Vascular and General Surgeon, Dr C

Public Hospital

A Report by the

Health and Disability Commissioner

(Case 01HDC09116)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Mrs A	Consumer
Mrs B	Complainant, Consumer's daughter
Dr C	Provider/Vascular and General Surgeon
Ms D	Practice Nurse
Dr E	General Practitioner
Public Hospital	Provider
Dr F	Surgical Registrar
Dr G	Surgical Registrar
Dr H	Radiologist
Dr I	Surgical Registrar

Complaint

On 20 August 2001 the Commissioner received a complaint from Mrs B about the services provided to her mother, Mrs A, by Dr C and a Public Hospital. The complaint was summarised as follows:

Dr C

Dr C, general surgeon, did not provide the appropriate standard of health care to Mrs A in 2001. In particular, he:

- *did not take sufficient care while performing two skin graft procedures on Mrs A's leg;*

- *did not appropriately monitor the condition of Mrs A's skin grafts after surgery. Later Mrs A had to undergo an angioplasty to prevent her leg from being amputated. This was unsuccessful and, despite another surgical operation performed by Dr C to address the complications from this, she died;*

- *did not take steps to ensure that Mrs A had adequate support in June 2001 while she was in the hospital when he told her that, because the two skin grafts had been unsuccessful, she needed to have a surgical operation to prevent her leg being amputated.*

Staff members of the Public Hospital

Staff members did not provide the appropriate standard of health care to Mrs A. In particular, in June 2001 he, she or they did not:

- *properly conduct an angioplasty procedure on Mrs A. Afterwards Mrs A required further surgery to address complications from this and later died;*

- *properly monitor Mrs A's condition after the angioplasty procedure and take the appropriate action when it was later discovered that she had internal bleeding.*

An investigation was commenced on 11 February 2002.

Information reviewed

- Relevant medical records
- Information from Dr E, general practitioner
- Response from Dr C
- Response from the Hospital

Independent expert advice was obtained from Professor Andre van Rij, general and vascular surgeon; Dr Mark Osborne, vascular and interventional radiologist; and Mrs Wendy Rowe, nurse.

Information gathered during investigation

Consultation with Dr C on 5 April 2001
Mrs A, an 80-year-old woman, was referred to Dr C, vascular and general surgeon, by her general practitioner, Dr E, for the management of her left leg ulcer. She was seen at Dr C's rooms at a town on 5 April 2001.

Mrs A gave a history of an injury to her leg about seven weeks earlier and development of a non-healing ulcer. Dr C received an accompanying letter from the district nurses, who indicated that they had been treating the ulcer since 22 February 2001 but that it had deteriorated despite constant supervision. The district nurses also indicated that Mrs A's general health and appetite were poor. Mrs A denied claudication (pain in the legs on walking) and pain on resting, and gave a history of varicose veins. Dr C noted that her past medical history included atrial fibrillation (rapid irregular heartbeat), ischaemic heart disease, cardiac failure, diverticulosis, gastro-oesophageal reflux, and hypertension.

Dr C recorded in his examination findings: "She has a venous ulcer of her left leg with surrounding cellulitus. She has palpable pulses." In view of Mrs A's pain and cellulitus, Dr C arranged for her to be admitted to the hospital for intravenous antibiotics and dressings, with a view to split-skin grafting of her ulcer.

Hospital admission on 6 April 2001
On 6 April 2001 Mrs A was admitted to the hospital. She was taking a number of medications including warfarin (anti-coagulation medication). Mrs A was treated with intravenous antibiotics (flucloxacillin and penicillin) and the ulcer was dressed. Swabs of the ulcer grew *Staphylococcus aureus*. On 9 April, when the ulcer had cleaned up satisfactorily, Mrs A underwent a split-skin graft of the left lower leg ulcer. The skin graft procedure was performed by Dr C's registrars, Dr F and Dr G.

Mrs A was assessed as making reasonable postoperative progress. However, it became clear to Dr C that Mrs A was developing further infarcts (areas of dead tissue) around the area of ulceration. The cause of the infarcts was investigated with an echocardiogram on 17 April. No cardiac source of emboli was evident.

Mrs A was further investigated with a pelvic and femoro-arteriogram on 18 April. The arteriogram (a radiograph of an artery after injection of a radiopaque substance) showed that the superficial femoral artery and popliteal arteries were patent but she had extensive tibial disease with single run-off into her anterior tibial artery, which had a stenosis at the origin. This was reported by a radiologist. The report stated:

> "Left leg. There is moderate diffuse disease through the SFA [superficial femoral artery], with multiple 50% stenosis. The popliteal artery is of similar quality, run off the calf via anterior tibial artery which forms a good quality dorsalis pedis. No medial plantar arch filling.
>
> Right leg: Diffuse SFA disease is again present with a tight stenosis disc distally, and two prominent popliteal stenosis. Run off is prominently via the peroneal artery, with distal filling of anterior tibial and dorsalis pedis. No posterior tibial or medial plantar arch filling."

As a result of the arteriogram, Dr C continued with conservative management. On 19 April Mrs A was discharged home on a course of flucloxacillin, district nurse follow-up, and an outpatient follow-up appointment in two weeks.

24 April 2001
At the request of the district nurse, Dr E's locum visited Mrs A at home on 24 April 2001. He recorded: "Edge of the graft sloughed, but most of it looks fine [no] cellulitis."

Outpatient review on 3 May 2001
On 3 May 2001 Dr C reviewed Mrs A at his rooms. Mrs A complained of pain in her ulcer. Dr C noted that the necrotic areas had fallen off and he documented in his examination findings: "green discharge ulcerated areas under necrotic areas". Dr C prescribed Mrs A a 10-day course of ciprofloxacin and arranged for further dressings by the district nurses, with a view to review in two weeks.

Outpatient review on 17 May 2001
On 17 May 2001 Dr C saw Mrs A in his rooms at a town. Her ulcers were painful and not healing. He documented:

> "O/E [on examination] necrotic ulcers
> Plan: Re-admit […] [the hospital]
> ? Revascularisation
> ? Debridement"

In his letter to Dr E, Dr C noted: "On examination today there is a considerable amount of slough and necrosis." Dr C arranged for Mrs A to be re-admitted to the hospital for further debridement and split-skin grafting.

Hospital admission on 18 May 2001
On 18 May 2001 Mrs A was admitted to the hospital with a view to revascularisation or debridement of the ulcer and further split-skin grafting. The left leg outer shin ulcer swab taken on 18 May grew *Pseudomonas aeruginosa* and *Staphylococcus aureus.* On 18 May Mrs A was commenced on oral ciprofloxacin and on 28 May flucloxacillin was started. On 19 May she was started on an Ilomedin infusion (Ilomedin is used in the treatment of peripheral circulation disorders). The infusion was continued until 24 May 2001.

On 20 May Mrs A suffered an exacerbation of congestive heart failure. She was treated with frusemide, morphine, and CPAP (continuous positive airway pressure). She was reviewed by the cardiology team, who diagnosed acute left ventricular failure secondary to an anginal episode and advised that it was not related to Ilomedin.

On 25 May Mrs A returned to the operating theatre for a further split-skin graft of her leg ulcer. This was performed by Dr G. On 30 May Mrs A was discharged home.

Outpatient appointment on 7 June 2001
On 7 June 2001 Mrs A was seen by Dr C at the town. Dr C's impression was that the ulcer was reasonable with a "good take of the skin graft" and less pain. He recommended that she continue with dressings and planned to review her in six weeks' time.

13 June 2001
On 13 June 2001 Mrs A was reviewed by Dr E. Mrs A complained of wound pain and exudates from the wound. Dr E debrided the wound and arranged for a district nurse to dress it, with a review by him in two weeks.

Mrs B explained that Dr E closely examined her mother's leg and proceeded to remove undissolved stitches and dead and rotting skin from around the ulcer. She further stated that Dr C would have noticed these if he had made an effort to take a closer look.

Mrs B attended three follow-up visits with her mother because her mother could hardly walk. Mrs B explained that at these visits Dr C's nurse would prepare Mrs A's leg for Dr C to view and he would look from some distance away, not within touching distance. Dr C

would say, "Keep exercising that leg Mrs [A] and I'll see you in 2, 6, or 10 weeks' time." Mrs B explained that the district nurse who dressed Mrs A's leg said: "I'm not happy with the way the leg is looking and it's not healing the way it should be", from the time Mrs A was discharged from hospital after the first skin graft.

