General Practitioner - Dr C

A Report by the

Health and Disability Commissioner

(Case 03HDC02828)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Mr A	Consumer
Mrs A	Consumer's wife
Mr B	Complainant / Consumer's son
Dr C	Provider / General practitioner
Dr D	Dermatologist
Dr F	Dr C's locum
Dr G	Temporary locum

Complaint

On 27 February 2003 the Commissioner received a complaint from Mr B about the service his father, Mr A, received from at his Medical Centre. The complaint was summarised as follows:

Between April and December 2002 general practitioner Dr C did not provide services of an appropriate standard to Mr A in relation to the deterioration of a varicose ulcer on his right leg. In particular, Dr C:

- *did not adequately consider the increased risk of harm to Mr A in view of his history of diabetes*
- *did not provide appropriate clinical management/intervention to Mr A despite evident deterioration and concerns expressed by the district nurse.*

An investigation was commenced on 11 August 2003.

Information reviewed

Information was obtained from the following sources:

- Mr B
- Dr C
- Dr D, dermatologist
- A Public Hospital
- Another Public Hospital
- ACC

Independent expert advice was obtained from Dr Wendy Isbell, a general practitioner. Dr David Kerr, a general practitioner, provided advice on behalf of Dr C in response to the provisional opinion.

Information gathered during investigation

This complaint concerns Dr C, general practitioner, whom Mr A, an insulin-dependent diabetic, had consulted for a number of years since 1988. The complaint centres on the care Dr C provided to Mr A for a persistent leg condition from April to December 2002. On 31 December 2002 Mr A (76 years old) had a below-the-knee amputation on his right leg.

Background
Mr A consulted Dr C on 26 April 2002, complaining that his right ankle was inflamed. Dr C recorded that the area was a bit tender and inflamed, but there was no ulcer or infection. Mr A had been seen by a consultant general and vascular surgeon two years earlier on 8 July 2000. At that time Mr A had no rest pain and his Doppler pressures were good, but some of his foot pulses were absent.

Mr A returned to see Dr C on 15 July 2002 complaining that his right ankle was still very sore, especially at night and when pressure was placed on it. Dr C examined the ankle and found a crusty lesion over the right lateral malleolus, which was very tender. Mr A was referred for an X-ray. The report (dated 16 July 2002) stated:

> "There is mild soft tissue swelling overlying the lateral malleolus but no radiological sign of osteomyelitis, fracture or other bony abnormality is identified. No joint effusion or joint malalignment is seen. Extensive arterial calcification is noted posteriorly."

Dr C also did a general check-up and found Mr A's blood sugar levels were high, with the figures recorded in his medical notes being 18mmol/l before lunch and 20.4mmol/l before tea (normal is 4-7mmol/l).

Mr A's next consultation was on 23 July 2002. Mr A reported that his left calf felt tight and had been swollen for the past month, particularly for the last two days. Dr C noted the left ankle was stiff on walking and that Mr A had pitting oedema up to the knee on both calves. Dr C recorded that both popliteal pulses were strongly palpable. A chest X-ray was obtained and reported "no left ventricular failure". Amoxycillin and frusemide were prescribed.

On 31 July 2002 Mr A consulted Dr C's locum, Dr F, who recorded that swelling and pain were persisting in both legs. Dr F diagnosed cellulitis and prescribed Amoxil and Flucloxin.

Mr A returned to the surgery on 6 August 2002. Dr C noted that he continued to have oedema up to both knees, and a crusty ulcer over the right malleolus. Amoxil and Flucloxin were continued and a swab was taken from the ulcer. Frusemide was increased.

Mr A's ulcer was reviewed again on 9 August 2002. The scab on his right ankle was noted to be soft. Amoxil was stopped and Diclocil continued. His leg was dressed with Cutifilm to try to soften the scab.

On 13 August 2002 Mr A again visited Dr C. The ulcer and oedema were still present, any pressure on the right foot was painful, and the ankle remained stiff. The area was recorded as being clear. Mr A's blood sugar level was also recorded as 18-20mmol/l.

Mr A's ulcer was re-dressed at the surgery on 20 August. A referral to the district nurses was sent to continue the dressings. The first district nurse visit was on 22 August.

The district nurse telephoned Dr C's surgery on 22 August reporting that the Doppler ultrasound showed arterial problems. She said that further tests were being undertaken, and would be reported to the practice. A note was made on the file (in the 'Plan and Treatment' column) "for referral to vascular surgeon" and "? Sympathectomy op[eration]". Only the latter note appears to be in Dr C's handwriting.

The district nurse telephoned the surgery on 2 September reporting a possible infection in Mr A's right ankle ulcer, and noting blisters on both legs. The district nurse sent a swab from the ulcer to the laboratory.

Mr A was seen on 3 September by Dr F (Dr C's locum). Dr F noted that the ulcer looked clean, with no cellulitis or inflammation, and that Mr A's legs would need to be reviewed by a dermatologist after surgery on his shoulder.

