Staphylococcus aureus* from the last 12 months to heighten awareness of this infection and identify any other gaps in clinicians' knowledge of the appropriate treatment.

With the help of the clinical microbiologist from a tertiary hospital, the DHB has also examined its systems for the management of *Staphylococcal* infections in its hospitals. This process found no systems problems "regarding laboratory testing or communication of laboratory results, particularly pertaining to blood cultures".

Dr B
Dr B said that "in retrospect I clearly did not make a correct diagnosis at [Mr A's] 1st admission. When I reviewed him on Friday I was falsely reassured by the absence of clinical stigmata of SBE [subacute bacterial endocarditis] and clinical signs of pneumonia, and felt the right diagnosis was pneumonia."

Dr B advised that he has changed his practice and now he considers that all patients who have *Staphylococcus* in their blood cultures have endocarditis unless proved otherwise. He undertakes further tests and treats aggressively.

In response to your concern that he may have made similar mistakes before, he has advised that in more than 20 years of practice he has not previously had adverse comments or findings in regard to his clinical skills. This has been supported by the DHB who have advised Dr B is held in high regard.

Your response to the provisional opinion
The facts in this case are not disputed. Dr B diagnosed your husband with pneumonia, which was confirmed on X-ray, and he treated your husband accordingly. Mr A responded well initially and he was discharged home. However, it is now clear that this response was most likely because the underlying infection was, in effect, partially treated by the antibiotics prescribed for pneumonia and this provided false reassurance to Dr B.

In your response to my provisional opinion, you reiterate your view that Dr B "completely ignored the evidence of endocarditis". You say that "it was in his blood." But there were no clinical signs of endocarditis. It seems from your letter that you may be confusing *Staphylococcus aureus* and endocarditis. *Staphylococcus* is a bacterium normally found on the skin of all individuals. Under certain circumstances, such as a patient with disease of a heart valve or one who has had a valve replacement, *Staphylococcal* infections can be dangerous but just because *Staphylococcus aureus* was found in Mr A's blood culture does not mean it was definitely on his artificial aortic valve.

The issue is not whether Dr B ignored signs of endocarditis, but whether he should have treated Mr A on the presumption he had endocarditis rather than wait until specific clinical signs appeared and/or tests confirmed it. According to Dr Matsis, your husband should have been treated for endocarditis without delay, even before it had been fully investigated.

As stated earlier, Dr B has accepted this. He has admitted he made a wrong diagnosis (pneumonia) and, as a consequence, treated Mr A inappropriately. Dr B was aware of the risks of heart infections because of the artificial valve. He said he monitored your husband for evidence of endocarditis, but all the clinical signs indicated pneumonia. I am satisfied that Dr B took your husband's illness seriously and that his error of judgement was in waiting for clinical signs of endocarditis to appear, rather than presuming he had endocarditis and treating it aggressively. He has also accepted that he underestimated the virulence of the staph organism. It appears this was an isolated error by Dr B. He has recognised his mistake, apologised, and changed his practice accordingly. Dr B has confirmed that he now treats all blood borne *staphylococcal* infections as endocarditis until proven otherwise. All the patients will have ECHO

cardiograms, intravenous antibiotics for 28 to 40 days, and remain in hospital until the bacteria is under control. He also asks relatives of patients if they are happy about the patient being discharged.

For its part, the DHB acted promptly to investigate your husband's treatment and reported its findings to you openly and honestly, although I acknowledge that you believe you were only informed as a result of Dr D's letter questioning aspects of your husband's care. The DHB ensured that you were well supported during its meeting with you, with an advocate and general practitioner present to support you and help interpret clinical terminology. I am also satisfied that the DHB has taken appropriate steps to ensure that its systems deliver timely reports of laboratory results, particularly blood culture results, to the referring consultant.

The expert advice
In your complaint you were not completely satisfied by the apology and actions taken by Dr B and the DHB, and you were concerned that the same mistake could happen to another family. For this reason I asked Dr Mary Seddon for independent, expert advice on the responses, particularly the new guidelines for the treatment of *Staphylococcal* infections. As you know from her report, which was included with my provisional decision letter, that Dr Seddon also believes that Dr B and the DHB have responded appropriately. Dr Seddon recommended some minor improvements to the guidelines and I brought these recommendations to the attention of Dr B and the DHB.

In your response to my provisional opinion, you also asked why Dr Seddon was not sent a copy of your husband's clinical records. A key purpose of an investigation by my Office is to find out what happened and to recommend any changes that need to be made to avoid similar problems happening again. But in this instance, two investigations had already been concluded by the DHB and ACC, and action was already being taken to address the issues identified. Therefore, a key focus of my investigation has been whether the subsequent actions were adequate and appropriate. As a recognised expert in hospital systems, Dr Seddon was asked to comment on this, rather than your husband's clinical care.

