

**A Public Hospital
Orthopaedic Surgeons, Drs C and D**

**A Report by the
Health and Disability Commissioner**

(Case 02HDC18746)



Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Mr A	Complainant / Father of consumer
Mr B (deceased)	Consumer
A Public Hospital	Provider
Dr C	Provider / Orthopaedic surgeon
Dr D	Provider / Orthopaedic surgeon
Dr E	Pelvic Surgeon
Dr F	Head of Orthopaedic Department at the public hospital

Complaint

On 12 December 2002 the Commissioner received a complaint from Mr A about services his late son, Mr B, received at a public hospital. The complaint was summarised as follows:

Dr C

Between 10-17 November 2001, Mr B did not receive services of an appropriate standard from Dr C, orthopaedic surgeon, in relation to his acetabular fracture. In particular, Dr C:

- *did not provide Mr B with anticoagulant drug therapy*
- *did not provide Mr B with non-drug based therapy for the purpose of reducing the risk of pulmonary embolism*
- *did not communicate/consult with other relevant providers involved in Mr B's care about any decision/s taken in relation to anticoagulant therapy*
- *did not document any decisions made in relation to anticoagulant therapy for Mr B.*

Dr D

Between 15-17 November 2001, Mr B did not receive services of an appropriate standard from Dr D, orthopaedic surgeon, in relation to his acetabular fracture. In particular, Dr D:

- *did not provide Mr B with anticoagulant drug therapy*
- *did not provide Mr B with non-drug based therapy for the purpose of reducing the risk of pulmonary embolism*
- *did not communicate/consult with other relevant providers involved in Mr B's care about any decision/s taken in relation to anticoagulant therapy*
- *did not document any decisions made in relation to anticoagulant therapy for Mr B.*

On 15 November 2001 Dr D, orthopaedic surgeon, did not provide Mr B with the information that a reasonable consumer, in Mr B's circumstances, would expect to receive in relation to the risks of proposed surgery to repair his acetabular fracture. In particular, Dr D:

- *did not inform Mr B of the risk/ increased risk of pulmonary embolism.*

An investigation was commenced on 7 May 2003.

Information reviewed

- Complaint material provided by Mr A
- Information from the public hospital
- Information from Dr C
- Information from Dr D
- Medical records of Mr B

Independent expert advice was obtained from Dr Peter Hunter, orthopaedic surgeon.

Information gathered during investigation

Background

On 11 November 2001, Mr B (aged 29) suffered a central fracture of his left acetabulum in a motorbike accident. He was admitted to a public hospital under the care of Dr C, orthopaedic surgeon. Following a CT scan of his hip, pelvis and lower lumbar spine on 12 November, Dr C referred Mr B to Dr D, a pelvic and acetabular surgeon, for assessment for surgery.

Dr D saw Mr B on 15 November and planned to perform an open reduction and internal fixation procedure on 17 November. Tragically, on 17 November 2001 Mr B died during surgery from a pulmonary embolism. Mr B did not receive any form of anticoagulation therapy during his time at the hospital. His family are concerned that he was not given prophylactic treatment to prevent the risk of deep vein thrombosis and pelvic embolism.

Mr A, Mr B's father, advised me:

“I wish to point out that my family does not blame or seek to blame any individual as such. What we would like to see is the hospital review the way it assesses the anticoagulant treatment and when it was given. It should change whatever is required to avoid this happening again.

...

It is very hard to believe that [Mr B] would not be here today if he had been given appropriate treatment. To be in a hospital for six days with no apparent treatment for a known complication of this type of injury is hard to accept.”

Mr B's partner provided a written recollection of the events that occurred that week. She stated, in part:

"[Mr B] had a CT scan or MRI ... on Monday 12/11/01, and did not see another doctor until Wednesday 14/11/01. This was only to tell him of his impending surgery the next day. [Mr B] found out on Thursday afternoon ... that he had been rescheduled for 'Black Saturday' 17/11/01.

...

[Mr B] asked why it had taken from the Sunday to Thursday to be operated on anyway, and [Dr D] told him he had only found out [Mr B] was there after he overheard some other people talking about him in the corridor on Wednesday 14/11/01."

Dr C

On 11 November 2001, Dr C assessed Mr B in the Emergency Department, prior to his admission to the Orthopaedic Ward. Dr C stated:

"I reviewed him [Mr B] in the emergency department on that evening. He suffered a central fracture of his left acetabulum. He was admitted and investigated with a CT scan. I referred him to [Dr D] who is a pelvic and acetabular surgeon for assessment for surgery. He was seen by [Dr D] on the 15th November and went forward for surgery on 17 November.

...

His surgery was delayed for a week as he required a CT scan to determine the fracture configuration. This was a complex fracture that required surgery from an expert in acetabular surgery. He was therefore referred to [Dr D] who was able to perform the surgery on Saturday 17 November."

Dr C noted in the medical records:

"Requires admission and CT of acetabulum, femoral head, pelvis and L5. He then needs referral to [Dr D] for further treatment."