On 4 September Mr A was admitted to the Public Hospital for elective surgery on his shoulder. He received intravenous antibiotics for 24 hours postoperatively for his leg, and was discharged on 6 September.

The district nurse visited Mr A on 7 September, and noted that areas on his legs were weeping. The dressings were changed.

On 9 September Mrs A telephoned the surgery to say that the ulcer was still looking green. Dr C prescribed Fluclox and Paradex.

An assessment was carried out by the wound care specialist nurse on 12 September. She contacted the practice nurse regarding the leg inflammation, and recommended a dermatology and vascular referral. An appointment was made for Mr A to see Dr F the next day.

Mr A was seen by Dr F on 13 September. Dr F noted cellulitis and that the infection seemed to be improving in the right leg, and that the left leg looked worse. An urgent referral was made to the Public Hospital Dermatology Clinic.

On 15 and 18 September the district nurse noted marked improvement in the ulcer and Mr A's legs.

On 27 September Mr A returned to the surgery. Dr C recorded that Mr A had solid pitting oedema bilaterally to his knees, and erythema with desquamating skin. Mr A was given an increased dose of frusemide.

Mrs A called the surgery on 30 September and 2 October regarding Mr A's blood sugar levels, which were 16-21mmol/l since the dose of frusemide was increased.

Mr A was reviewed on 4 October. Dr C noted oedema, erythema, crusting, weeping skin and blistering lesions on Mr A's lower legs. Dr C recorded that Mr A's legs were supersensitive to touch at night. Mr A mentioned that his son had had bullous pemphigoid in his lower legs and queried whether that was what he also had. Dr C wrote "? Bullous pemphigoid +2° infection", and commenced Mr A on prednisone and Diclocil. Mr A's blood sugar levels were reported as remaining high.

On Mr A's next visit to Dr C on 11 October it was recorded that his legs still felt tight, but he was moving much more easily. Dr C noted that Mr A was still sleeping in a chair, as it was still too sore to lie in bed. Dr C wrote to Dr D, dermatologist, at the Public Hospital. Mr A's blood sugars were 14-18mmol/l.

Mrs A contacted the district nurses on 20 October stating that Mr A's leg was blistered and inflamed. She was advised that he should see his GP.

On 23 October Mr A visited Dr D. She noted erythema in Mr A's lower legs.

Leg oedema with serous exudates was noted by the district nurse on 30 October. Mr A's leg was re-dressed and visits increased to daily.

On 1 November the district nurse telephoned the surgery and reported that Mr A's legs were more swollen and the blisters had returned. Dr C telephoned Dr D the same day and, after discussing Mr A's condition, arranged a biopsy of one of the blisters for histology and immunofluorescence studies. Mr A was then recommenced on prednisone.

Dr C performed the biopsy on 5 November. Severe bullous inflammation was noted in both lower legs. Mr A was given doxycycline in addition to prednisone.

Mr A saw Dr D again on 11 November, and some oedema was noted in addition to the erythema. Dr D asked Mr A to continue with the doxycycline and increased his prednisone while they awaited the results of the biopsy.

Wound improvement was recorded by the district nurses on 25 November.

On 27 November, Dr D noted that Mr A's legs looked better, and the biopsy results from 5 November were suggestive of bullous pemphigoid, but were not diagnostic. Prednisone was reduced, but the doxycycline was continued.

On 2 December Mr A returned to the surgery and was seen by a temporary locum, Dr G. He noted that Mr A had been suffering hypoglycaemic attacks (low blood sugar levels), and

recommended reducing the dosage of insulin. Dr G observed that Mr A's foot was swollen and erythematous, and there were vascular insufficiency problems in his right foot. Dr G noted that he would discuss this with Dr C when he returned from leave.

On 4 December 2002 the diabetic nurse telephoned the surgery, concerned about the vascular situation in Mr A's right foot.

On 5 December, Mr A's blood sugars were recorded as varying between 8-21mmol/l. The district nurse noted that the wound had deteriorated, Mr A was feeling unwell, and his blood sugars were unstable. The diabetic nurse was contacted.

Mr A was reviewed by Dr G on 6 December. Erythema was noted up to mid-calf. The notes record that a vascular review would be arranged by the Diabetic Clinic. Dr G noted that Mr A was due to see Dr D on Wednesday of the following week.

On 7 December the district nurse noted that Mr A's leg was red, swollen and tender. His blood sugars were recorded to be peaking during the night.

On 9 December Dr C visited Mr A at home after being called by the district nurse. Mr A's right lower leg had erythema, tissue ooze and bullae. His blood sugar level was 22mmol/l. Dr C arranged for Mr A to be admitted to the Public Hospital.

At the Public Hospital Mr A was treated with intravenous antibiotics, and had an inpatient review by the vascular surgery registrar on 24 December. At this review there were "good doppler signals on post tibialis and dorsalis pedis, and no ulceration or blisters on the dorsum of the right foot".