Dr C explained that he did not get any closer to examining the ulcers in his rooms because when the practice nurse took down the dressings, the ulcers were cleaned with antiseptic. Dr C stated that he examined the ulcers at a distance, which was adequate to make an appropriate clinical assessment without any further contamination.

Dr C advised that Mrs A's skin grafts were adequately monitored. He viewed the skin grafts on ward rounds during Mrs A's hospital admissions, and he liaised with his practice nurse Ms D, and the district nurses.

Dr C stated that he explained to Mrs A from the outset that the problem was ischaemia of the lower limb and that an angioplasty (surgical repair of a blood vessel) was not arranged earlier in the treatment because of the high-risk situation – with single vessel run-off into her anterior tibial artery and stenosis at the origin, if angioplasty led to an occlusion of her anterior tibial artery, this would result in limb loss.

Dr C said that he "clearly recognised that Mrs A was a high risk case for an angioplasty and [his] clinical management initially endeavoured to avoid this high risk procedure". Therefore, he attempted to perform the skin graft initially.

Dr C further stated that Mrs A underwent an angioplasty because she had two failed skin grafts. The reason for the failure of the skin grafts was multi-factorial and related to the multiple medical problems, nutrition, and ischaemia (inadequate blood flow to the area).

Admission on 27 June 2001
On 27 June 2001 Dr E referred Mrs A to Dr C because he felt the skin grafts had failed. In the medical notes Dr E recorded:

> "Site L[eft] lower leg Size … Pain ++ Bleeding … Inf'n [infection] Slough debrided Exudate ++ Dressing algisite + dry dressing DN y NV … admit […]"

Mrs A was admitted to the hospital with a failed graft and a history of fevers and night sweats since her last discharge from hospital. Dr C explained to Mrs A that one of the reasons the graft was failing was the poor blood supply.

On 28 June Dr C advised Mrs A that she would benefit from an angioplasty of the anterior tibial artery to improve the inflow, and that if the process was unsuccessful then the only option would be amputation. Dr C explained that Mrs A required angioplasty because she presented with a recurrent ischaemic ulcer, which had been skin grafted twice, she had only a single vessel run-off down the anterior tibial artery, and she had a stenosis at the origin of that vessel.

In his response to my provisional opinion, Dr C stated that "considerable thought and management were put into the timing of the angioplasty". He explained that the timing of

the angioplasty procedure was appropriate because while he was managing a chronic condition, it became acute because of the failure of the skin graft and the secondary infection. Dr C considered that Mrs A's leg was acutely threatened and that if she did not undergo some form of revascularisation the limb would be lost.

Dr C said that he also took into consideration the increasing anxiety of Mrs A and her daughter, and Mrs A's general deterioration. He was also influenced by the fact that it was possible to have the angioplasty performed on a particular day, although the overriding decision of the timing of the procedure was dictated by the clinical state of the leg.

Mrs B complained that no attempt was made by Dr C's team to contact her as the next of kin to support her mother when she received the news. Mrs B explained that her mother needed support because she suffered from a weak heart, her husband was hospitalised with Alzheimer's, and the news was "horrific". During the morning of 28 June 2001, Mrs B phoned every hour to find out how Mrs A was. She was told that "everyone was [too] busy to come to the phone" and was asked to "phone back later". At 2.30pm a nurse informed Mrs B that one of Dr C's team should have called to ask her to go to the hospital to have a "chat" about Mrs A. The nursing notes of 28 June record that Mrs A was seen by the doctors and was "shocked by the news [that] she's not go[ing] today" and that the doctors were not happy with the ulcers.

Dr C did not accept that he took no steps to ensure Mrs A had adequate support when he told her that she required a surgical operation. Dr C stated that Mrs A was informed about the angioplasty during one of his ward rounds when there were junior medical staff present. He believed that Mrs A would have had adequate support from the nursing staff and the junior medical staff. Dr C stated that the team leader of the ward felt she personally provided a considerable amount of support to Mrs A. Dr C advised me that he ensured that the junior medical staff were instructed to contact Mrs B about what was happening.

In response to my provisional opinion, Dr C stated: "It is my practice and the practice of the staff in the ward to ensure that support persons are available for patients whenever practically possible." He explained that considerable attempts were made to contact Mrs A's daughter but there were problems because she was not directly available and did not respond to messages left on her phone.

The nurse documented that on 28 June 2001 Mrs B was notified about what was happening. The hospital advised that the nurse looking after Mrs A during the morning shift of 28 June spoke to Mrs B at 2.30pm. The nurse informed Mrs B of the information given to Mrs A regarding the proposed management of her diseased leg. The hospital further stated that it is usual for nursing staff to attend to priority patient care needs before being available to speak on the phone.

The hospital stated that on an acute care surgical unit often the whole of the morning is devoted to attending to the direct personal care needs of patients and that is why someone would have asked Mrs A to telephone later. Calls from relatives can be considerable at

times and at peak times the hospital does not have the resources to be able to service additional needs.

Arteriogram and angioplasty
On 28 June 2001 Dr C requested an urgent arteriogram and angioplasty. Dr H, radiologist, explained that he was "led to believe that this was an urgent attempt to save Mrs [A's] leg from amputation". An urgent angioplasty was arranged on the same day.

On 27 June 2001 warfarin 1mg had been charted for Mrs A but, according to her Medication Chart, it was not given. On admission to hospital the INR (a blood test used to control the dosage of warfarin) was 2.1 (INR is normally less than 1.3 without warfarin). In response to my provisional opinion, Dr C submitted that it is not universally accepted that stopping warfarin before an angioplasty reduces the risk of bleeding.

Mrs B arrived at the hospital to see her mother, and an orderly arrived soon after saying he was taking Mrs A to the Radiology Department. Mrs A asked "what for". The orderly advised Mrs B that a catheter was to be inserted. On hearing this and seeing how frightened her mother was, Mrs B demanded that someone speak to her before Mrs A went anywhere. The orderly was unable to find anyone and informed Mrs B that there would be someone in the Radiology Department who would answer questions.

The hospital stated that Dr C and his team explained the angioplasty process to Mrs A before Mrs B arrived. The hospital further stated that the radiologist would have repeated the information to Mrs A before the procedure, while Mrs B was present.

Mrs B walked to an unauthorised area in the Radiology Department to demand information about what was happening to her mother, and a doctor came to speak to them. Mrs B recalls that Dr H explained the insertion of the catheter and then said, "If this process doesn't work Mrs [A], we then have to chop off your leg," and he brought his hand down in an action to describe "chopping off her leg".

Dr H stated that before the procedure, he discussed and explained the situation to Mrs A in clear and easily understandable language and a kind and compassionate manner. Dr H clearly recalls that she had a full understanding of the issues. Dr H explained the need for the angioplasty, the risk of this invasive procedure, and the consequence if the procedure was not performed or was unsuccessful. Mrs A consented to the procedure.

The record of the procedure indicates that it commenced at 4pm and was completed at 4.45pm. Dr H's report stated: "A single needle jab entered the left common femoral artery below the inguinal ligament" and two focal stenoses were identified and dilated. Mrs A was given 3000 units of heparin (an anticoagulant to prevent blood clots) and was constantly monitored during the procedure. Her blood pressure was stable throughout and the arterial puncture was performed without difficulty. The radiological report recorded: "Procedure uneventful and a compression device was put onto the left groin for 30 minutes for haemostasis."

After the procedure, check X-rays were taken, which showed no artery rupture or bleeding. Mrs A's blood pressure was stable. A compression device was used to stop the arterial wound from bleeding and she was transferred back to the ward for close monitoring.

The radiology record sets out the instructions for care following the procedure:

> "As per protocol
> Fem stop on 130 mm until 1715
> 110 mmHg until 1725
> 105 mm Hg until 1735"

The Radiology Department's "Post Procedure Angiogram/Angioplasty protocol" sets out the recommended nursing care following angiography. It also states: "This protocol may need to be modified depending on the medical condition of the patient."