Dr C advised that Mr B was not placed on chemical anticoagulant therapy because of the risk of bleeding:

"[Mr B] was not placed on chemical anticoagulant therapy for two reasons. The use of anticoagulation in acetabular fractures is controversial due to firstly the increased risk of bleeding following injury and secondly the significant bleeding that may occur during surgery."

Non-chemical based therapies such as compression stockings or an AV foot pump were also not used. Dr C stated that the most effective non-chemical therapies are pneumatic compression devices such as an AV foot pump. These pumps were not available at the hospital at the time. Dr C noted that the effectiveness of compression stockings is highly

debatable and commented that in his view an AV foot pump provides the best non-chemical preventive measure.

Dr C advised that there was no documentation in Mr B's records regarding a decision on anticoagulant therapy. At the time there was no formal policy at the hospital on the use of anticoagulant therapy following pelvic fractures. It is now Orthopaedic Department policy to consider chemical anticoagulant therapy 48 hours after injury.

Dr C believed that Mr B had been transferred to Dr D's care on 12 November. Dr C discussed Mr B informally with Dr D on Monday 12 November and left ward round instructions to transfer his care. In fact, Dr D did not see Mr B until 15 November because of a miscommunication about transfer of care, and until then Dr D had not formally accepted Mr B as a patient. Dr C advised that the process of tertiary referrals has now been formalised:

“We now make a phone call to refer the case and write a formal referral letter. The patient remains under the care of the admitting surgeon until the referred surgeon has documented that he has taken over the patient. This prevents the occurrence where an admitting surgeon believes a patient has been transferred without the referred surgeon accepting the patient. This was the case with [Mr B].”

Dr D

As noted above, Dr D initially saw Mr B on 15 November 2001. During this consultation, the proposed surgery was discussed. Dr D recalled:

“At this time I noted him to have a fracture concerning the anterior column of the acetabular with some displacement of the medial wall. With [Mr B] and his partner present, we spoke about the pros and cons of fixing this fracture preoperatively.”

Dr D stated that the risks and benefits of surgery were discussed. He told Mr B that occasionally things could “go wrong” under general anaesthetic. He stated:

“Included in this discussion was mention that there were, on rare occasions, terrible things that could go wrong under a general anaesthetic, but [I] emphasised that this was unusual in a patient who was young and fit, as [Mr B] was.”

Mr B's family were concerned that he was not specifically informed of the risk of thrombosis. This has been confirmed by Mr B's partner. She stated:

“When [Dr D] came to see us on Thursday, he gave [Mr B] some information on the procedure and, in his opinion with a man of [Mr B's] tender years, the preference for surgery and left the decision up to us. [Mr B] put his utmost trust in him, and went along with his recommendation. [Mr B] actually asked [Dr D] to tell him the things that could go wrong and he was told something along the lines of, ‘there is always a risk with any operation using a general anaesthetic’ and continued to say this was not a high risk procedure. At no time did he tell us of a higher than normal risk of clotting with lower body injuries, or the absence of a heart and lung machine in the whole hospital in the

‘remote’ chance of anything happening along those lines. I can guarantee that if [Mr B] was told of this medical risk, he would have asked for all of the preventative measures known to man.”

Dr D stated that Mr B underwent a general anaesthetic prior to surgery on 17 November 2001 at the hospital. The procedure involved an open surgical approach to his left acetabular. Dr D advised that the operation proceeded in a straightforward manner until approximately 1700 hours when Mr B went into an acute cardiac arrest. He stated:

“The diagnosis [of pulmonary embolism] was reasonably clear, the Cardiothoracic surgeon on-call at [another public hospital] was consulted who felt it was not possible to remove the embolus surgically given the lack of bypass equipment at [the hospital]. Therefore conventional non-surgical resuscitation was performed extensively. The patient was declared deceased at 1757 hours.

Regarding the role of anticoagulation in the multi trauma patient this is controversial. This man was previously healthy and young and did not receive chemical prophylaxis preoperatively.”

Dr D commented that the use of prophylaxis against deep vein thrombosis in patients with pelvic fractures is controversial and is not standard practice amongst orthopaedic surgeons in New Zealand. Dr D included an opinion from Dr E, a pelvic surgeon from a different public hospital (see Appendix 1), which discusses the relative benefits of the use of thromboprophylaxis in the treatment of major pelvic and acetabular fractures.

Dr E notes that he is not aware of any published research that shows that chemical thromboprophylaxis decreases the fatal pulmonary embolism rate in orthopaedic trauma patients, let alone the very small group with pelvic and acetabular fractures.

He also notes that pelvic and acetabular surgery is complex and specialised and that intra-operative anticoagulation would, in his opinion, make the surgery much more difficult because of increased bleeding. This would place the patient at more risk of major complications, particularly haemorrhagic shock.

Dr D observed that no study has ever shown that the use of stockings or chemical prophylaxis will significantly reduce the incident of fatal embolism. He emphasised his concern over excessive bleeding:

“Surgery on patients with these fractures is routinely associated with bleeding which at times can be massive. If a patient is receiving anticoagulant therapy at the time massive bleeding is encountered intraoperatively then this can be a dangerous scenario for the patient.”