However, Mr A's clinical situation deteriorated, and on 31 December he was transferred to another Public Hospital and underwent a right below-knee amputation.

Dr C stated: "At all times I was duly cognizant of the fact that his diabetes increased the risk of progression of the condition of his legs and would reduce the rate of healing. It is for this reason that we kept [Mr A] under close scrutiny during this time. When it was apparent that vascularity was compromised, the appropriate referral was made."

Dr C continues to treat Mr A as his general practitioner.

ACC

Mr A submitted a claim to the Medical Misadventure Unit of ACC, which was declined on 9 February 2004. In reaching its decision, ACC considered independent advice from a general and vascular surgeon. In his report to ACC, the general and vascular surgeon stated:

> "[Mr A] required below knee amputation due to infection and gangrene and there is no doubt that he did have peripheral vascular disease secondary … to his long standing diabetes.
>
> …

Although it is unlikely that any vascular reconstruction could have been done it would have been appropriate to refer him for vascular assessment given his non healing and pain in August.
…

The deterioration in his leg and admission to [the Public Hospital] was probably due to infection which was not responding to antibiotics and this infection led to tissue destruction. Both the infection and tissue destruction were more severe due to his peripheral vascular disease and amputation was probably inevitable by the time of his admission to hospital.
…

The rapid deterioration of [Mr A's] leg was mainly due to his Pemphigus and infection and I believe this was appropriately treated.
…

On balance I do not believe there was a failure by a registered health professional to observe a standard of care and skill to be expected in the circumstances and although the outcome was tragic for [Mr A], it is a common end result for the diabetes. I do not consider there was medical error in this case."

Independent advice to Commissioner

Initial advice
The following expert advice was obtained from Dr Wendy Isbell, an independent general practitioner:

"**Table of Contents**

Agreement

I have been asked to provide an opinion to the Commissioner on case number 03/02828/KH.

I have read and agree to follow the Commissioner's Guidelines for Independent Advisors.

Qualifications, Training and Experience

My **qualifications** are MB, ChB (University of Otago) 1970, MRCP (UK) 1975, FRACP 1983, and FRNZCGP 1998.

I **trained** at the University of Otago Medical School, underwent postgraduate training at Christchurch Hospital and The Princess Margaret Hospital, and undertook a Course in Advanced Medicine at the Royal Postgraduate Medical School, University of London, 1975.

I have also had training in Nutrition for Health professionals (New Zealand Nutrition Foundation) 1994-1995, and have undertaken a number of courses in homeopathy.

I have had informal training in lipid disorders and diabetes at the Lipid and Diabetes Research Group in Christchurch, headed by Professor Russell Scott, 2003-2004.

My **experience** has been as a junior medical doctor in Christchurch (1971-1976), and at Hammersmith Hospital in London (1977), and as a Physician in Health Care of the Elderly at The Princess Margaret Hospital (1977-1987, including maternity leave).

Since 1987 I have been in practice on my own accord as a physician and homeopath, and later also included general practice, becoming a member of Pegasus Health and Partnership Health.

From 2003 I have also been working three-tenths as a physician in the Lipid and Diabetes Research Group, Christchurch.

My **Curriculum Vitae** is enclosed (Appendix 1).

Purpose

To advise the Commissioner whether the services provided to [Mr A] by [Dr C] were of an appropriate standard.

Complaint

Between April and December 2002 general practitioner [Dr C] did not provide services of an appropriate standard to [Mr A] in relation to the deterioration of a varicose ulcer on his right leg. In particular, [Dr C]:
- *did not adequately consider the increased risk of harm to [Mr A] in view of his history of diabetes*
- *did not provide appropriate clinical management/intervention to [Mr A] despite evident deterioration and concerns expressed by the district nurse.*

Referral Instructions

To advise the Commissioner whether, in your professional opinion, the care [Mr A] received from [Dr C] was of an appropriate standard. In particular:
- What were the likely causes of the oedema, cellulitis, and blisters/ulceration that developed in [Mr A's] leg(s)?
- Was [Mr A's] diabetes a contributing cause to his leg condition?
- Please comment on [Dr C's] management of [Mr A's] diabetes between April and December 2002. Was this appropriate?
- What is 'bullous pemphigoid'? Did [Mr A] have this, and was it a contributing factor to the deterioration of his leg(s)?
- Was the medication [Dr C] prescribed for [Mr A] appropriate? In particular, was the prescribing of antibiotics appropriate? If not, why not?
- Was it appropriate to prescribe Prednisone for [Mr A] given that he was an insulin dependent diabetic? (See documents numbered 187 and 188)
- Should action have been taken earlier in relation to the Doppler ultrasound reports reported by the district nurses in August 2002, which showed an arterial problem?
- Were referrals to specialists appropriate and timely? In particular, please comment on the timeliness of the vascular referral.
- Were [Dr C's] responses to concerns communicated by the district nurses appropriate and timely?
- Are there any other matters relating to professional standards or other matters which you believe to be relevant to this complaint?