> "Peripheral/Abdominal Angiography
> Check Blood Pressure, Pulse, puncture site and neurovascular obs of foot/hand distal to puncture site
> ¼ hrly for 1 hour
> ½ hrly for 1 hour
> hourly for 2 hours
> 2 hourly for 2-4 hours"

Mrs A returned to the ward from the Radiology Department at 5.15pm. The hospital explained that in 2001, the surgical wards regularly took patients after an angiogram, and the nursing staff in both areas were skilled at providing post-angiography observations.

Later in the evening of 28 June 2001 Mrs A developed rapid atrial fibrillation, hypotension (low blood pressure), a reduced level of consciousness, and severe abdominal pain. The nursing staff noticed abdominal swelling.

The observation chart indicates the first ward recordings at 5.30pm. The chart indicates recordings at various times:

- 5.30pm: pulse 132/min, blood pressure 156/60 mmHg, oxygen saturation 92% on 3 litres nasal prongs
- 6.00pm: pulse 132/min, blood pressure 140/70
- 6.30pm: pulse 150/min, blood pressure 130/66
- 7.00pm: pulse 160/min, blood pressure 114/56
- 7.40pm: pulse 164/min, blood pressure 82/40
- 8.00pm: pulse 154/min, blood pressure 62/30

- 8.15pm: pulse 100/min, blood pressure 86/42

The nursing notes record:

> "28/06/01 pm
>
> Pt received from Radiology at 1615.
> Conscious C/o [complains of] pain Lt lower abdomen.
> Bp was 140/80 mm P 120 min. O_2 90% with 3 lit N/P [nasal prongs].
> Had artial pressure on Lt femoral area and pressure 15 mm released every 15–25 min.
> Stated that pain gradually increased in lower Lt abdomen and panadol 1gm & codeine 30mg given.
> Continues vitals observed BP was 110/70 mm @1800.
> She is having ice cubes for dry mouth and refused to drink any fluids.
> At 1830 Bp ↓ 80/60 mmHg pulse 160/min and O_2 sat 89%
> Informed house surgeon and cont monitoring O_2 sat decreased up to 88% and kept R M 6 lit then came up 95%
> Informed Registered as well, and IV line open to 2U [Haemacel] given 12 lead ECG done NG [nasogastric] inserted
> Mrs [A] gradually respiratory deteriorated and O_2 100% supplied via Ambu Bag and transfer to operating theatre @2040."

The hospital advised that the staff nurse's documentation of the immediate time returning to the ward appears to have been made after Mrs A went to theatre, and records her actions. The nurse appears to have made an error documenting the time on return to the ward – "it should have been 17.15, as at 16.15 Mrs [A] was still having the procedure". The hospital stated that there is no policy or guideline for the management of hypotension.

In the hospital's response to my provisional opinion, the hospital stated that when Mrs A was transferred to theatre the full clinical record went with her. Therefore, the ward nurse had to write her account of events without the benefit of the observation chart. Between the time Mrs A's deteriorating status was detected and her transfer to theatre, the nurse was fully occupied with providing resuscitative measures and unable to document events at the time they occurred. This resulted in the discrepancy between the recorded times.

The hospital stated that the documentation of written comments and recordings of observations are in line with the protocol for angiogram care.

In response to my provisional opinion, the hospital submitted that while the recommendations in the radiology protocol for post-angiography care were not strictly adhered to in the first hour, the observations taken between 5.30pm and 6.30pm appear to have been within normal limits for Mrs A. The hospital stated that it would have been reasonable to interpret the initial increase in pulse at 6.30pm as a response to pain and, when the pulse increased further with the drop in blood pressure, the nurse reacted appropriately by notifying medical staff.

The hospital also stated: "It would appear that the nurse did not recognise the significance of Mrs [A's] abdominal pain, as there is no documentation that the nature of the pain was ascertained before administering analgesia, nor is there documentation relating to the decrease of the 'Femstop' pressure to an increase in pain."

There is no indication in the patient notes of the time when Mrs A was seen by surgical registrar Dr I. She recorded that Mrs A had hypotension with a blood pressure of 80/-, rapid atrial fibrillation with a heart rate of 130 beats per minute, and severe lower left abdominal pain. Her impression was of a retroperitoneal bleed. The hospital recorded a 777 (emergency) call from the ward at 7.58pm.

At about 8.30pm Dr C received a call from Dr I, who advised him that Mrs A's blood pressure had collapsed and she had developed an extended abdomen. Dr C arranged for Mrs A to be rushed to theatre for an urgent laparotomy. On arrival, Dr C found Mrs A markedly hypotensive and performed a laparotomy.

The operation note of 28 June 2001 was entitled "Exploration left external iliac artery and common femoral artery for bleeding post anterior tibial angioplasty". The operation took place between 8.40pm and 9.40pm. Dr C's operation note recorded his findings:

> "There was an extensive rich retroperitoneal haematoma and the bleeding point was a tear in the external iliac vein where it was joined by the deep epigastric vein. Presumably there had been a puncture at that point and this had caused the retroperitoneal haematoma. The actual puncture site in the common femoral artery was not bleeding very much and this was clearly not the source of bleeding."

The puncture site was identified and oversewn. Mrs A required a transfusion of five units of blood to resuscitate her during the procedure. When she was haemodynamically stable she was transferred to the Intensive Care Unit for postoperative care.

Mrs A was intubated and placed on a ventilator. Her INR on admission to the Intensive Care Unit on 28 June was 3.3. Her condition stabilised overnight in the Intensive Care Unit and she was weaned off the ventilator the next morning. Her heart function remained reasonable although she had bouts of chest pain.

Dr C requested the hospital staff to contact Mrs B to inform her of the complications, the emergency operation, and that Mrs A's condition was critical. Mrs B stated that no one attempted to phone her at home, where she would have been contactable at that hour of the night and that the hospital had her home and work phone numbers. A voicemail message was left on her work number at 11pm on 28 June 2001. Mrs B stated that she did not know about her mother's condition until 10 hours after the message had been left.

The hospital explained that Dr I, who attended Mrs A when she deteriorated on the ward, was unable to contact any family members on the telephone numbers recorded on Mrs A's admission sheet. At 10pm Dr I attempted to call Mrs B's telephone number twice and the rest home. A registered nurse in the Intensive Care Unit made a further attempt to contact

Mrs A's next of kin. The nurse stated that there was no response. A message was left on Mrs B's voicemail.

On 29 June the Intensive Care Unit team discussed Mrs A's condition with her daughter, Mrs B, and her granddaughter. In view of Mrs A's extensive heath problems, it was felt that it was inappropriate to resuscitate her again or put her on a ventilator if she deteriorated. Gradually over the day Mrs A's condition deteriorated with worsening breathing, poor circulation, and impaired renal function.

Mrs A was extubated on 29 June 2001 and transferred to the ward. She was provided with comfort cares overnight and died on 30 June 2001.

A post mortem examination on 2 July 2001 reported the cause of Mrs A's death as:

- direct cause – extensive bronchopneumonia
- antecedent cause – acute renal tubular necrosis
- underlying condition – haemorrhage external iliac artery
- significant conditions – ischaemic heart disease.

Documentation
In response to my provisional opinion, Dr C stated that he routinely encourages all junior medical staff to record all appropriate clinical proceedings in the notes. He also explained that when he does a ward round, there is a nurse and junior medical staff present, and it is his expectation that proceedings are documented. He stated that at the time of the events in question, it was not possible to ensure that this was routinely happening because he was performing a one-in-two call.

In response to my provisional opinion, in relation to documentation by nursing staff, the hospital stated: "Despite gaps in the documentation it is still evident that Mrs [A] was closely observed and received intensive nursing input."

Changes by the hospital
The hospital advised that over the last eight months a working party had been developing a clinical pathway for angiography procedures. This involved reviewing both the post-procedure protocol and the pre/post-procedure documentation requirements.

The hospital stated that as a result of my provisional opinion and the latest review of Mrs A's case, the hospital intends to undertake further actions by the end of March 2004, in particular:

- nursing education to highlight the requirements for care pre- and post-angiography procedure with an emphasis on the significance of abdominal pain as a sign of emerging problems
- development and provision of resource books for the ward that contain specific information such as anatomy, protocols, and expected/unexpected responses.

The hospital advised that the consent form used for Mrs A is no longer in use and that the current radiology consent form "Request for Treatment/Procedure" implemented in December 2002 is under review.

