

23 October 2002

Dear Dr B

Complaint by Ms A

Thank you for your detailed response to my provisional opinion. I provided a copy of my independent expert advice to Ms A and have also received a response to that from her. I have carefully considered these responses and have amended my report accordingly. However, my opinion is largely unchanged and I remain of the opinion that you breached Right 6(1)(b) of the Code of Rights.

Ms A's complaint was summarised as follows:

Dr B

Dr B, General Practitioner, did not provide the appropriate standard of health care to Ms A in January 2001. In particular he:

- *Did not undertake any tests to determine the nature of the bacterium in her bursa.*
- *Inappropriately placed a peripherally inserted central catheter (PICC) line into her.*

In particular, this procedure was performed by Dr B:

- *Without properly informing Ms A of the nature and risks of inserting a PICC line.*
- *When Ms A's need for treatment was not an emergency.*
- *With no experience in placing a PICC line such that he had to follow written instructions.*
- *In a place which was not surgically sterile.*
- *In a place which was not equipped to cope with any emergencies, such as an embolism, which might arise from the use of a PICC line.*

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- *Without using any imaging techniques.*
- *Did not adequately inform her of the risks of the side effects of gentamicin.*
- *Did not undertake appropriate blood tests after prescribing gentamicin.*

Information

During my investigation I considered information from you, your employer, a private company providing healthcare, Ms A, and the Public Hospital.

Advice

I also received independent expert advice from Dr Shane Reti, who is a general practitioner in a semi-rural practice. I enclose a copy of his advice.

Opinion

Treatment

Right 4(1) of the Code provides that every consumer has the right to have services provided with reasonable care and skill.

I accept the advice of my expert that it was acceptable practice not to test the bursa for organisms but to treat Ms A with antibiotics. However, I note the comments of my expert advisor that your decision to choose and insert a PICC line into Ms A was inappropriate because they are used mostly for chronic disorders where long term access is required and for difficult venous access in emergencies. In addition, you could have encountered technical difficulties with the insertion due to Ms A's poor venous access, which you may not have been able to address because this was your first use of a PICC line. My expert also said that you had other treatment options available, such as persisting with a peripheral IV and accepting a slower infusion rate.

Dr Reti also advised me that you should have tested Ms A's blood to measure the serum concentration levels after her initial dose of gentamicin. This was required by your employer's protocols.

However, in my opinion you did not breach Right 4(1) of the Code of Health and Disability Services Consumers' Rights. My decision is based on the following grounds:

PICC line

- I accept my expert advice that your actions were at a low level of non-compliance with professional standards and did not place Ms A at substantial risk.
- Although this was your first attempt at inserting a PICC line, Ms A did not suffer any adverse consequences.
- You initially attempted to use another type of IV line.

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- The private company has informed me that the tip of the PICC line was correctly placed even though this was not confirmed with an x-ray as required by the manufacturer's instructions. I also acknowledge that as a result of an internal review the private company no longer stocks PICC lines and that you have taken x-rays when you have used the new brand of midline catheters that replaced the PICC lines.
 - Although Ms A's treatment was not an emergency, she required urgent treatment.
 - Ms A had poor venous access in both her arms. This was partly due to a previous mastectomy and a lymphedema on her left side which made the use of other IV lines on that arm more difficult.

In her response to my expert advice Ms A stated that the PICC line was inserted into her right side, not the left, as the left arm had poor drainage due to the previous removal of the lymph nodes in that arm.

- The procedure was undertaken in sterile conditions. In your response to my provisional opinion you said that you used a large sterile guard, sterile gloves and a mask.
- The private company has informed me that the hospital was equipped to deal with emergencies, such as complications arising from the use of the PICC line, appropriate to a Level II hospital.
- You have enrolled in a post-graduate diploma in rural hospital medicine to increase your knowledge and skills.

In response to my provisional opinion you said that an IV line was appropriate for Ms A's treatment because it was more effective than antibiotics taken orally. You also said that the use of a PICC line was appropriate as Ms A had a potentially serious cellulitis of a lymphedematous arm, it was difficult to find suitable IV access sites with conventional cannulae and she refused to go to another city for treatment. In addition you said that the only other option was for Ms A to seek treatment in another city, which she refused.

I have acknowledged that Ms A's treatment was urgent. However, I accept the advice of my expert that you did not have to use the PICC line as you had other treatment options available locally even if you did not consider these ideal. Even if there were no other available treatment options locally, you were not obliged to treat Ms A by using a PICC line if it was not clinically indicated or was otherwise inappropriate.

I also wish to emphasise that I accept Ms A's statement, in response to the expert advice, that she was reluctant to go to a public hospital because there was no reason for her to think that it was dangerous to stay owing to the risks of the PICC line. It is of note that when she became concerned about these she requested a transfer to a

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public hospital. Therefore, I am of the opinion that if you had properly explained the risks of the PICC line to Ms A in the first place then it is likely that she would have sought treatment in a public hospital.

Finally, I consider your decision to insert the PICC line without monitoring the placement of the tip was unwise, particularly because you did not have any previous experience with insertion. In your response to my provisional opinion you acknowledged that your actions were an error and unwise. It is clear from the information that I have received that the insertion of a PICC line requires some knowledge and expertise and that “tip migration” is one of the potential complications.