Supporting Information

I have reviewed the supporting information sent by the Commissioner.

These include:
- Letter from [Mr B] to the Commissioner dated 21 February 2003, marked 'A', (numbered 1).

- Report dated 24 July 2003 from advocate […] with enclosed medical notes, marked 'B' (numbered 2-142).
- Investigation letter to [Dr C] dated 10 September 2003, marked 'C' (numbered 201-218).
- Letter and enclosures from [Dr C] dated 10 October 2003, marked 'D' (numbered 146-200).
- Medical records from [Dr D] received on 28 October 2004, marked 'E' (numbered 201-218).
- District nurse medical notes received from [the Public Hospital] on 19 November, marked 'F' (numbered 321-343).

Factual Summary

On 31 December 2002 [Mr A] (76 years old) had a below the knee amputation on his right leg. Prior to that he consulted his general practitioner, [Dr C], whom he had seen since 1988. [Mr A] suffered from insulin dependent diabetes.

[Mr A] consulted [Dr C] on 26 April 2002 with inflammation of his right ankle, and on 15 July 2002 with pain in his right ankle, especially at night and with pressure. A tender crusty lesion was forming over the right [lateral] malleolus (inside of the ankle). [Mr A's] blood sugar levels were high (18 before lunch and 20.4 before tea).

A plain X-ray on 16 July 2002 showed soft tissue swelling, no X-Ray evidence of osteomyelitis, and extensive arterial calcification.

On 23 July 2002 [Mr A] had pitting oedema (swelling) of both legs up to the knees. The popliteal pulses (behind the knees) were palpable (present). A chest X ray showed no heart failure. He was prescribed amoxycillin and frusemide. On 31 July 2002 [Dr F], a locum, diagnosed cellulitis, and prescribed amoxycillin and flucloxacillin. On 6 August 2002, [Mr A] still had oedema, and a crusty ulcer over the right [lateral] malleolus. A swab was taken, and treatment continued. On 13 August 2002 the ulcer and oedema were still present, and his right foot was painful under pressure. Blood sugar levels were 18-20. He was referred to the District Nurses.

A District Nurse first saw [Mr A] on 22 August 2002, reported back to [Dr C's] surgery that a Doppler test showed arterial problems, and suggested referral to a vascular surgeon. The District Nurses also reported a possible infection in the ulcer and blisters on both legs on 2 September 2002. The locum doctor saw [Mr A] on 3 December 2002, and commented that [Mr A's] legs would need to be reviewed by a dermatologist.

On 4 September 2002 [Mr A] had elective surgery on his shoulder, received intravenous antibiotics for 24 hours, and was discharged 2 days postoperatively.

On 9 September 2002 the District Nurse noted that parts of [Mr A's] legs were weeping, and on 9 September 2002 [Mrs A] rang the surgery to say that the ulcer was still looking green. A wound care specialist nurse contacted the practice on [12] September 2002 regarding leg inflammation, and recommended a dermatologist and

vascular surgeon. On 13 September 2002, the locum doctor arranged an urgent referral to the [the Public Hospital] Dermatology Clinic.

[Mrs A] reported on 30 September 2002 and 2 October 2002, saying that [Mr A's] blood sugars were noted to be high at 16-17.

On 4 October 2002 [Dr C] noted oedema, crusting, weeping skin and blistering skin on [Mr A's] legs. [Mr A] was started on prednisone. High blood sugars were recorded. Leg oedema with serous exudates was noted by the district nurse on 30 October 2002, and on 1 November 2002 she reported to the surgery that [Mr A's] legs were more swollen and blisters had returned. [Dr C] discussed the situation with the dermatologist, who had seen [Mr A] on 23 October 2002. On 5 November 2002 [Dr C] took a biopsy from [Mr A's] leg and the report was interpreted as a diagnosis of bullous pemphigoid.

On 2 December 2002**,** a temporary locum noted that [Mr A] had been suffering from hypoglycaemia, so his insulin was reduced. He observed that [Mr A's] foot was swollen and erythematous, and there were vascular insufficiency problems. On 4 December 2002 the diabetic nurse called the surgery about the vascular situation in [Mr A's] right foot, and on 5 December 2002 the district nurse noted that the wound had deteriorated, [Mr A] was feeling unwell, and his blood sugars were unstable.

On 6 December 2002 the locum recorded that a vascular review would be arranged by the Diabetic Clinic, on 7 December 2002 the district nurse noted that Mr A's leg was red, hot and tender. On 9 December 2002 [Dr C] was called to [Mr A's] home by the district nurse. His right leg had erythema, tissue ooze and bullae (blisters), and his blood sugar levels were 22. [Dr C] arranged for Mr A to be admitted to [the Public Hospital].