Dr D stated that his patients with pelvic and acetabular fractures now receive stockings preoperatively or, if possible, a foot pump when available. Chemical prophylaxis against deep venous thrombosis is given to patients who are otherwise haemodynamically stable.

However, Dr D is uncertain whether these measures will significantly reduce the incidence of fatal embolism.

Orthopaedic Department response

Dr F, Head of the Orthopaedic Department, commented that it is recognised that fractures of this type have an increased risk of thrombosis:

“Concerning the issue of prophylactic anticoagulation for possible thromboembolic events, it is recognised that patients with fractures of the acetabulum are at increased risk of thromboembolic disease, the exact incidence of which is variably reported in literature up to 60%. The incidence of pulmonary embolus is in the region of 4–22% depending on which study one looks at. Mortality from pulmonary embolus is variable from 0–3.6%.

The use of chemical prophylaxis is still controversial. Whilst some papers report a decreased incidence of thromboembolic complications with such agents as low molecular weight Heparins, there is a risk of increased bleeding complications during and after surgery, as well as increased wound ooze, possibly increasing infection.

Mechanical prophylactic measures such as use of graduated compression stockings, or mechanical compressive devices are advocated by some.

Most authorities, particularly in North America and Europe, advocate routine prophylaxis in patients with acetabular fractures undergoing operative reduction and fixation, whereas the issue is more controversial in the United Kingdom.

[The hospital’s] Orthopaedic departmental policy on prophylactic anticoagulation involves making an individual decision in each particular case, weighing up the potential gains and benefits.

In this particular case it is not clear whether prophylactic measures including anticoagulation were considered. Chemical prophylaxis was not used.

In retrospect, there would have appeared to have been a case for prophylactic anticoagulation with low molecular weight Heparin or other anti-thrombotic agents as well as the use of the TED stockings, but this would have had to be balanced by the possible complications of bleeding and infection, as a result of the anticoagulation.”

Policy changes at the hospital

Dr F advised me:

“The issue of communication between teams has again been emphasised partly as a result of this case. I certainly use this case as an example to the Junior Staff during their orientation to the Orthopaedic Department. I have emphasised this is particularly important in an extremely busy department with huge patient loads.

I have also identified that there was a lack of documentation of the decision making processes with respect to prophylactic coagulation or not in this particular case. Again, this is emphasised to junior and senior staff.”

Dr C and Dr D both advised that as a result of Mr B’s tragic death, changes have been made at the hospital. Dr C summarised three significant changes to the Orthopaedic Department’s policy:

- Referrals between consultant surgeons have been formalised
- AV foot pumps have been purchased
- Departmental policy on anticoagulant therapy for multi-trauma patients has been formalised.

The revised Orthopaedic Department Policy for multi-trauma patients is as follows:

“Group 3

Multi-trauma patients

(eg multiple long bone/spinal/pelvic fractures)

1. *If no history of DVT/PE:*

AV Foot pumps – whenever in bed (on uninjured feet) with stockings removed.

plus

Short Antiembolism Stockings (when practical) for 6 weeks

plus

If there is no contraindication to aspirin:

Cartia: 100mg daily from time of admission for 6 weeks

Note:

If these patients are to be on bed rest beyond 48 hours either, from the time of admission if not for surgery, or from 48 hours post op if surgery has been performed; or aspirin is contraindicated then change pharmacological prophylaxis to:

Clexane: 40mg subcut daily at the 48 hour mark.

Continue until discharge if no surgery performed.

Continue until 6 weeks post op last procedure if had surgery.

NB

If there is clinical suspicion of ongoing blood loss at the 48 hours mark, the patient must be discussed with one of the team consultants before starting Clexane.

2. *If positive history of DVT/PE*

In addition to the above guidelines these patients are to be considered for placement of an **IVC filter** as soon as practical after admission/surgery. [This is a Consultant to Consultant Only request via Interventional Radiology.]”

Dr F advised that the protocols for prophylaxis have been refined since Mr B's death:

“Because of the diverse conditions in the trauma situation, there is no single protocol for all trauma patients. Each patient is assessed individually. Certainly there has been a major emphasis on prophylactic measures, such as TED stockings, active mobilisation with physiotherapy, Aspirin and in some cases chemical prophylaxis, usually with Low Molecular Weight Heparins.

I would emphasise however that the decision to implement chemical prophylaxis remains an individual one considering the particular risks and benefits. The entire issue of deep vein thrombosis prevention remains uncertain across the world. At [the hospital] chemical prophylaxis is being used more frequently, but we are also encountering occasional complications of this intervention and occasionally deep vein thrombosis/pulmonary embolism occurs in spite of the use of anti-coagulation.”

Independent advice to Commissioner

The following expert advice was obtained from Dr Peter Hunter, an independent orthopaedic surgeon:

“Thank you for your letter of 11-11-03 requesting my medical/professional expert advice on Case No: 02/18746/....