Blood test

In response to my provisional opinion you acknowledged that you should have undertaken the required blood test after the initial dose of gentamicin. However, I accept the advice of my expert advisor that Ms A was relatively fit and well and unlikely to be at high risk of complications, the duration of the dosing was relatively brief and venous access for a blood test would have been difficult. I also acknowledge that you did undertake a second blood test at the appropriate time.

However, I wish to emphasise to you the importance of conducting the required blood tests in the use of gentamicin to ensure that patients are safe from its potentially toxic effects.

Information disclosure

Right 6(1) of the Code states that every consumer has the right to information that a reasonable consumer, in that consumer’s circumstances, would expect to receive. Right 6(1)(b) of the Code specifies that this information includes an assessment of the expected risks of treatment.

PICC line

Although you told me in your response that you spent a great deal of time discussing with Ms A the risks and benefits of the various options of IV treatment, you have subsequently told me that you did not inform Ms A about the risks of the PICC line. You confirmed this in your response to my provisional opinion.

Ms A needed to make an informed decision about the use of the PICC line. She was reliant on you to give her the appropriate information about potential complications. Some of these, such as thrombosis and air emboli, are serious. As noted above I accept Ms A’s statement in response to the expert advice that she was reluctant to go to a public hospital because there was no reason for her to think that it was dangerous to stay and that once she became concerned about the treatment she requested a transfer to a public hospital.

Because you did not give Ms A the information she was entitled to about the risks of the PICC line she was not able to make an informed choice, including whether she

should be treated locally or at a public hospital. In my opinion you breached Right 6(1)(b) of the Code by failing to give her sufficient information.

Gentamicin

I accept that you told Ms A that there was a small risk that gentamicin could affect her hearing and kidneys. I am satisfied that you did provide some information about the risks of gentamicin. However, Ms A made it clear to you that she required more details about the risks of gentamicin. I am not satisfied that you provided sufficient information for a patient in Ms A's circumstances. My view is based on the following grounds:

- Ms A told me that her employment involves risk analysis and that she thought, from the information you provided about the side effects of gentamicin, that there was a risk to one in 5000-10,000 people.
- Ms A has told me that after she had received information from hospital staff that the probability of hearing or kidney damage was up to 2%, she refused any more gentamicin. She repeated this in her response to my expert advice. Her account is confirmed by the medical records.
- You state that you did not go into "great detail" about the risks because you feared "she would reject the gentamicin" and in the circumstances you thought it was important to use it.

In response to my provisional opinion you stated that you explained as much as Ms A appeared to want to know about gentamicin and that you find it hard to accept the claim that you did not properly inform Ms A about the risks. You also said that Ms A had not made it clear to you that she required further information about gentamicin. I do not accept this. The statement in your initial response that you did not go into great detail about the risks because you feared she would reject the gentamicin suggests that you realised she needed more information. This view is confirmed by comments Ms A made in response to my expert advice. She advised that when she found out the gentamicin was an "antibiotic of last resort", a nurse brought her a manual in which she read about the risks herself. She then asked you not to administer her any more.

If you had provided Ms A with more detailed information about the risks of gentamicin – information that was readily available and that you suspected she required – it is almost certain she would have refused to have it administered. It was inappropriate for you to deliberately withhold this information. Consumers are entitled to be given the information they need to make treatment decisions. Your decision meant Ms A was denied this opportunity.

Therefore, in my opinion you breached Right 6(1)(b) of the Code.

Vicarious liability

You initially saw Ms A in your private practice; however, the events complained of happened while you were employed by the Public Hospital.

In my opinion your employer is not vicariously liable for your breach of the Code in relation to adequately informing Ms A. Your employer could not reasonably have prevented your actions. Furthermore, it is clear that your employer had made sufficient information available for you to guide Ms A. My expert advisor has also commented that your employer's relevant protocols were satisfactory.

It follows that your employer did not breach the Code.

Recommendations

- I recommend that you review your practice in the light of my report.

Comments

In response to my question whether you had made any changes to your services since the complaint you replied, "I am less willing now to listen to patients. I will no longer be amenable as to take their feelings into consideration. From now on I will make decisions in a more autocratic and dictatorial manner."

I encourage you to reflect on your response to this incident. Ms A was perfectly entitled to complain about the treatment she received from you. The patients' complaint system is not designed to be punitive, but rather to resolve complaints by answering questions, identifying substandard practice, and promoting improvements in the quality of health care.

I acknowledge your comments about the challenges of the workload in your rural practice and that you are a committed doctor. I accept that rural practice has some unique characteristics. I am personally familiar with the area in question. I have taken these factors into account in forming my opinion.

I also acknowledge the comment in your response to my provisional opinion that there is no comparison between your practice and that of my expert advisor, Dr Reti. However, I do not accept that these differences mean that no comparison can be drawn. I am satisfied that Dr Reti was appropriate to advise me on the particular matters in issue.