[Mr A's] clinical situation deteriorated, and on 31 December 2002 he was transferred to [another Public Hospital] and underwent an amputation below the knee on his right leg.

Guidelines

In preparing this report, I have relied on three sets of current guidelines about the management of diabetic foot disease. These guidelines are from:

1. Evidence-Based Best Practice Guidelines, Ministry of Health, New Zealand.
2. Diabetes Australia and The Royal Australian College of General Practitioners
3. Hospital and Referral Guidelines, Canterbury District Health Board

I acknowledge that these guidelines were not in place at the time of the treatments under consideration. However in my opinion each of the guidelines has ratified the standard of care that was current before they were formulated.

The guidelines represent what would have been appropriate treatment at the time of the case under consideration. They are also tenets I would have followed before I developed my special interest in diabetic research.

The guidelines are as follows:

1 Management of Type 2 Diabetes.
Evidence-Based Best Practice Guidelines. Ministry of Health, New Zealand Guidelines Group, December 2003. (Appendix 2)

Arterial Revascularisation (page 72)
– All people with diabetic foot disease with tissue loss and arterial disease should be referred for consideration of arterial revascularisation procedures.

People with diabetes are more prone to peripheral arterial disease (PAD) than people without diabetes. This includes both proximal (aorto-iliac and femoral) and distal (calf and foot) disease. Rates of limb salvage following distal bypass surgery are relatively high. Salvage rates of around 80% are reported in the initial presence of tissue loss (gangrene and ulceration). Increased frequency of distal bypass is associated with reduced frequency of amputation. No evidence was found to support recommendations on the optimum stage to make a vascular intervention.

Treatment of Foot Ulcers (page 72)
– Treatment of a clinically infected diabetic foot ulcer should be commenced with a broad spectrum antibiotic regime in conjunction with appropriate debridement. Subsequent antibiotic regimens may be modified based on the swab culture and sensitivity results.
– Intravenous antibiotics are indicated in the presence of cellulitis or osteomyelitis, and prompt referral to hospital is required in these circumstances.
– Wound dressings for diabetic foot ulcers should be chosen with consideration of clinical experience, cost, patient preference and the site of the wound.
– Wounds should be closely monitored, and dressings changed regularly.

Antibiotic Therapy (page 73)
There is no clear evidence of the benefit of routine antibiotic therapy in the management of infected diabetic foot ulcers. If antibiotics are used, there is no evidence regarding the optimal duration or route for antibiotic treatment. No single broad spectrum antibiotic regimen was shown to be more effective than another in the treatment of diabetic foot ulcers. Diabetic foot ulcers are often colonised by a mixture of organisms, and routine swabs may be of limited value.

2 Diabetes Management in General Practice.
Diabetes Australia and The Royal Australasian College of General Practitioners, 2003/4 (Appendix 3)

Foot Problems (page 50)
The foot of a person with diabetes is at risk of damage due to a combination of small and large vessel disease, nerve damage and mechanical instabilities in the foot. Tissue is more susceptible to injury and infection and heals more slowly.

If vascular disease exists, surgical intervention on the foot can result in poor healing, ulceration, and, at worst, gangrene. Such procedures should be carried out by practitioners used to working with patients who have diabetes.

Ulcers (page 50)
The most common sites of ulceration are on the plantar surfaces under the metatarsal heads. Abnormal shearing forces initially form a bruise under the epidermis. Infection then intervenes, the overlying skin or callus becomes necrotic, sloughs and reveals the ulcer. Complications include cellulitis, thrombotic arterial occlusion and gangrene.

If the ulcer is deep, or if cellulitis is present, hospitalisation and bed rest are necessary.

The Ischaemic Foot (page 51)
In patients with diabetes the disease is usually bilateral and symmetrical.

Clinically leg ischaemia presents as claudication, ulceration, rest pain or gangrene.

Patients with claudication should be encouraged to exercise since this may increase the claudication distance and improve blood supply.

Surgical treatment is indicated if there is severe claudication, intractable rest pain or ulceration not responding to medical treatment.

Surgical treatment may consist of:

– Sympathectomy: can occasionally help with rest pain but may not improve circulation sufficiently for ulcer healing.

– Arterial reconstruction if there is a correctable obstruction.

– Major amputation: for rampant infection, extensive tissue destruction or rest pain not responsive to arterial reconstruction.

3 Hospital Referral and Management Guidelines.
A Guide for Canterbury General Practitioners. Canterbury District Health Board, April 2003 (Appendix 4)

Referral and Management Guidelines : Diabetes

Foot Ulceration (page 7)
Evaluation
– Is the ulcer neuropathic or vascular (or both) in origin?