I note the purpose of my report is to advise the Commissioner whether services provided to the late [Mr B] by [the hospital], [Dr C] and [Dr D] were of an appropriate standard.

The background to this case is that [Mr B], aged 29, suffered a fracture of his left hip and its socket (acetabulum) in a motorcycle accident on 11-11-01. He was admitted to [the hospital] and during surgery to repair the fracture on 17-11-01, suffered a cardiac arrest from pulmonary embolism from which he died in spite of intensive resuscitation measures.

I have reviewed the extensive documentation, numbered pages 1 to 117 and in particular, the submissions by [Dr C] and [Dr D] in order to give my advice.

In particular, I would draw attention to a letter dated 25-9-03 [see Appendix 1] from [Dr E], Orthopaedic Surgeon, [...] who reviews contemporary practice in this field and has wide experience in the repair of acetabular fractures, a technically exacting specialist field in orthopaedic surgery.

I propose to answer serially the questions posed under the heading Expert Advice Required on page 3 of your letter.

- (1) *What factors should be considered in any decision to provide anticoagulant therapy (chemical or non-chemical) to a patient in [Mr B's] circumstances?*
- 1.1 Acetabular fractures cause fragmentation of bone with an excellent blood supply and can be followed by catastrophic haemorrhage in more severe cases. Anticoagulation would not be considered for at least 48 hours to allow blood clotting and stabilisation of the patient's haemodynamic and cardiovascular status.
 - 1.2 Other injuries must also be taken into account, particularly visceral head or spinal injuries although this was not a factor in [Mr B's] case.
 - 1.3 These fractures are sometimes treated conservatively if not widely displaced, involving a period of traction and physical and chemical methods of anticoagulation would then be instituted. If a decision is made to operate on the fracture then it would be undesirable to have anticoagulants present to reduce the risk of bleeding during surgery, obscuring the operative field with a risk of exsanguination of the patient.
 - 1.4 In this case the surgery was planned to be as soon as feasible, four or five days post injury and it would be barely practical to institute chemical anticoagulant treatment and then reverse it in a short space of time.
 - 1.5 The hospital records contain a full A & E evaluation but there is only a short medical note on admission to the Orthopaedic Ward. It appears [Dr C] confirmed the diagnosis of a left acetabular fracture, recommended a CT scan the following day together with repeat blood tests. Medication for pain relief was prescribed but it is not apparent, from the notes, how the injured leg was to be treated or whether it was put in traction or elevation.
 - 1.6 There is no documentation as to whether anticoagulants were considered. Generally speaking, TED stockings would be rather impractical in a recently injured and painful leg when a decision has been made to treat the injury surgically. (Physical treatment with a foot compression pump was not available at the hospital at that time.)
 - 1.7 It is reasonable to observe that [Mr B] would come in under the trauma team on duty and was seen by one of the three consultants in that team. A registrar and house surgeon would be involved in the ward assessment and management but there is only brief documentation of the management plan and a dictated note by [Dr C] advised that the patient be discussed with [Dr D], the pelvic surgeon who was also on that particular team. It appears, as a result of verbal communication, [Dr D] saw [Mr B] four days after admission to discuss the planned surgery but the record of when the decision was made to proceed surgically appears to have been by verbal communication amongst the medical team involved.

(2) *Was the non-provision of anticoagulant therapy by [Drs C and D] reasonable in the circumstances?*

- 2.1 In my view it would have been unwise to give [Mr B] anticoagulant therapy on admission and, as his surgery was planned for four days after a major injury, it would have been inappropriate to prescribe anticoagulant medication, adding to the known risks of haemorrhage in this type of surgery.
- 2.2 Physical means of reducing the risk of DVT can be considered with elevation of the foot of the bed and static leg muscle exercises. As mentioned, TED stockings may not be practical and are of doubtful value as the leg veins are not necessarily the source of embolism, rather more likely the pelvic veins in trauma of this nature. The foot pressure pumps were not available but it is in the record that they have now been obtained by the hospital.
- 2.3 It is doubtful whether the delay by 24 hours of the surgery was a factor and it is generally accepted that the best time for surgery is between two and fourteen days post injury.

(3) *Does the risk of thrombosis increase over time with this type of injury?*

- 3.1 The risk of thrombosis increases with time and the degree of venous stasis, which bears some relationship to the patient's general cardiovascular and haemodynamic stasis.
- 3.2 It is noted in the pathology report that the pathologist was unable to be certain of the site of the venous thrombosis, which subsequently separated to cause the fatal pulmonary embolism, and surmises it to be either the leg or pelvic veins.