Independent advice to Commissioner

Surgical advice
The following expert advice was obtained from an independent general and vascular surgeon, Professor Andre van Rij:

"Herewith report in response to your request of 7 May 2003 and modified on 4 July 2003. This is based on the documentation provided – this included:

- Hospital records for relevant admission.
- Reports from Mr [C], Dr [H], [the hospital], Dr [E].
- District nurse records.
- [the hospital] Customer Services.
- HDC letters to myself dated 7th May and 16th June.
- Complaint by [Mrs B].
- Post mortem report.

The delay in this response was unfortunately largely the result of the request for more information, in particular a copy of the letter of explanation from Mr [C] and a letter from [the hospital]. Added to this was the difficulty wading through so much material over several admission and outpatient activities.

The report is limited by the material provided and the quality of the documentation contained in it.

Decision required – **were the split skin grafts properly performed?**

I believe from the account that these procedures were technically well performed. The timing of the grafts may be debatable particularly after the second admission when the ulcer area though described as clean was shown on 18/5/01 to have a heavy growth of Staph Aureus as well as Pseudomonas. However this can be a clinician's call weighing up the risks. It may however be one of the most likely explanations for the failed grafts.

What was the most likely cause of the failure of the two split skin graft procedures?

There are numerous possible causes that may have played a part. Infection has already been alluded to. Bleeding under the graft can be a technical problem – she had been on anticoagulation which would increase the risk of this but her INR test was only 1.1 and therefore this is not a significant systemic factor. Early mobilisation and early dressing manipulation over the delicate graft in its early days can be factors. This patient was sent

home modestly promptly but this is in the range of normal practice. Ischaemia of the tissues is very likely to have been an important factor. The surgeons were aware of this – though the documentation of the clinical measures of this was very poor. Ischaemia was of course the reason for the subsequent angioplasty. This was suitably delayed because of the high risk type of lesions that needed this treatment with real possibilities for risk of amputation. The patient's nutritional status was poor and this can substantially affect healing. Again the team were well aware of this and there is considerable evidence of dietetic inputs to assist with the improvement of this.

On May 3 2001 Mr [C] was in a very difficult situation. There was little he had to offer except for a high risk angioplasty with the possibility of subsequent amputation. Hence to put that possibility off and the possibility of local infection being an important player it was worth a trial of antibiotics in conjunction with the continuing dressings. The chances of success were not high but worth the attempt. A follow-up in a couple of weeks was appropriately made.

At the 7 June visit the circumstances were even less optimistic. A somewhat last ditch attempt to improve tissue blood flow with Ilomedin had failed in the previous hospital admission to create a better environment for the grafting.

The timing of follow-up varies with state of the ulcer, the treatment options and the access and skill of the community team – in this case the district nurses and the general practitioner. Clearly they were skilled and proactive as seen from the documentation and their ready referral back to Mr [C]. When there is little specialist input required it is appropriate to refer the patient to the other supportive care givers in the team until specialist input is again required. In this instance holding out for a longer time may be appropriate always with the opportunity for earlier review as happened.

The patient's daughter and the patient were obviously aware that perceptions of what was going on with the ulcer was not always the same for each of the carers. This can at times create unfortunate dissatisfactions.

It is my view that this 6 week period working in conjunction with the patient's GP was reasonable. It is not clear why this was extended to 10 weeks and no comment can be made – as it was the patient was seen well before this.

Monitoring of the skin grafts

Arrangements were appropriately made by the surgical team for the patient to be followed up following discharge from hospital. Assessment is by looking at the appearance of the ulcer/graft at the time of dressing change. It does not necessarily require direct contact or manipulation unless there is an appearance that suggests the need for it. Hence examination at a distance especially through the eyes of a very experienced person can capture all the impressions required. At a distance of course means within reasonable range as for example for reading. The documentation does not make clear what distances are being suggested. As to the concept of maintaining a distance in order to avoid contamination this I cannot readily grasp – not touching with

unprotected hands or clothing or coughing over the wound makes more sense. These wounds of course are not sterile, clean at best and most often have a level of bacterial contamination. However contact is essential if debridement is required.

My conclusion is that assessment at first can be at a distance if all that is needed is visual evaluation but if all is not well close up contact would be required with appropriate equipment. What the circumstance was exactly when the patient was seen by Mr [C] cannot be elucidated. It does seem that when next seen by the GP some 'tidy up' was requested but this change may well have occurred after the visit with Mr [C].

However what is missing from the assessment is the content of any communication by the surgical team with the patient at the hospitalisations and outpatient visits regarding the ulcer, graft and possible outcomes. The notable paucity of what the medical staff communicated does not allow any specific comment. It is pertinent that if this is not done well it readily feeds a dissatisfaction, something which is described in the complaint made.

Some more general comments

The Assessment of the clinical problem

From the very start the documentation of the severity of her vascular disease both venous and arterial was inadequate. This assessor is still not sure whether she really had a venous ulcer in a limb with venous insufficiency, or a typical poorly healing traumatic ulcer in the lower limb either of which was compromised with arterial insufficiency. Where was it exactly, what size and what characteristics were there. These should be recorded as they are the focus of the problem.

Pulses were documented by different doctors both as present and as absent and then without any detail. Ankle brachial indices would be expected as a routine in a vascular surgery unit but these were never done. Only the arteriogram done on 18 April gave clearer evidence of her problem.

My concern is mostly related to the events of the patient's last admission. **There seemed to be an unreasonable rush of events on this occasion.**

An urgent referral was made for the angioplasty in a patient with a very chronic course to this point. It seems the only urgency that would be reasonable was to minimise hospital stay. Why the radiologist was led to believe there was urgency is not clear at all.

The consent form for angioplasty is, to say the least, very confusing and certainly daunting. Where this consent was obtained and signed is not clear to the assessor. What she signed for is not evident from the copy provided (i.e. no box is checked). Whether this simply confirms the patient's seeming lack of knowledge of why the orderly was taking her to the radiology department cannot be determined. (This form should be re evaluated by an independent group possibly the local regional ethics committee.) The account of the way in which the patient was informed in the radiology department differs significantly from that witnessed by the daughter.

The daughter was frustrated with the lack of communication with her about a critical event in the care of her mother. While the explanation given concerning nursing priorities on a busy surgical ward are appropriate in general, this particular occasion was not about just another progress telephone call but related to a priority issue preparing a patient about to undergo a significant intervention at short notice. Was there no time to allow family to come in and participate in the process?

She was on Warfarin which increases risk of bleeding and raises the complication rate for angioplasty. This was prescribed on 27 June at 6pm, the day before the angioplasty, her INR on admission was 2.1 and was 3.3 in the ICU postoperatively. The radiology work up sheet documents that she was on Warfarin. The radiologist's description of the events written after the fact makes no reference to this despite the very severe bleeding complication. This is rather surprising. Did he know about the patient being anticoagulated, and if he did was the option of delaying the procedure discussed with the surgical team? This must have been an important factor in the severity of the bleeding and it was avoidable. Without the seeming haste the issue of Warfarin could have been clarified and its effect temporarily reversed to minimise the risk of bleeding.

Unfortunately on the day of the procedure there is no medical staff documentation of the decision making leading up to angioplasty or of the communication by the medical team. Were the team aware of her anticoagulation and was this taken into account in the risk assessment and urgency given? There is a nurse's note in the morning shift report which does suggest the medical team talked to the patient. It seems that this occurred sometime later in the morning. The time of request at the radiology dept was recorded as being 3.42pm. This lack of documentation may also be a reflection of the haste as well as the constraints placed on a busy junior surgical staff.

Attention needs to be given to more thoughtful, timely and reflective process to working up patients for treatment. This may require more time for the medical staff to do this.

The lack of documentation by medical staff is a recurring short coming in this patient's record making evaluation difficult but also compromising management.

The full clinical evaluation of the presenting vascular problem at each admission is incomplete.

The lack of doctor's comment on communication content with patient and family is persistent. The nurse record is exemplary.

The factual variance is significant, see below the different diagnoses placed in the record for the operation.