– Is there active infection. Is there invasive infection with spreading cellulitis? Is there bony infection (X-ray and if required bone scan)? Wound swab for culture.
Management
– Podiatry treatment to debride and to remove callus.
– Antibiotics if infection.
– Stop weight bearing.
– Orthotic device, scotch boot or total contact plaster.
– Revascularisation for peripheral vascular disease.
Referral Guidelines
– Patients with invasive infection should be admitted to hospital immediately.
– Patients with infected ulcers should be started on appropriate antibiotics after swabbing and be addressed urgently by the Diabetes Centre Podiatrist and semi–urgently by the Physician.
– Patients with simple neuropathic ulcers should be referred to the Diabetes Centre semi-urgently.
– Patients with peripheral vascular disease as the primary cause for the ulceration should be referred to the Vascular surgeons for prompt review.

Referral and Management Guidelines: Vascular Surgery

Arterial Ischaemia (page 5)
Evaluation
– Incapacitating claudication
– Standard history and risk factors
– Peripheral pulses
Management
– Managing risk factors, particularly smoking and diabetes.
– Advice re graduated exercise programme.
– Caution with beta blockers – consider using more selective blocker if required.
Referral Guidelines
– Refer urgently – Category 2 – those with ischaemic changes, or rest pain. Other cases refer according to clinical judgement.

Diabetic Disease (page 5)
Evaluation
cf Diabetes referral guidelines
Note: Significant acute infection of an ulcer, fissure or ischaemic digit should be an indication for admission/urgent review, especially in the **diabetic**.
Management
– Managing diabetes.
– General foot care. Consider podiatry assessment.
Referral Guidelines
– Semi-urgent – Category 3 – referral if increasing rest pain/ ulceration/ trophic changes.

Comments on Selected Consultations

15 July 2002
Rest pain is suggestive of serious arterial insufficiency. [Mr A] had rest pain from this date until his eventual amputation.

Although the position of the developing ulcer was not typical for arterial foot ulcers, in a diabetic patient with vascular disease and possible peripheral neuropathy, a diabetic foot ulcer would be the first consideration.

His diabetes was very poorly controlled, and bringing his blood sugars under control would be a priority.

Poor blood sugar control was also reported to [Dr C] by the District Nurse on other occasions, and also by [Mrs A] on 30 September 2002 and 2 October 2002.

16 July 2002
The plain X-Ray of his right ankle showed soft tissue swelling, and no X-ray evidence of osteomyelitis. It was also stated that if there remained clinical concern this could be assessed further with a bone scan. This was not followed up, despite later deterioration.

The X-Ray also showed extensive arterial calcification posteriorly, which is an alert to the presence of severe peripheral vascular disease.

23 July 2002
[Mr A] had pitting oedema of both legs, and a chest X-Ray did not show heart failure, in other words there was no fluid overload. This is another alert to significant local pathology in the legs.

31 July 2002, 6 August 2002, 13 August 2002
Cellulitis in an uncontrolled diabetic is a serious concern, and would warrant referral to a diabetic specialist and/or a vascular surgeon, or admission to hospital.

22 August 2002
The District Nurse correctly assessed the situation on her first visit. She reported to [Dr C] that [Mr A] had arterial problems, and suggested a referral to a vascular surgeon. This was noted in [Dr C's] notes but was not acted on.

The District Nurse reported further deterioration to [Dr C's] practice on 22 September 2002, 30 October 2002 and 1 November 2002.

A Vascular surgeon opinion was still not arranged when it was later recommended by a wound specialist nurse on [12] September 2002, and by a diabetes nurse on 4 December 2002.

9 September 2002, 4 October 2002
Blistering and serous exudates occurred on [Mr A's] legs. The wound specialist nurse recommended a dermatology referral on [12] September 2002.

A relative said he had had a similar condition of his legs that had been diagnosed as bullous pemphigoid.

[Dr C] started [Mr A] on prednisone because of a provisional diagnosis of bullous pemphigoid on 4 October 2002. There was some initial improvement.

23 October 2002
A letter from the dermatologist stated 'if this is something like pemphigoid then he would probably [be] better controlled on a tetracycline rather than long term Prednisone given his insulin controlled diabetes. Once I see him in a fortnight I'll take a biopsy if required and start treatment as appropriate.'

On 4 November 2002, [Dr C] discussed [Mr A's] skin problems with the dermatologist, and on 5 November 2002 he himself took a skin biopsy. The report was noncommittal, that the result was 'very suggestive but not quite typical of bullous pemphigoid'.

Further deterioration continued from 4 December 2002, [Mr A] was admitted to hospital on 9 December 2002, and he underwent a right below knee amputation on 31 December 2002.

Advice on Referral Instructions

Whether the care [Mr A] received from [Dr C] was of an appropriate standard. In particular:

1 What were the likely causes of the oedema, cellulitis, and blisters/ulceration that developed on [Mr A's] leg(s)?

We are considering [Mr A's] leg problems against the background of long standing diabetes.