(4) *What consultation, if any, was appropriate between [Dr C] and [Dr D] in relation to the provision of anticoagulant therapy to [Mr B]?*

- 4.1 It would seem inappropriate to prescribe chemical anticoagulant therapy once the decision was made to operate on the fracture. The actual decision as to when to pursue surgical management is not documented but is implicit from the time of admission. The decision to transfer the case from the nominal care of [Dr C] to that of the operating surgeon [Dr D]. This is not necessarily unusual as the patient was under the care of a surgical team.
- 4.2 As stated above, once the decision was made to treat the fracture surgically, anticoagulant medication would be inappropriate.
- 4.3 It does seem there is somewhat of an over-emphasis on lack of anticoagulant medication in the light of the subsequent events in this case. If a patient is to

be operated on particularly for fractures of this nature, the last thing the surgeon wants is bleeding and blood that does not clot.

- 4.4 If the case was to be managed conservatively then there would have been a completely different management plan.
- (5) *What effect on [Mr B's] care do you consider any confusion over who was responsible for his care may have caused?*
- 5.1 The patient would normally be under the care of a surgical team comprising consultants, registrar and house surgeon as there is no evidence as to there being any confusion with two consultants in the same team being involved in this case.
- 5.2 The clinical notes show that at a ward round on 13-11-01 [Dr C] saw the CT scan and advised discussion with [Dr D], his colleague who eventually made a short note on 15-11-01. Surgery was planned for that day but was postponed for reasons that are not recorded (elsewhere it is stated that this was because of another major surgical case taking priority in the queue for trauma treatment).
- (6) *What information should a patient in [Mr B's] circumstances be provided with in relation to the risks involved in this type of surgery?*
- 6.1 The agreement to treatment form signed by [Mr B] on 16-11-01 is available and the risks discussed were bleeding, infection, damage to local structures in addition to the risks of anaesthesia.
- 6.2 There is nothing to suggest that [Mr B] was not aware of the nature of his treatment and that surgical management was the best way of restoring function to his damaged hip.
- (7) *Do you consider the Orthopaedic Department policy in relation to anticoagulant therapy at the time of [Mr B's] death to have been appropriate?*
- 7.1 In my view the Orthopaedic Department policy in relation to anticoagulant therapy at the time of [Mr B's] death was appropriate in that each individual case would be assessed on its merits, the presence of risk factors and the presence of other injuries.
- 7.2 This matter is covered in the report of [Dr F], Clinical Head of Department, dated 5-6-03 (pages 053 and 4).
- (8)
- 8.1 [Dr C's] report of 1-10-03 (pages 114–116) notes that the management of anticoagulant therapy in multi trauma patients has now been formalised and a written protocol is available.

- 8.2 It is clear that [Mr B's] death has resulted in a re-evaluation of anticoagulation for trauma patients at this major tertiary referral hospital.
- 8.3 [Dr D] has re-evaluated his practice and appears more likely to provide anticoagulant medication but notes that this must always be assessed on a case by case basis.
- 8.4 I think it is reasonable to point out that anti-embolus stockings are of somewhat uncertain value in deep vein thrombosis although widely prescribed, they can be uncomfortable and can crease and roll and act in some situations as a venous tourniquet.
- 8.5 The provision of foot pressure pumps is by no means a universal panacea, some patients finding them uncomfortable, disturbing of rest and unlikely to be of benefit if the clot is proximal in the leg or pelvis.

(9)

- 9.1 Standards involved have really been covered in the preceding part of this report and are also touched on in [Dr E's] letter (pages 112, 113). It is not clear that there has been any departure from relevant standards in this case, although it has to be said that the documentation of the management plan for this patient is not given in any great detail. This is no doubt a function of a very busy unit under pressure. However, such a situation makes the documentation of decisions made by a team, if anything, more important.

(10) *Are there any other matters relating to professional standards which you believe to be relevant to this complaint?*

- 10.1 I think, in summary, it may be said there have been no departures from appropriate clinical care in this case but there may be some shortcomings in the documentation of the overall management and the decisions as to the best treatment available.
- 10.2 It is two years since this tragic sequence of events which have initiated a re-evaluation of certain clinical processes.

...

I have endeavoured to answer the specific questions posed as the basis of my advice. Please let me know if I can be of further assistance in this case."

Additional advice

Dr Hunter provided additional advice to the Commissioner concerning the information Dr D provided to Mr B about the risks of this type of surgery. Dr Hunter considered that the written consent information Dr D provided to Mr B was adequate and that it was not necessary to specifically mention or discuss the risk of pulmonary embolism because of the low probability of such an occurrence in a patient in Mr B's circumstances.

Dr Hunter also commented that the risk of pulmonary embolism always increases over time with immobility after a fracture. However, he also stated that the length of time prior to surgery would not have been determinative or have had a particular relationship to Mr B's outcome. Dr Hunter emphasised that it was not appropriate to use anticoagulants (once the decision to operate had been made) because of the greater risk of massive bleeding associated with pelvic fracture (with large blood vessels in the pelvic region), and that a fatal pulmonary embolism in these circumstances is a rare and catastrophic occurrence.