Differences with ACC
You have also questioned why I was proposing no further action when ACC had found that your husband suffered a treatment injury. The fact that Dr B failed to treat your husband's aortic valve endocarditis when Mr A first presented to the public hospital is not disputed. Even Dr B himself has admitted that he made a misdiagnosis, and he has subsequently changed his practice to reflect the advice from Dr Phillip Matsis, that given Mr A's history and risk factors, Dr B should have made a presumptive diagnosis of endocarditis, taken steps to confirm and then treat it.

It is important to note that ACC and HDC fulfil two quite different roles. In determining eligibility for cover under a treatment injury claim, ACC is focussed on the outcome of care. In contrast, HDC is charged with facilitating the fair, simple, speedy, and efficient resolution of complaints. We have a number of different options for doing this, and we focus on lessons that can be learnt when mistakes occur.

You have also asked why, before you left the public hospital on 30 September, you and your husband were not told that his previous aortic valve replacement could cause

other underlying problems. I am unable to comment on what you were told about the possible complications of your husband's present illness that day, but I accept that you would never have taken your husband home or delayed bringing him back to hospital if you had known Dr B suspected a more serious, underlying problem.

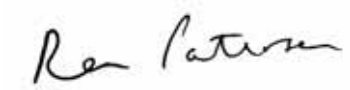
I have advised Dr B that, in not sharing his concerns with you, you were misled into thinking that your husband's condition was improving. While it would be very difficult to establish what was said before you left the hospital, I think the general point still applies. In my view, when giving information to family members health professionals should strive to be as accurate and factual as possible, particularly if another complication could arise. Although there may be a temptation to try to cushion the impact of information in order to keep families from becoming upset, this may cause more problems than it solves. I have included this advice to Dr B and the DHB.

Final decision
In all the circumstances my view is that further investigation of Dr B and the DHB is not warranted. It is clear Dr B and the DHB have learned important lessons from this case. I know that this is no consolation for the loss of your husband, but I hope it will bring you some comfort to know that changes have been made.

Follow-up actions
I intend to send a copy of this letter to the Royal Australasian College of Physicians and the Royal New Zealand College of General Practitioners. I will place a copy on my website and bring it to the attention of all District Health Boards for education purposes. Of course your family name, Dr B and the DHB will not be identified in my letter.

Thank you for bringing your concerns to my attention.

Yours sincerely



Ron Paterson
Health and Disability Commissioner

6th April 2006

Expert Opinion Provided By Dr. Mary Seddon

I have been asked to provide an opinion to the Commissioner on case number 05HDC18414/WS, and I have read and agree to follow the Commissioner's Guidelines for Independent Advisors.

Qualifications: MBChB, FRACP, MPH, FAFPHM.
Training: Graduated Otago Medical School 1987, MPH (Auckland) 1999.
Experience: Medical Registrar appointments in Auckland and Tauranga 1990-1995.
General Physician Middlemore Hospital 2000-2002.
Head of Quality Improvement Medicine and Acute Care, Middlemore Hospital
Clinical Director for Patient Safety Campaign, CMDHB.
Senior Lecturer in Quality Improvement, Epidemiology and Biostatistics, School of Population Health, University of Auckland,

Referral instructions: Expert Advice Required

1. Is [Dr B's] response to the Commissioner's investigation appropriate?
2. Did [the DHB] adequately investigate and isolate any deficiencies in its systems?
3. Are the guidelines developed by [the DHB] appropriate and adequate for the treatment of *Staphylococcal* infections?
4. If not, what additions or alternatives to these guidelines would you recommend?
5. Are there any other relevant issues that you wish to bring to the Commissioner's attention?

The following documentation was received and reviewed.

1. Incident form
2. Responses from [Dr B], [Dr E] and [the DHB] to the Commissioner's investigation
3. Letter from [Dr D]
4. [The DHB] guidelines for the treatment of *Staphylococcal* infections

Note: I was not supplied with the original clinical notes.

Brief synopsis of case:

[Mr A] a 63 year-old man was transferred to [the public hospital] from the [provincial hospital] on the 28th of September having presented with fever, poor air entry and low oxygen saturations. Blood cultures were taken and the referring doctor's differential diagnosis was pneumonia or endocarditis.

Significant in his past history was a porcine aortic valve replacement in February 2005.

[Mr A] was admitted by a medical registrar late at night - blood cultures were taken and an examination specifically looking for stigmata of sub-acute bacterial endocarditis (SBE) was negative. The CXR was consistent with pneumonia and [Mr A] was started on a broad-spectrum antibiotic.

[Dr B] saw [Mr A] the next day, noted the fever, the signs of consolidation in the lungs and recommended continuing the antibiotic. He also heard a heart murmur, but apparently this was not a new sign.

When [Mr A] was reviewed on the 30th his fever had settled and he was much improved. Again a thorough examination found no stigmata of SBE. The result of the first blood culture was positive for *Staphylococcal aureus* on the 29th but according to his letter this was not communicated to [Dr B] until the 30th. When he received the result he reviewed [Mr A] and found that he was continuing to improve, felt well and was haemodynamically stable. He was discharged with a diagnosis of pneumonia however, [Dr B] had not ruled out SBE and therefore arranged to see [Mr A] in outpatients 5 days later. [Mr A] was discharged on oral antibiotics.