Most important was the failure to record critical events. On the day of the angioplasty, not until the patient was severely compromised was there evidence of substantive medical staff input. The nursing record describes a patient who arrives back to the ward with left lower abdominal pain – this is not normal following angioplasty. This continues to get worse requiring pain relieving medication. By 6pm the BP is 110/70 (170/110 at admission), and at 6.30pm down to 80 systolic with an increased tachycardia and O2 sats

at 89%. This is a surgical emergency and house surgeon and registrar are informed. The registrar makes a correct assessment but the time of this is not recorded. Mr [C] describes not getting the first call until 2030 hours – This is 2 hours after the hypotensive crisis. The patient gets to theatre at 8.40pm, the anaesthetist writes 'no recordable obs' (unfortunately the anaesthetic record did not include the 'auto read out'). What happened to cause this delay or what happened during it is not recorded at all – it certainly is very relevant to this patient's outcome.

There is a need for greater priority to be given to good documentation of the important aspects of patient management.

A final issue is **the marked disparity in the final diagnosis** as to the cause of bleeding. While Mr [C's] account would appear to be the most clear and likely to be correct and in the light of the incisions he made – having the bleeding right in front of him. He describes the injury to the left iliac vein. The registrar records it as something else. The post mortem report describes sutures to both external iliac artery and external iliac vein. The pathologist signs out death to have been contributed to by external iliac artery haemorrhage. The radiologist describes a technique with one needle pass – antegrade i.e. down the left leg but a femoral artery puncture is identified at surgery in addition to the tear of the iliac vein. How the vein <u>above</u> the inguinal ligament is lacerated by a needle directed in a single pass down in the femoral artery <u>below</u> the inguinal ligament in a slim patient is hard to conceive. It is possible with some techniques but usually in the obese with difficult access. Was Dr [H] aware of the findings at the time he made his report?

However for the patient to have bled so vigorously so soon after the procedure to produce a retroperitoneal haematoma up to the diaphragm and inducing the degree of hypotension is unusual for bleeding from a vein alone. (The anticoagulation may explain some of this.)

With so many diverse descriptions it is difficult to resolve what led to the injury and why it was such an extensive blood loss.

This requires greater attention to accurate documentation as part of sound clinical practice."

Radiology advice

The following expert advice was obtained from an independent vascular and interventional radiologist, Dr Mark Osborne:

"I have been asked by the Office of the Health & Disability Commissioner to provide independent advice regarding the radiological treatment and management of the above patient. I have made a review of numerous submissions and clinical notes provided together with x-ray films of Mrs [A's] diagnostic angiogram dated 18/04/01 together with the appropriate procedural notes and also of the subsequent angioplasty procedure dated 28/06/01. I have also reviewed standard instruction protocols used by [the hospital] for angiography patients.

I am performing this review in my capacity as a vascular and interventional radiologist and as such I believe it is appropriate only for me to comment on those parts of this case which have direct relevance to the vascular radiological procedures performed.

From the history available to me, I understand that Mrs [A] was admitted one day prior to the angioplasty procedure with an ischaemic ulcer on her left leg. Diagnostic angiography had been performed some two months previously and shown diffuse atheromatous change with focal stenotic disease in the anterior tibial artery. The clinician treating Mrs [A] made the decision that the most appropriate treatment was angioplasty of the tibial artery stenoses, the alternative being below knee amputation, and referred the patient to the Radiology Department for urgent tibial angioplasty. Consent for this procedure has been sought and obtained, Mrs [A] signing a consent form to that effect.

Angioplasty of vessels below the knee is considered to be a specialised vascular interventional procedure because of the increased risks entailed in treating small vessels with low blood flow. It is my understanding that Dr [H] has the appropriate qualifications and experience to be undertaking such a procedure. In the clinical circumstances, it is understandable that the procedure was treated as an urgent case and fitted in on the same day as the request was made.

This procedure was performed on the 28/06/03. The angiographic films obtained at the time of the procedure show a good result has been achieved by the angioplasty. There is no evidence of immediate complications such as spasm or dissection. The patient was then transferred to the ward for post-procedural observation. The standing orders for observation provided by [the hospital] appear satisfactory and would be consistent with post angioplasty observations performed at other similar hospitals throughout the country.

Following the procedure the patient was transferred to the ward and complained of lower abdominal pain on the left side. This pain was noted to be increasing despite reducing pressure on the femstop device. At 1830 hrs, approximately two hours after the procedure, the patient was noted to be hypotensive, urgent assistance was requested and active resuscitation commenced. This led to the patient being transferred ultimately to theatre where a retroperitoneal haematoma was identified with the source of bleeding presumed to be the left external iliac vein.

Events after this are beyond the scope of my review.

On review of these findings I have several concerns.

1. Left lower abdominal pain following angioplasty. It is most unusual for patients to experience significant lower abdominal lower pain following angiographic procedures. It is well recognised that pain of this sort is a pointer to potential retroperitoneal haematoma or ongoing bleeding. In such cases the patient may remain stable for some time prior to the blood pressure dropping catastrophically as appears to have happened in this case. If the staff involved in post angiographic care at [the hospital] are not aware of the significance of ongoing pain post angiography,

this is a serious shortcoming which should be addressed. I believe the medical staff should have been notified of the pain much earlier in this case.

2. Consent process. The consent form used at [the hospital] is very comprehensive but non specific with a one page form used to cover virtually all radiological procedures. In my opinion this form would be more appropriately used as an information sheet with a more specific and less busy consent form tailored to the specific procedure, in this case angioplasty that the patient is being asked to give consent to. From review of the notes, it would appear that the patient was aware that the angioplasty procedure was a last ditch effort to avoid a below knee amputation. Given the relatively urgent nature of the procedure, it would appear other family members were not advised prior to the procedure. Whilst this is not an absolute requirement I think some consideration should be given to this if similar situations arise in the future.

3. Site of bleeding. In my opinion the procedural notes and films obtained during the angioplasty indicate clearly a needle puncture below the inguinal ligament, reportedly a single puncture of the common femoral artery. The operation note clearly indicates the finding of a laceration in the external iliac vein at the time of surgery. These are entirely separate vascular structures, one an artery the other a vein. In almost all circumstances of significant retroperitoneal bleeding as a consequence of angiographic procedures the bleeding is arterial in nature and secondary to either a surgically scarred groin or inadvertent puncture of the external iliac artery above the level of the inguinal ligament, at which level post procedural compression is more difficult. Such bleeding is a rare but recognized complication of angiography and angioplasty and is identified as a complication on the signed consent form.

   If, as is stated, surgery revealed a laceration of the external iliac vein, I cannot see or envisage any circumstance in which this could have occurred as a result of the radiological procedure given my understanding that there was a single arterial puncture below the inguinal ligament. In my experience, bleeding tracking upwards from a puncture site in the common femoral artery is unusual. On rare occasions spontaneous retroperitoneal bleeding is described, this is usually in the context of an anticoagulated patient. I find it difficult to explain the discrepancy between the clinical events surrounding the angiogram and the surgical findings. It is possible that arterial bleeding causing the initial pain and subsequent hypotension, stabilised prior to the operation and that the laceration occurred during surgical dissection and was not the cause of the major retroperitoneal haemorrhage. It would be of value to get the independent specialist assessment of an experienced vascular surgeon to review this possibility.

In answer to the questions posed:

1. I believe that the decision to proceed to angioplasty in view of the patient's clinical circumstances was an appropriate decision, the only alternative option being amputation. In my opinion Dr [H] was an appropriately qualified radiologist to perform this procedure. The request to undertake the procedure was a reasonable one and the completion of the procedure on the same day is perfectly normal and

acceptable. The angiographic result of the procedure as regards improved flow down the anterior tibial artery was successful.

2. Retroperitoneal bleeding/haematoma is a recognized complication of angiography and angioplasty particularly where antegrade puncture of the common femoral artery is required. It is clear that on the patient's return to the ward, there was evidence to suggest a retroperitoneal haematoma was developing. There appears to have been a significant delay in the recognition of the severity of these signs by the ward staff and this is the most serious short coming in the events surrounding this case. The fact that the procedure was performed urgently has no bearing on this eventuality.

3. I am however unable to explain the surgical findings of a laceration of the external iliac vein when the angiographic report describes a single, arterial puncture and films show a needle and guidewire positioned in the common femoral artery below the level of the inguinal ligament. A laceration of this vessel would not be apparent during the angioplasty procedure as all injections and images obtained show only the arteries of the leg. I find it difficult to believe an external iliac vein laceration could have arisen as a result of the angioplasty procedure."