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.*
- ...
- 5) *Every consumer has the right to co-operation among providers to ensure quality and continuity of services.*

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; ...*

Opinion: No breach – Dr C / Dr D

Provision of anticoagulant therapy

On 11 November 2001, Mr B was assessed by orthopaedic surgeon Dr C in the hospital's Emergency Department, following a motorbike accident. He was admitted to the Orthopaedic Ward with a view to surgery to repair the fracture of his left acetabulum. Mr B was seen by pelvic and acetabular surgeon Dr D on 15 November. Tragically, Mr B died on 17 November 2001 from a pulmonary embolism during relatively routine surgery by Dr D. His family are concerned that Mr B was not provided any form of anticoagulant therapy during his time at the hospital.

Anticoagulant therapy may be chemical or non-chemical. Prophylactic drugs include those that contain low molecular weight heparins (heparin is a naturally occurring anticoagulant), for example Clexane. Aspirin can also be used. Non-chemical techniques include mobilisation with physiotherapy and compression stockings or foot pumps (which are not always practical, and suitability depends on the nature of the injury).

Mr B was not given any form of anticoagulant therapy (also known as thromboprophylaxis). Dr C explained the reasons:

“[Mr B] was not placed on chemical anticoagulant therapy for two reasons. The use of anticoagulation in acetabular fractures is controversial due to firstly the increased risk of bleeding following injury and secondly the significant bleeding that may occur during surgery.”

Dr D advised that Mr B presented as a fit young man, without risk factors for thrombosis such as obesity or previous thrombosis. Dr D commented that the use of prophylaxis in patients with pelvic fractures is controversial and not standard practice amongst orthopaedic surgeons in New Zealand. He included an independent opinion from Dr E, a pelvic surgeon from a different public hospital (see Appendix 1), which refers to published research. Dr D stated that no study has ever shown that the use of stockings or chemical prophylaxis will significantly reduce the incidence of fatal embolism. He also emphasised concern over excessive bleeding:

“Surgery on patients with these fractures is routinely associated with bleeding which at times can be massive. If a patient is receiving anticoagulant therapy at the time massive bleeding is encountered intraoperatively then this can be a dangerous scenario for the patient.”

Dr C commented that the effectiveness of non-chemical based anticoagulants is controversial. In his view, AV foot pumps, which were not available at the hospital at that time, are the best non-chemical measure. Dr D now orders compression stockings or foot pumps for his patients with pelvic and acetabular fractures and has increased the use of chemical prophylaxis, but he is uncertain whether these measures will significantly reduce the incidence of fatal embolism.

The Head of the Orthopaedic Department, Dr F, confirmed that there were no formal departmental policies concerning anticoagulant therapies at the hospital in November 2001. Decisions involving prophylactic anticoagulation therapy were assessed on a case-by-case basis. Departmental policies have since been formalised. The policy now states that for multi-trauma patients with no history of deep vein thrombosis or pulmonary embolism, physical measures such as foot pumps and stockings (where practical) are used. As a chemical prophylactic, Clexane is considered after 48 hours (see page 7 above).

My advisor, Dr Peter Hunter, was of the opinion that it was reasonable not to have provided Mr B with anticoagulant therapy on admission. He made the following particularly relevant points:

- Acetabular fractures can be followed by catastrophic haemorrhage
- Anticoagulation therapy would not be considered for at least 48 hours to allow haemodynamic stabilisation
- Anticoagulation therapy is appropriate when a decision is made to adopt conservative management (without surgery)
- It is undesirable to have anticoagulant present during surgery
- There was insufficient time to institute anticoagulant therapy and reverse it before surgery
- Physical treatment with TED stockings may have been impractical owing to the nature of the injury.

Dr Hunter stated:

“In my view it would have been unwise to give [Mr B] anticoagulant therapy on admission and, as his surgery was planned for four days after a major injury, it would have been inappropriate to prescribe anticoagulant medication, adding to the known risks of haemorrhage in this type of surgery.

Physical means of reducing the risk of DVT can be considered with elevation of the foot of the bed and static leg muscle exercises. As mentioned, TED stockings may not be practical and are of doubtful value as the leg veins are not necessarily the source of embolism, rather more likely the pelvic veins in trauma of this nature. The foot pressure pumps were not available but it is in the record that they have now been obtained by [the hospital].

It is doubtful whether the delay by 24 hours of the surgery was a factor and it is generally accepted that the best time for surgery is between two and fourteen days post injury.”

Dr Hunter emphasised that it was not appropriate to use anticoagulants because of the greater risk of massive bleeding with the large blood vessels in the pelvic region, and that a fatal pulmonary embolism in these circumstances is a rare and catastrophic occurrence.

My advisor also drew particular attention to Dr E's report (Appendix 1), which summarises the lack of conclusive evidence to date with regard to the effectiveness of thromboprophylaxis. I accept that the provision of anticoagulant therapy for pelvic fractures has an uncertain role in the prevention of fatal pulmonary embolism. Furthermore, while physical preventative measures do not have a corresponding risk of bleeding, the benefits are even more difficult to assess clearly and such measures may often not be practical to implement.

I accept Dr Hunter's advice that it was not appropriate to provide Mr B with chemical anticoagulant therapy in these circumstances. Accordingly, in my opinion Dr C and Dr D did not breach Right 4(1) of the Code in their care for Mr B.