[Mr A] could have been suffering from osteomyelitis (infection of the bone), as [Dr C] considered on 15 July 2002. A plain X-Ray might show changes if osteomyelitis is present, but a normal plain X-Ray cannot rule out osteomyelitis, and in this situation a bone scan (or if in hospital an MRI scan) would be necessary. [Dr C] had the option of arranging a bone scan at any time while [Mr A's] leg continued to deteriorate.

The oedema could be related to vascular insufficiency, it could be a side effect of his medication, and it was definitely related to infection as it developed and worsened despite treatment. It was not related to heart failure, as was shown by the clear chest X-Ray.

The cellulitis was related to tissue infection in a diabetic foot and leg. Because diabetics do not heal well, every care needs to be taken to prevent small injuries which can act as portals for the introduction of infection.

In the neuropathic (damaged nerve supply) and ischaemic (impaired circulation) diabetic foot, cellulitis is a serious complication, and if the cellulitis doesn't settle quickly, then an urgent diabetic physician and/or vascular surgeon referral is indicated, or direct admission to hospital.

The blisters and serous ooze (ooze of serum out of the skin) could just be related to his severely swollen legs, in the presence of infection. I will discuss the possibility of bullous pemphigoid below.

The ulcer was almost certainly a diabetic foot ulcer, in the setting of a neuropathic and ischaemic foot. There is no evidence to suggest it was a varicose (venous) ulcer.

The ulcer was infected, and this would be very difficult to heal unless the patient was on bed rest, and having intravenous antibiotics, and even that may not be successful.

Hyperbaric oxygen can be used in centres that have a hyperbaric oxygen chamber.

2 Was [Mr A's] diabetes a contributing cause to his leg condition?

Yes. [Mr A's] problems were typically that of the diabetic foot. This occurs in longstanding diabetes, and is more likely if there has been poor diabetic control.

Contributing factors include peripheral neuropathy (poor sensation in the feet), and poor blood supply, which is both macrovascular (in the large vessels), which [Mr A] certainly had, and microvascular (in the small vessels), which [Mr A] probably had.

Patients with such complications should be referred to a diabetes physician (not just a nurse) and/or a vascular surgeon (again not just a nurse).

3 Please comment on [Dr C's] management of [Mr A's] diabetes between April and December 2002. Was this appropriate?

[Mr A] was a type 2 diabetic (see section on nomenclature of diabetes, page 14 of this report). He was taking oral antidiabetic agents, and a small amount of insulin.

[Mr A's] blood sugars were very high from as early as 15 July 2002 (18 and 20.4 before meals), still high on 30 September 2002 and 2 October 2002 (16-17), and extreme on 9 December 2002 (22).

A normal blood sugar is 4-8 in treated diabetics, and further action is usually taken once the figures go consistently into double figures.

It was necessary to treat [Mr A's] diabetes aggressively, so that his leg problems would have a chance of healing, hence the need for referral to a diabetes physician (not just a nurse).

It was also necessary to treat [Mr A's] leg problems aggressively, so that his diabetes could be brought under control, hence the need for referral for a vascular surgeon (not just a district nurse and a wound care specialist nurse).

Again, this could be done more easily if [Mr A] was hospitalised to establish control of his diabetes, and his cellulitis and ulcer.

4 What is 'bullous pemphigoid? Did [Mr A] have this, and was it a contributing factor to the deteriorating condition of his leg(s)?

Cutaneous (skin) blisters are referred to as vesicles when they are small, and bullae when they are large. There are a number of blistering skin diseases, including pemphigus and bullous pemphigoid. Bullae can also occur secondary to other illnesses, and in association with various infections. Drugs can also be a cause. Rarely, frusemide can cause bullous eruptions indistinguishable from the primary bullous disorders.

Several metabolic diseases are associated with bullae. In diabetes, tense bullae with clear serous fluid can occur, especially on the legs and arms. Poor blood flow to the skin is another factor.

Bullous pemphigoid is treated with prednisone and immunosuppressive drug therapy, but by no means is this treatment suitable for other causes of bullae.

The diagnosis of bullous pemphigoid may have been made by [Dr C] because [Mr B] (a son) commented that he had had bullous pemphigoid, and the condition looked similar to [Mr A's] (see document numbered 002).

The skin biopsy on 5 December 2002 was reported as showing microscopic changes which were 'very suggestive but not quite typical of bullous pemphigoid. The biopsy could represent an older vesicle that is re-epithelialising [developing new skin] and this may explain the atypical histological and immunofluorescent features.'

In any case, the biopsy findings would not necessarily be diagnostic, because [Mr A] had been taking prednisone until 13 days earlier.

In summary, I haven't seen enough information to decide whether [Mr A] had bullous pemphigoid or not.

I can't give an opinion as to whether the blistering of [Mr A's] legs was a contributing factor to the deterioration of his legs. It could be more likely that the deterioration of [Mr A's] legs caused the blistering.

5 Was the medication [Dr C] prescribed for [Mr A] appropriate? In particular, was the prescribing of antibiotics appropriate? If not, why not?