Unfortunately [Mr A's] condition deteriorated and he returned 4 days later with high fever, sweats and lethargy. His ECG had changed and an echo suggested a possible problem with his aortic valve. He was diagnosed with endocarditis, started on flucloxacillin and transferred to [the city hospital], where he died [a short time later].

Specific questions:

1. Is [Dr B's] response to the Commissioner's investigation appropriate?

[Dr B] has written a detailed letter that outlines his actions. It is clear that he considered SBE as a diagnosis and was cognisant of the increased risk in someone with a previous valve replacement. What he did not recognise was the significance of *S.aureus* in the blood culture - if he had [Mr A] would have been kept in hospital for a prolonged course of antibiotics. The broad spectrum antibiotic given would have partially treated the *S. aureus* and falsely reassured [Dr B] that [Mr A] was improving.

[Dr B] documents in his letter the actions taken in response to this incident, namely:

- visited with [Mrs A] to disclose the information and acknowledge the error in judgement (See [Dr E's] letter)
- the case was discussed at the departments mortality meeting
- discussions were held with infection control at [the city hospital] and cardiology at [the city hospital].

He also outlines the changes that he has made to his clinical practice as a result of this incident, with a standard approach to all patients with *S. aureus* bacteraemia, involving investigations for SBE and prolonged antibiotic course.

I feel that this response by [Dr B] to the Commissioner was appropriate.

2. Did [the DHB] adequately investigate and isolate any deficiencies in its systems?

It is somewhat difficult for me to answer this question, this far removed from the investigation. The letter from [Dr E] dated the 27th of February, outlines in some detail the investigation process which seems thorough.
[Dr E's] letter states that the case was discussed at the Incident and Complaints Review Meeting, though I have no notes as to what the outcome of this was. As stated above the case was also discussed at the M&M meeting, but again I have no information as to the recommendations of this group as it was a protected QA activity.
[Dr E] does outline his discussion with:
[A city hospital cardiologist]
[An Infectious diseases physician]
[A clinical microbiologist] (but with a supervisory role for [the DHB]) and,
[Mrs A].

So although I cannot say that the investigation done by the Incidents and Complaints Review Group or at the M&M meeting were adequate it is clear that there was recognition of the incident and wide consultation as to how to prevent such problems in the future.

There did not seem to be a deficiency in the laboratory system of alerting positive blood cultures. *S. aureus* bacteraemia is not common and though increasing many general physicians will have had limited exposure to cases of community acquired *S. aureus* bacteraemia in their working life-times. There are other members of the Staphylococcal family (e.g. *S. Epidermidis*) which are common contaminants in blood cultures and usually of little significance. According to [Dr E's] letter, the laboratory will now alert clinicians to the importance of further investigating positive *S. aureus* blood cultures.

As stated I am unable to ascertain whether the error in recognising the significance of the community –acquired *S.Aureus* bacteraemia was totally due to a knowledge-deficit or whether it was compounded by other factors. I do not for instance know whether there was pressure on time, whether the ward was busy, or whether there were other distractions. A full Root Cause Analysis might have uncovered such problems, but [the DHB] has investigated as best as can be expected in the current environment.

From the information at hand it would appear that [the DHB] has sought expert opinions and adequately investigated this case.

3. Are the guidelines developed by [the DHB] appropriate and adequate for the treatment of *Staphylococcal* infections?

The Staphylococcus Aureus Bacteraemia (SAB) Management Recommendations and Flow Diagram are appropriate. The distinction between hospital-acquired and community-acquired SAB is well made.

4. If not, what additions or alternatives to these guidelines would you recommend?

There are some minor improvements that I would suggest:

- The Management Recommendations could be better written with the investigations and treatment separated into that for hospital-acquired (usually i.v. line associated) and community-acquired as it is in the flow diagram

- I am unsure of the significance to the statement: "25% of cases of SAB develop Staphylococcal bactiuria." I think that if this is kept in, it should appear below "Even one positive blood culture is significant and is rarely caused by contamination." This is the key statement of the whole document and should be more visible and in bold.

- Neither the flow diagram nor the Management Recommendations have an author, nor a date for review, which would be important so that they can be up-dated in the future.

- My only specific comment on the flow diagram is that it is not clear that if a trans-thoracic echo is negative that they should still do a trans-oesophageal echo and this could be amended simply.

The key to making flow-diagrams and management recommendations useful is to make them available at the point of decision-making. It would appear that this will happen with the change in practice from the laboratories – the decision to directly advise clinicians of the significance of a blood culture positive for *S. Aureus*. It would be good if the recommendations and flow diagram were electronically linked to the laboratory results so that clinicians could quickly find the information that they needed. However, I am not aware of the electronic capability of [the DHB] to know whether this is possible.

It is also not clear how these recommendations and guidelines will be extended to cover primary care. In this case a blood culture was taken initially at [the provincial hospital] and was presumably also positive. In future it would be useful to circulate these documents to other clinicians in the DHB which might find themselves confronted with SAB.

5. Are there any other relevant issues that you wish to bring to the Commissioner's attention?

No