Nursing advice
The following expert advice was obtained from an independent nurse, Ms Wendy Rowe:

"11 July, 2003

Medical /Professional Advice File 01/09116

IN CONFIDENCE

Documents Reviewed:

- Letter of complaint from Mrs [B]
- Notification letter, dated 11 February 2002, from the Commissioner to the [hospital]
- Information provided by [the hospital]
- Information provided Dr [C]
- Information provided by Dr [E]
- Action notes dated 20 November 2001, 18 January 2002 and 19 March 2003
- Additional evidence: response [the hospital] Manager, dated 27th of June, 2003

Did the nursing staff adequately monitor Mrs [A's] condition?

- Clinical note entry 28/06/01 a.m. indicates Mrs A 'may have angioplasty or have even told her there may be need of a BKA'. No time entered as to when on the morning shift this was written. If this was a nurse making this entry they did not give any indication of their registration status. 'Recs stable' indicates that before the angioplasty Mrs [A's] recordings (vital signs) were stable.

- Next clinical entry in the notes is made by a Dr re the 777 call. There is no time stated for the entry. There is no documentation from any staff member that an angioplasty is to be performed. Next page is an entry made by the Dr on a different form (none of these progress forms are numbered).
- On a separate page there is an entry from a nurse called […] who identifies herself as (SN) 'staff nurse'. There is no time documented as to when this was written. [The nurse] states in this entry that she informed house surgeon of decrease in blood pressure at 1830 hours and continued to monitor. She goes on to state she informed registrar (note says registered) as well but no time is given. Exact times are not given for 777 call out, registrar notification or at what stage transfer to operating theatre was decided. Times of recordings being completed and actual recordings stated in this report by [the nurse] do not correlate to the temperature and pulse chart. It is my opinion that this report from [the nurse] was written after the event as it is on a separate page from the clinical notes that were probably already in operating theatre. This entry has then been added after the entry made by the doctor. This entry should follow the morning nurse's entry for the same day. There is no time or identifying information on the top of the page except the patient's name which indicates to me that the rest of the clinical notes were not available when nurse […] wrote this entry. Therefore as the nurse did not document the events as they happened between 1715 hours and 2040 hours it is very difficult to make a call on whether Mrs [A] was adequately monitored.

Did nursing staff keep accurate records?

- [Nurse] […] states on the examination and progress form blood pressure on return from Radiology was 140/80 at 1615 hours (additional information corrects this time to 1715 hours) and that Mrs [A] was in pain. This information was not entered on the temperature and pulse chart.
- [Nurse] […] states in the examination and progress notes that the blood pressure was noted to be 110/70 at 1800 hours. The Temperature and pulse chart indicates that these recordings at 1800 hours were 140/70. Notes indicate that house surgeon was not notified at this stage but ½ an hour later at 1830 hours when the blood pressure was recorded as 80/60 and other vital signs noted also.
- Although the examination and progress form indicates that at 1830 hours blood pressure decreased to 80/60, this is recorded on the temperature and pulse form as being 130/66, and not being recorded as 80/60 until 1940 hours. Two hours later after further deterioration Mrs [A] is transferred to operating theatre documented as 2040 hours. [The nurse] does not give her full name (note this page of the progress form is poorly labelled with no sticky labelled attached to the top of the page identifying patient's details at all).
- Additional information provided by the [hospital] Manager includes a protocol for Post procedure angiogram/angioplasty. Number 1 of this protocol indicates that the Blood pressure, pulse, and neurovascular observations checked ¼ hourly for 1 hour then ½ hourly for 1 hour. This was not completed or documented. Observations are documented as being taken ½ hourly for 2 hours.

Did nursing staff communicate with medical staff effectively and in a timely manner regarding Mrs [A's] deteriorating condition?

- Nurse […] indicates in the clinical notes that she did contact the house surgeon and the registrar when Mrs [A's] condition deteriorated. The exact times, which she did this, are not clear, however they correspond with the decrease in blood pressure and the notes written by the doctor who attended the 777 call. If the doctor had not attended to the patient when called by the nurse this would have been clearly documented in the clinical notes. Poor clinical documentation on behalf of the nurse makes it difficult to answer this question accurately.

Did nursing staff otherwise take appropriate actions regarding Mrs [A's] deteriorating condition? If not, what should they have done and at what point?

- Clinical entry made by Nurse […] has been made some time after the deterioration of this patient, so it is very difficult to say whether the actions taken by Nurse […] where appropriate or not. There are discrepancies between the recordings documented and the clinical notes. What happened between the time of 1830 and 2040 is not well documented by Nurse […]. She does not mention at what time she made the 777 call, nor does she mention contacting the family at this stage. Clearer documentation of the events as they happened should have been written at the time to show the series of events, which led to Mrs [A's] transfer to Operating Theatre.

Comments:

- Poorly labelled documentation by all staff members
- Pages not numbered so sequence of events unclear
- Time of entries not always given, and person making entry not always identified correctly.
- Mrs [B's] concerns about not being able to talk to the nurse caring for her mother on the phone until 1430 on the 28th of June 2001 is inexcusable as Mrs [B] was her next of kin (considering the age and condition of this patient).
- [Hospital], letter dated 16 April 2002 indicates that Dr [I] 'wrote in the progress notes that she was unable to get any family member on the telephone number we had on record … entry recorded at 2200 and states she attempted to call the daughter's number x2'. (point 3, page 2). There is no entry indicating this ever happened.
- There is no assessment and/or care plan written for Mrs [A] for her 3-day stay in hospital as requested
- Poor documentation and inability to follow protocol indicate that Mrs [A] was not adequately cared for by the nurse following her angioplasty."

Code of Health and Disability Services Consumers' Rights

The following Rights in the Code of Health and Disability Services Consumers' Rights (the Code) 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.

…

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

RIGHT 8

Right to Support

Every consumer has the right to have one or more support persons of his or her choice present, except where safety may be compromised or another consumer's rights may be unreasonably infringed.

Opinion: No breach – Dr C

Performing skin graft procedures with sufficient care

Mrs A developed a non-healing ulcer following an injury to her leg and subsequently developed surrounding cellulitis. In view of the pain and cellulitis, on 5 April 2001 Dr C arranged for Mrs A to be admitted to the hospital. She was commenced on treatment with intravenous antibiotics. On 9 April when the ulcer had cleaned up satisfactorily, Mrs A underwent a split-skin graft of the left lower leg ulcer. The skin graft procedure was performed by Dr C's registrars, Dr F and Dr G. The patient notes indicate that in the immediate postoperative period there was reasonable wound healing at the graft site.

Mrs A was reviewed by Dr C at an outpatient clinic on 17 May. On 18 May she was readmitted to the hospital because the ulcers were painful and not healing. Mrs A was commenced on antibiotics and an Ilomedin infusion. On 25 May Mrs A underwent further split-skin grafting to her leg ulcer. This was performed by Dr G. The patient records note that in the immediate postoperative period the wound was healing well and the graft had taken.

Dr C explained that the reasons for the failure of Mrs A's skin grafts were multi-factorial and related to her multiple medical problems, nutrition, and ischaemia. I accept my expert advice from Professor van Rij that there were a number of reasons for the failed grafts, which included infection, ischaemia of the tissues, and Mrs A's nutritional status. Professor van Rij stated that early mobilisation and early dressing manipulation can also be a reason for graft failure. However, I accept his advice that the time when Mrs A was sent home fell within the range of normal practice.

I accept Professor van Rij's advice that the split-skin grafts were properly performed. In view of all the clinical circumstances, it was Dr C's decision, weighing up the risks, as to the timing of the second skin graft procedure.

In my opinion, the skin graft procedures conducted by Dr C were undertaken with reasonable care and skill. Accordingly, Dr C did not breach Right 4(1) of the Code.

Monitoring and examination of skin graft

Monitoring the condition of Mrs A's skin graft after surgery
Between 6 April (the date of Mrs A's first hospital admission) and 27 June 2001 (the date of the last admission) a number of providers were involved in the management of Mrs A's condition. I am satisfied that there was a team approach to the monitoring of Mrs A's condition following surgery. This team consisted of Dr C, the district nurses, and Mrs A's general practitioner.

Following Mrs A's first consultation with Dr C on 5 April, Mrs A was reviewed by Dr C on 3 May, 17 May and 7 June. The community health records for Mrs A record almost daily district nursing care. Dr E saw Mrs A on 13 and 27 June. On 13 June Dr E debrided the wound and arranged for the district nurse to dress it. On 27 June Dr E arranged admission to the hospital. Dr E explained that his locum visited Mrs A on 24 April.