Actions

- A copy of this opinion will be sent to the Medical Council of New Zealand.
- A copy of this opinion, with identifying features removed, will be sent to the Royal New Zealand College of General Practitioners and the Rural General Practice Network, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Thank you for your co-operation with this investigation.

Yours sincerely

Ron Paterson
Health and Disability Commissioner

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Ref:01/01820/AM

Independent Expert Advice

“... With regard to the information forwarded to me by the commissioner, and in my own personal and professional opinion as a medical practitioner given the information is correct, I would make the following points:

1. WAS THE INSERTION OF A PICC LINE APPROPRIATE ?

No. Accepting that [Ms A] required IV antibiotics, it is my opinion that a PICC line was inappropriate as follows:

a. Medical History – this patient had poor veins anyway, and the only accessible venous access was on the same side that a mastectomy had been performed with underlying lymphoedema. Amongst other complications, this raised the possibility of technical difficulties with the insertion which required a higher level of experience and backup than Dr [B] appeared to have.

b. PICC line indications

PICC lines are mostly used for disorders of chronicity, where long term venous access is required e.g. over several weeks, and for difficult venous access in emergencies. It would be unusual to insert a PICC line for a bursitis, however, the difficulty in venous access is recognised in this case.

c. Experience

Dr [B] comments that this was his first application of this technique. In view of the 2 general indications for PICC lines, chronicity and poor venous access, it may not have been prudent for his first application to be on someone with poor veins anyway.

I note here, that Dr [B] states his preferred and recommended course of action was for transfer to [Public Hospital B] on the basis of required IV access, but that [Ms A] declined this advice several times on the basis of wanting to stay [locally]. This would underlie a degree of patient understanding and self responsibility in the actions that Dr [B] undertook at this point.

2. INFORMATION ABOUT PICC LINES

This could be considered a low level invasive procedure. Accordingly, patient consent and understanding should be obtained. This would entail a description of the reasons for the procedure, the most common complications, other options, and the clinicians’ advice. I would reasonably expect the list of complications that might be conveyed would be those in the attached nursing documents ‘PICCS – What Can Go Wrong & What To Do’.

3. MANAGEMENT OPTIONS

a. Management Options

Given that [Ms A] required IV antibiotics, several options were available to Dr [B]:

- persist with a peripheral IV or IVs and simply accept a slow infusion rate
- remove the ‘harsher’ penicillin from the drug mix and maintain fluclox alone (unless

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gentamicin was absolutely indicated)

- depending on progress (which appeared to be satisfactory albeit slow), 24hrs of IV antibiotics may have been sufficient to warrant a return to oral antibiotics. The advice of the orthopaedic registrars was to return to oral antibiotics, but this is several days later
- refer to [Public Hospital B].

b. Gentamicin

The use of gentamicin for a bursitis, as stated by Dr [B], is indeed unusual, and I am not aware of any particular reasons for this to be used in lymphoedema. The greater indication would be for the potential organisms found in the garden as the initial source of inoculation. The patient states that the infection was improving, but then levelled out, and Dr [B] writes ‘add gentamicin to hasten progress’, so there is no indication of a deteriorating clinical picture particularly warranting gentamicin. In summary then, its use would need to be validated on the basis of suspected gram negative organisms from the garden.

c. Bursa Testing For Organisms

I would not expect a GP to routinely test a bursitis for organisms, but rather, to treat empirically with antibiotics in the first instance as Dr [B] correctly did.

4. GENTAMICIN

a. Was Sufficient Information Provided – Yes.

From the information available, it would seem likely that sufficient information about gentamicin was provided. The evidence for this is:

- [Ms A] talks about the risks being explained of deafness and kidney damage validating that some risk explaining event did take place.
- Dr [B] states that initially [Ms A] declined, and then later accepted. This also suggests some in depth contemplation of risks.

b. Gentamicin Monitoring Satisfactory – Overall Yes.

It is my view that in the circumstances, the correct procedures for monitoring gentamicin levels was not followed, however, this is likely to be at a low level of non-compliance for the following reasons:

- as stated by Dr [B], the patient was relatively fit and well and unlikely to be a high risk for complications
- the duration of dosing was only 48hrs rather than many days or weeks
- venous access for a blood test would have been difficult.

5. HOSPITAL SYSTEMS

On review of the literature forwarded to me regarding protocols at [Public Hospital A], I would state that they appear satisfactory. The particular aspects that this case raises were mostly covered by existing systems, and by the subsequent changes. In my view, the points to highlight in this case are:

- a. adequate patient understanding & consent for invasive techniques such as a PICC line including patient handouts, especially where the patient is convalescing out of

hospital for periods of time

b. adequate experience in inserting a PICC line

c. adherence to protocols as it relates to gentamicin monitoring and catheter radiological imaging

d. adequate patient understanding & consent for the use of toxic medications such as gentamicin. Adequate, not exhaustive information giving is acceptable.

In summary, it is my view that the overall management of this case was at a low level of non compliance, and did not place the patient at substantial risk. The notes also reflect a degree of patient involvement in decision making which suggests reasonable understanding and compliance, and a degree of autonomy.

**Yours Sincerely,
Dr Shane Reti”**