Documentation of decision in relation to anticoagulant therapy

Under Right 4(2) of the Code every patient has the right to have services provided that comply with professional standards. Any significant clinical decision made in relation to a patient's care must be clearly documented, to ensure that health professionals involved in treatment (at the time and subsequently) can ascertain what care has been provided and (ideally) what care was considered.

At the time, there was no policy at the hospital on the use of anticoagulant therapy following acetabular and pelvic fractures, and anticoagulant therapy was considered by medical staff on a case-by-case basis, without reference to a formal protocol. There was no policy in place about the need to document a decision not to provide anticoagulant therapy.

While my advisor noted that there was no documentation of any decision in relation to consideration of anticoagulant therapy, he stated:

“It is not clear that there has been any departure from relevant standards in this case, although it has to be said that the documentation of the management plan for this patient is not given in any great detail. This is no doubt a function of a very busy unit under pressure. However, such a situation makes the documentation of decisions made by a team, if anything, more important.

I think, in summary, it may be said there have been no departures from appropriate clinical care in this case but there may be some shortcomings in the documentation of the overall management and the decisions as to the best treatment available.”

All medical staff involved in this case agree that chemical anticoagulant therapy should not be considered until at least 48 hours post injury, because acetabular fractures are associated with bleeding that can at times be massive. By then surgery was contemplated. I am advised that it would have been inappropriate to prescribe anticoagulants in this situation as it would have added to the known risks of surgery.

I accept my advisor's view that the documentation in relation to Mr B's care was less than optimal. Mr B's referral, the decision to proceed to surgery, and the decision not to start anticoagulant therapy were not well documented. I endorse my advisor's comment that accurate documentation is particularly important in a busy unit. Nevertheless, in light of all the circumstances at the time, I do not consider that these shortcomings amounted to a breach of the Code. Accordingly, in my opinion Dr C and Dr D did not breach Right 4(2) of the Code.

I am pleased that Dr F has taken the opportunity to emphasise the importance of quality documentation to staff following Mr B's tragic death.

Communication/consultation concerning anticoagulant therapy

Under Right 4(5) of the Code every patient has the right to co-operation among providers to ensure quality and continuity of care. When referrals between consultants occur it is especially important that there is effective communication.

In this case, the transfer of care was less than ideal. Dr C believed that Mr B had been transferred to Dr D's care, but because of a miscommunication apparently unrelated to either surgeon, care was not immediately transferred and Dr D had not formally accepted Mr B as a patient.

An issue considered as part of this investigation was whether Dr C and Dr D should have jointly discussed whether thromboprophylaxis was appropriate for Mr B. My advisor stated:

“It would seem inappropriate to prescribe chemical anticoagulant therapy once the decision was made to operate on the fracture. The actual decision as to when to pursue surgical management is not documented but is implicit from the time of admission.

...

If the case was to be conservatively managed then there would have been a completely different management plan.”

I accept my advisor's comments in relation to this matter. Dr C considered that Mr B presented as being in the category of patients who were candidates for acetabular surgery and consulted Dr D. Dr D agreed that surgical intervention was appropriate but it appears there was a breakdown in communication about the transfer of care which could account, in part, for the lack of a documented management plan. However, in my view, there was no requirement for Drs C and D to specifically discuss chemical anticoagulant therapy for Mr B, for the reasons discussed above.

Accordingly, in my opinion Dr C and Dr D did not breach Right 4(5) of the Code.

I am pleased that the process of referrals between consultant surgeons at the hospital has now been formalised.

Opinion: No breach – Dr D

Under Right 6(1)(b) of the Code every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including an explanation of the options available, and an assessment of the expected risks, side effects, benefits, and costs of each option. Mr B's family were concerned that he was not specifically informed of the risk of thrombosis. Mr B's partner stated:

“[Mr B] actually asked [Dr D] to tell him the things that could go wrong and he was told something along the lines of, ‘there is always a risk with any operation using a general anaesthetic’ and continued to say this was not a high risk procedure. At no time did he tell us of a higher than normal risk of clotting with lower body injuries, or the absence of a heart and lung machine in the whole hospital in the ‘remote’ chance of anything happening along those lines.”

Dr D noted that Mr B was a fit young man without known risk factors for deep vein thrombosis, such as obesity, previous deep vein thrombosis or disseminated carcinoma. He stated that the risks and benefits of surgery were discussed. He told Mr B that occasionally things could “go wrong” under general anaesthetic. He stated:

“Included in this discussion was mention that there were, on rare occasions, terrible things that could go wrong under a general anaesthetic, but [I] emphasised that this was unusual in a patient who was young and fit, as [Mr B] was.”

It appears that Mr B was not provided with any specific information in relation to the risk of thrombosis or pulmonary embolism.

My advisor noted that the risks discussed with Mr B were listed on the written consent form as bleeding, infection, damage to local structures in addition to the risks of anaesthesia. He stated:

“There is nothing to suggest that [Mr B] was not aware of the nature of his treatment and that surgical management was the best way of restoring function to his damaged hip.”