In my view, appropriate intervention took place when Mrs A's condition deteriorated. Following Dr C's outpatient review on 17 May Mrs A was admitted to the hospital. On 27 June, Dr E referred Mrs A to Dr C for a further admission to the hospital. The patient records indicate that between 5 April and 28 June, the district nurses liaised with Mrs A's general practitioner, the ward charge nurse, and Dr C.

I accept the advice from Professor van Rij that the timing of follow-up varies depending on the ulcer, the treatment options, and the access and skill of the community team – the district nurses and the general practitioner. The health professionals involved were skilled and proactive and readily referred Mrs A back to Dr C. Where little specialist input is required, it is appropriate to refer a patient to other supportive caregivers in the team until specialist input is required.

Mrs B expressed concerns about the district nurses' comments that Mrs A's leg was "not healing the way it should". I accept Professor van Rij's advice that while Dr C initially put off the possibility of high-risk angioplasty, it was worth managing Mrs A's leg with a trial of antibiotics in conjunction with continued dressings.

Following surgery Mrs A's skin grafts were monitored regularly by a team of health professionals, and action was taken to ensure review by Dr C and admission when Mrs A's condition deteriorated. In my opinion the monitoring of Mrs A's leg by the district nurses, Mrs A's general practitioner, and Dr C when required, was appropriate. Accordingly, Dr C did not breach Right 4(1) of the Code.

Examination of the skin graft
Mrs B expressed concern that Dr C did not examine Mrs A's wound sufficiently, reviewing the leg from some distance away. In response, Dr C agreed that he had examined the ulcers at a distance, but advised that this was adequate to make an appropriate assessment without any further contamination.

I accept Professor van Rij's advice that assessment is by looking at the appearance of the ulcer/graft at the time of dressing changes and does not necessarily require direct contact or manipulation unless there is an appearance that suggests the need for it. Examination at a distance, especially through the eyes of a very experienced person, can capture all the impressions required. I acknowledge Professor van Rij's comment, however, that the wounds are not sterile and it would make more sense that the reason to maintain a distance is so that the wound is not touched with unprotected hands or clothing, or to avoid coughing over the wound, rather than to avoid contamination. In my opinion, it was appropriate for Dr C to make an assessment of Mrs A's leg at a distance. Accordingly, Dr C did not breach Right 4(1) of the Code.

Support for Mrs A

Mrs B raised concerns that no attempt was made by Dr C's team at the hospital to contact her to support her mother when she received the news on 28 June 2001 that she required an angioplasty. Mrs B explained that her mother required support because she suffered from a weak heart, her husband was hospitalised, and the news was "horrific". Mrs B was worried about her mother's condition and, during the morning of 28 June, she phoned every hour to find out how her mother was. She was told that everyone was too busy to come to the phone.

Dr C said he considered that Mrs A would have had adequate support from nursing staff and junior medical staff who were present with him on his ward round at the time. In his response to my provisional opinion, Dr C stated: "It is my practice and the practice of the staff in the ward to ensure that support persons are available for patients whenever practically possible." He explained that considerable attempts were made to contact Mrs A's daughter but there were problems because she was not directly available and did not respond to messages left on the phone.

The hospital advised that on an acute care surgical unit often the whole of the morning is devoted to attending to the direct personal care needs of patients. Calls from relatives can be considerable at times and at peak times the hospital does not have the resources to be able to service additional needs.

I accept Professor van Rij's advice that, in general, the hospital's explanation relating to nursing priorities on a busy surgical ward is appropriate. However, Mrs A was about to

undergo a significant intervention at short notice. I am satisfied that before the angioplasty procedure took place on 28 June, Mrs A's daughter attempted to contact the ward on a number of occasions to find out about her mother's condition. My expert advisors Professor van Rij and Dr Osborne both questioned why there was no time to allow Mrs A's family to come in and participate in the process. I share their concerns.

The presence of a support person, particularly when a patient is being informed about a serious condition and treatment options, is an integral part of providing health care. The right to support is set out under Right 8 of the Code, which states:

> "Every consumer has the right to have one or more support persons of his or her choice present, except where safety may be compromised or another consumer's rights may be unreasonably infringed."

I draw this matter to the attention of both Dr C and the nursing staff of the hospital. I note my expert nursing advice that, given Mrs A's age and condition, Mrs B's inability to talk on the phone to the nurse caring for her mother, until 2.30pm on 28 June 2001, is "inexcusable".

I accept that Mrs A had some support from the staff of the hospital in circumstances where an angioplasty was considered urgent. In my view, it would have been appropriate to allow Mrs A's family to come in and provide her with support, particularly in light of the significance of the intervention planned and Mrs B's attempts to find out about her mother's progress during the morning of 28 June. However, it would be unduly harsh to single out Dr C as solely responsible for ensuring that Mrs A had appropriate support from her family when she received the news. Accordingly, in my opinion Dr C did not breach Right 8 of the Code.

Opinion: No breach – the hospital

Angioplasty procedure

On 28 June 2001 Dr C requested an urgent arteriogram and angioplasty for Mrs A. This was performed by Dr H, radiologist, on 28 June. Dr H explained that during the procedure Mrs A was constantly monitored, her blood pressure was stable, and the angioplasty procedure itself was uneventful. Later that evening Mrs A developed a retroperitoneal haematoma that required urgent surgical intervention.

I accept my expert radiology advice that Dr H was an appropriately qualified radiologist to perform the angioplasty procedure, and that the angiographic result of the procedure – in relation to the improved flow down the anterior tibial artery – was successful. I also accept my expert advice that retroperitoneal haematoma is a recognised complication of angiography and angioplasty, particularly when antegrade puncture of the common femoral artery is required. In my opinion, staff members of the hospital provided the appropriate

standard of health care to Mrs A when she underwent an angioplasty procedure on 28 June 2001. Accordingly, the hospital did not breach Right 4(1) of the Code.

Opinion: Breach – the hospital

Monitoring of and response to condition after angioplasty procedure

Dr H completed the arteriogram and angioplasty procedure at 4.45pm on 28 June 2001. Mrs A's blood pressure was stable throughout the procedure, a compression device was used to stop the arterial wound from bleeding, and at 5.15pm Mrs A was transferred to the ward for post-procedure observation. The hospital explained that patients are regularly transferred to the surgical wards after an angiogram and that the nursing staff in both areas are skilled at providing post-angiography observations. Between 5.30pm and 8.15pm Mrs A developed a rapid pulse rate, low blood pressure, and severe abdominal pain. At 8.40pm she was transferred to the operating theatre where a retroperitoneal haematoma was identified with the source of bleeding presumed to be the left iliac vein.

The Radiology Procedure Patient Record set out the instructions for care following arteriogram and angioplasty. It stated that the care was to be given "as per protocol" and indicated the pressures of the compression device to be applied at various times. The Radiology Department's "Post Procedure Angiogram/Angioplasty Protocol" set out the recommended nursing care, including the times to check the patient's blood pressure, pulse, puncture site, and neurovascular observations distal to the puncture site.

Mrs A's patient notes indicate that recordings were done less frequently than outlined in the protocol. Observations are documented as being taken half hourly for two hours. In response to my provisional opinion, the hospital submitted that while the radiology protocol was not strictly adhered to in the first hour, the observations taken between 5.30pm and 6.30pm appear to have been within normal limits for Mrs A.

My expert nurse advisor commented that what happened between 6.30pm and 8.40pm is not well documented and thus it is very difficult to say whether the actions taken by the nurse concerned were appropriate. I accept my expert advice that as the nurse did not document the events as they happened between 5.15pm and 8.40pm, it is very difficult to determine whether Mrs A was adequately monitored. I also accept my expert advice that poor documentation and inability to follow protocol indicate that Mrs A was not adequately cared for by the nurse following her angioplasty.

The hospital stated that it would appear that the nurse did not recognise the significance of Mrs A's abdominal pain. I accept my radiology advice that it is clear that on Mrs A's return to the ward, there was evidence to suggest a retroperitoneal haematoma was developing. I also accept Dr Osborne's advice that there appears to have been a significant delay in the recognition of the severity of the signs by the ward staff. I am advised that it is most unusual for patients to experience significant lower abdominal pain following angiographic

procedures; if the staff involved in post-angiographic care at the hospital are not aware of the significance of ongoing pain post-angiography, this is a serious shortcoming, which should be addressed.