My advisor further commented that it was not necessary to specifically mention or discuss the risk of pulmonary embolism because of the low probability of such an occurrence for a patient in Mr B's circumstances.

I am guided by my advisor's comments in relation to this issue. In my view, although pulmonary embolism in a patient with an acetabular fracture is a known risk, it was not considered by Dr D to be an expected risk during surgery in a young, fit man without known risk factors. I also note my advisor's comments that the length of time prior to surgery would not have influenced the outcome for Mr B. Any increased risk because of immobility was negligible and, as such, not a matter that Dr D could reasonably be expected to discuss.

In my opinion, Dr D provided reasonable information about the expected risks of surgery and did not breach Right 6(1)(b) of the Code.

Opinion: No breach – The Public Hospital

Vicarious liability

Employers are responsible under section 72(2) of the Health and Disability Commissioner Act 1994 for ensuring that employees comply with the Code of Health and Disability Services Consumers' Rights. Under section 72(5) it is a defence for an employing authority to prove that it took such steps as were reasonably practicable to prevent the employee's breach of the Code.

In the absence of a breach of the Code by Dr C or Dr D, no question of vicarious liability arises.

Actions taken

I note that since this case, Dr C, Dr D and the Orthopaedic Department at the public hospital have undertaken a review of their respective practices and policies in relation to the provision of anticoagulant therapy. In particular, the Orthopaedic Department has introduced a formal policy in relation to anticoagulant therapies, and has made AV foot pumps available. The Department has also formalised referrals of patients between consultants, and has emphasised the importance of quality documentation.

I commend the hospital on the appropriate action taken in light of this tragic case.

Follow-up actions

- A copy of this report will be forwarded to the Medical Council of New Zealand.
- A copy of this report, with details identifying the parties removed, will be sent to the New Zealand Orthopaedic Association and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix 1

September 25, 2003

To whom it may concern.

Dear Sir/Madam,

I have been asked to give an opinion on the use of thromboprophylaxis in the treatment of major pelvic and acetabular fractures. My current practice is to fit all such patients with below knee TED stockings, if possible, and once the patient has had surgery, if it is appropriate, to mobilise the patient aggressively. I do not use routine chemical prophylaxis unless the patient has a demonstrated thrombotic event.

I would like to make the following comments:

- Pre-operative ultrasound of the lower limbs is of minimal clinical use in these patients as a large number of the patients have been shown to have pelvic thromboses rather than in the legs. I refer you to the work by David Helfet from New York.
- MRI venography is the only reliable method of demonstrating pelvic thromboses and it is not to my knowledge standard practice other than in New York to do this test where it is being evaluated in research.
- TED stockings have been shown to decrease the DVT rate in abdominal surgery but questionably in major joint replacement. To my knowledge no study has been performed on their efficacy in patients with lower limb or pelvic trauma. Indeed most of these patients have other limb trauma precluding their use even if shown efficacious.
- No study has demonstrated TED stockings decrease the pulmonary emboli rate or fatal PE rate in orthopaedic patients, even those undergoing joint replacement who have been extensively investigated. Plus no study has shown that by decreasing DVT rate do you stop patients dying from thromboembolic events.
- Pre-operative demonstration of a limb or pelvic DVT would by necessity either preclude surgical intervention, and the patient would then be treated with anticoagulants, or necessitate the pre-operative use of a vena cava filter. The latter is not without significant risks and I would avoid this if at all possible.
- Chemical thromboprophylaxis has been extensively investigated in elective surgery. There is good evidence in orthopaedic patients undergoing lower limb joint replacement that pre-operative use of anticoagulants can decrease the DVT rate. There remains however no convincing evidence that by decreasing the DVT rate that the fatal PE rate is altered. This is despite studies incorporating 10,000 + patients. The evidence remains so cloudy that in 2001 two separate editorials from the Journal of Bone and Joint Surgery looking at this topic in elective joint replacement came to diametrically opposite opinions as to the role of chemical thromboprophylaxis.
- There is no published research I am aware of showing that chemical thromboprophylaxis decreases the fatal PE rate in orthopaedic trauma patients let alone the very small group with pelvic and acetabular fractures. This latter group of patients is small and extremely heterogeneous as to

confounding variables that such a study is probably impossible to perform. If there is such confusion in large groups of elective homogeneous patients like those undergoing joint replacement then I do not believe we can ever prove benefit in the small group of pelvic and acetabular fracture patients.

- Pelvic and acetabular fracture surgery is very complex and specialised. In my opinion intra-operative anticoagulation would make the surgery much more difficult because of increased bleeding, in a procedure that often already produces much blood loss, and poor visualisation. This would undoubtedly place the patient at more risk of major complications particularly haemorrhagic shock. Poor visualisation would also most likely lead to a less anatomic reduction of the fracture and it has been shown that the quality of reduction of a fracture in this site affects the long and short term result.