In response to my provisional opinion, the hospital stated that it would have been reasonable for the nurse to interpret the initial increase in pulse at 6.30pm as a response to pain, and that she reacted appropriately when the pulse increased further with a drop in blood pressure. If the nurse did interpret the increase in Mrs A's pulse rate as a response to pain, I am of the view that appropriate steps should have been taken at the time when the pain was detected.

It appears that the hospital had in place appropriate protocols for post-angiography care. However, in my opinion, the staff did not adequately follow the protocols and did not recognise the significance of Mrs A's ongoing abdominal pain at an earlier stage. As employer, the hospital is responsible for hospital protocols, and in particular it has a responsibility to ensure staff are adequately aware of the protocols in place.

The failure of staff on the ward to adhere to the protocol, and the significant delay in the recognition of the severity of her signs meant that Mrs A did not receive appropriate services at a time when her condition was deteriorating. Accordingly, the hospital breached Rights 4(1) and 4(4) of the Code.

Other comments

Timing of angioplasty

The timing of the angioplasty was not a matter under investigation but requires comment. On 27 June 2001 Dr E referred Mrs A to Dr C for admission because he felt the skin graft had failed. On 28 June Dr C advised Mrs A that she would benefit from an angioplasty of the anterior tibial artery to improve the inflow. Dr C subsequently explained that Mrs A required angioplasty because she presented with a recurrent ischaemic ulcer that had been skin grafted twice, had only a single vessel run-off down the anterior tibial artery, and had a stenosis at the origin of that vessel. On 28 June Dr C requested an urgent arteriogram and angioplasty for Mrs A, which was performed later that afternoon.

My expert advisor, Professor van Rij, advised that "there seemed to be an unreasonable rush of events" on Mrs A's last admission and that an "urgent referral was made for the angioplasty in a patient with a very chronic course to this point". Professor van Rij advised that attention needs to be given to a more thoughtful, timely, and reflective process to working up patients for treatment. The urgency of Mrs A's procedure precluded a more thorough work-up, which was required in her situation.

In his response to my provisional opinion, Dr C submitted that the timing of the angioplasty procedure was appropriate because while he was managing a chronic condition, the condition was rendered acute by the failure of the skin graft and the secondary infection. Dr

C considered that Mrs A's leg was acutely threatened and that if she did not undergo some form of revasularisation at that time, loss of the limb would have resulted.

It is not necessary for me to form an opinion on this issue, which was not under investigation. Nevertheless, I accept Professor van Rij's caution that a thoughtful, reflective process for preparing patients for angioplasty procedures is the appropriate standard and I draw this to Dr C's attention. I also accept that in some circumstances a patient's condition may declare urgency.

Nursing notes

I draw the attention of the hospital to my nursing advisor's comments about Mrs A's patient notes. There was poorly labelled documentation by all staff members, including pages that were not numbered, so that the sequence of events was unclear, the time of entries was not always given, and some entries throughout the nursing notes are difficult to read and incomplete. I also note my nursing advisor's comments that there is no assessment and/or care plan written for Mrs A for her three-day stay in hospital.

In the hospital's response to my provisional opinion, it is stated that when Mrs A was transferred to theatre the full clinical record went with her. Therefore, the ward nurse had to write her account of events without the benefit of the observation chart. Between the time Mrs A's deteriorating status was detected and her transfer to theatre, the nurse was fully occupied with providing resuscitative measures and unable to document events at the time they occurred. "Despite gaps in the documentation it is still evident that Mrs A was closely observed and received intensive nursing input."

I acknowledge that in emergency situations, the priority is to provide resuscitative measures to the patient. However, it is important to keep accurate notes that contain all information relevant to the patient's care. Patient records should be updated as soon as reasonably practicable.

The "Code of Conduct for Nurses and Midwives" (Nursing Council of New Zealand 1998) states:

> "Principle 2.9
>
> The nurse or midwife accurately maintains required records relating to nursing or midwifery practice."

I draw to the attention of the hospital the comments of my nursing advisor on the documentation by nursing staff relating to the care of Mrs A. The notes were not always clear and accurate and this made it very difficult to assess whether Mrs A was provided with adequate care.

Medical notes

Professor van Rij commented that the lack of documentation by medical staff is a recurring shortcoming in Mrs A's patient records. This made evaluation difficult and also

compromised management. In particular, he advised that the full clinical evaluation of the presenting vascular problem at each admission is incomplete. Professor van Rij made reference to the clinical measures of ischaemia of the tissues, the severity of Mrs A's vascular disease, both venous and arterial, the exact location of the ulcer, its size and characteristics, and the documentation of pulses without any detail. He also advised that there was a failure to record critical events – on the day of the angioplasty there was no record of any substantive input by the medical staff until Mrs A was severely compromised.

In response to my provisional opinion, Dr C stated that he routinely encourages all junior medical staff to record all appropriate clinical proceedings in the notes and that it is his expectation that the proceedings are documented.

Professor van Rij advised that there was a lack of comment by medical staff on the content of communication with Mrs A and her family. He noted that the content of any communication by the surgical team with the patient during the hospital admissions and outpatient visits relating to Mrs A's ulcer, graft, and possible outcomes, is missing from the assessment. He further stated that the notable paucity of recorded medical staff communication does not allow any specific comment. I accept my expert advice that if communication is inadequate, it readily feeds a dissatisfaction for the patient and his or her family, as is evident in this case.

In light of Professor van Rij's comments, I wish to draw the attention of Dr C and the hospital to "Good Medical Practice: A Guide for Doctors" (Medical Council of New Zealand 2000) which states:

> "3. In providing care you must:
>
> … keep clear, accurate, and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed."

In addition, the Medical Council of New Zealand's "Guidelines for the Maintenance and Retention of Patient Records" (October 2001) states:

> "1. Maintaining patient records
>
> (a) Records must be legible and should contain all information that is relevant to the patient's care.
>
> (b) Information should be accurate and updated at each consultation. Patient records are essential to guide future management, and invaluable in the uncommon occasions when the outcome is unsatisfactory."

Consent form for angioplasty

My medical advisors commented on the consent forms used by the hospital. The "[hospital] Radiology Services General Consent Form" signed by Mrs A on 28 June 2001 is **attached** as Appendix 1.

Dr Osborne commented that the consent form used at the hospital is very comprehensive but non-specific, with a one-page form used to cover virtually all radiological procedures. In his opinion the form would be more appropriately used as an information sheet with a more specific and less busy consent form tailored to the specific procedure, in this case angioplasty, that the patient is being asked to give consent to.

Professor van Rij commented that the consent form for angioplasty is very confusing, particularly in relation to where the consent was obtained and signed. He stated that what Mrs A signed for is not evident, and recommended that the form be re-evaluated.

I am pleased that the hospital has begun to take appropriate steps to address this matter. In its response to the provisional opinion, it stated that the consent form used for Mrs A is no longer in use and that the current radiology consent form "Request for Treatment/Procedure" implemented in December 2002 is under review.

Site of bleeding

Both my medical expert advisors made comments about the site of bleeding. This is not a matter that forms part of my investigation but I note Professor van Rij's comment that greater attention needs to be paid to accurate documentation as part of sound clinical practice.

Actions taken by the hospital

I am pleased that the hospital has been developing a clinical pathway for angiography procedures and that it proposes to undertake further actions by the end of March 2004 as a result of my provisional opinion and the Board's review of Mrs A's case. The steps include nursing education to highlight the requirements for pre- and post-angiography care, and the development of resource books for the wards.

Recommendations

I recommend that the hospital:

- apologise to Mrs B for breaching the Code. The apology is to be sent to my Office and will be forwarded to Mrs B

- ensure that medical and nursing staff are aware of their obligations in regard to record keeping

- ensure that medical and nursing staff are aware of their obligations to enable patients to have one or more support persons present, where practicable.

Follow-up actions

- A copy of this report will be sent to the Coroner and to the New Zealand Medical Council.

- A copy of this report, with personal identifying details removed, will be sent to the Nursing Council of New Zealand, the Royal Australasian College of Surgeons, and the New Zealand Society of Vascular Surgery, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.