Yes, I think the prescribing of broad spectrum antibiotics for [Mr A's] cellulitis was appropriate. A swab grew *Staphylococcus aureus*, and the antibiotic choices were appropriate.

Oral medication may not be sufficient in cellulitis, especially in diabetics, and domiciliary intravenous antibiotics may be an option if available, or failing that admission for a course of intravenous antibiotics, to be followed be oral antibiotics at home. Also, hospital specialists have a broader range of antibiotics to call on.

Frusemide, a diuretic, was prescribed for [Mr A's] swollen legs, and was initially successful. However, frusemide would tend to decrease fluid from the intravascular space (inside the blood vessels), rather than from the extracellular space (inside the tissues, where the serous ooze and blisters were coming from).

There would be a risk of dehydration if frusemide, a potent diuretic, was used in a patient without fluid overload. There could also be a worsening of diabetic control, increasing renal (kidney) impairment, especially in a diabetic, and a low serum potassium (potassium level in the blood).

6 Was it appropriate to prescribe Prednisone for [Mr A] given that he was an insulin dependant diabetic?

Not in this circumstance. Prednisone, especially in doses such as 20mg per day (the starting dose for [Mr A]) would be expected to have an adverse effect on diabetes control, and special attention should be given to managing diabetes in this situation.

Possibilities would be more frequent testing of blood sugar, a background of twice daily long acting insulin, and 4 times daily short acting insulin with meals and supper. This would be best arranged by a diabetic physician, or as an impatient. In fact, [Mr A's] diabetes did worsen while he was on prednisone, showing blood sugars in the 20s.

I think it is inappropriate to give prednisone as a treatment challenge, without a specific diagnosis, because then one may lose one's chance for a clear picture to be seen by a specialist, and for a clear response to be shown on biopsy.

Also one is reluctant to give prednisone in the presence of infection, especially in an ischaemic, neuropathic diabetic foot, and if there is poor diabetic control, because prednisone will further suppress the immune response to infection.

In his referral letter to the dermatologist dated 16 October 2002, [Dr C] stated: 'His Prednisone dose was 20mgms per day for one week from 4/10/02, reducing by 5mgms per week. I prescribed this reluctantly as he is diabetic on insulin, *but his legs were a mess.*' [Italics mine.]

In my opinion this is not a sufficient reason for prescribing prednisone, for the reasons given above. In complicated situations like this a specialist should be contacted first. Specialist or specialist registrar opinions can always be obtained if necessary, or else the patient can be admitted to hospital.

In her letter about [Mr A's] outpatient assessment on 23 October 2002, the dermatologist stated 'This could well be pemphigoid or another autoimmune disease. It is difficult to assess at present because he has significantly improved on the Prednisone. There would be no point in doing a biopsy today as the Prednisone would have wiped out any immunoreactants.' This confirms my comments about the non-advisability of prescribing trials of prednisone in an undiagnosed patient.

The dermatologist concluded: 'I have therefore suggested that he stop the Prednisone (he is about due to anyway) and we will review him in two weeks time. … If this is something like pemphigoid then he would probably be better controlled on a tetracycline than long term Prednisone given his insulin controlled diabetes. Once I see him in a fortnight, I'll take a biopsy *if required* and start treatment as appropriate.' [italics mine]

After talking by phone to the dermatologist on 4 November 2002, [Dr C] performed the biopsy himself on 5 November 2002. In my opinion this was most unwise. Taking a biopsy in a neuropathic, ischaemic, infected leg of a diabetic who has recently been on prednisone poses a great risk.

The Guidelines on Diabetes Management in General Practice specifically state 'If vascular disease exists, surgical intervention on the foot can result in poor healing, ulceration, and at worst, gangrene. Such procedures should be carried out by practitioners used to working with people who have diabetes' (see page 6 of this report, and appendix 3 page 50).

7 Should action have been taken earlier in relation to the Doppler ultrasound reports reported by the district nurses in August 2002, which showed an arterial problem?

Yes. On 22 August 2002 the district nurse reported to [Dr C] that [Mr A] had arterial problems, and suggested referral to a vascular surgeon. This was recorded in the case notes, but was not actioned.

[Dr C] mentioned '?sympathectomy', although the armamentarium of the vascular surgeon is much wider that this, and this particular procedure would probably not have been appropriate in [Mr A's] case.

I think that [Dr C] should have definitely reassessed his management, and decided to act on this important piece of advice passed on by the District Nurse.

8 Were referrals to specialists appropriate and timely? In particular please comment on the timeliness of the vascular referral

No. Interestingly, [Mr A] was seen by a consultant general and vascular surgeon two years earlier on 8 July 2000 (document labelled 018). [Mr A] had no rest pain then. His Doppler pressures were good, but he had some absent foot pulses.

The surgeon commented in his letter 'I suspect he has some minor distal vascular disease and associated neuropathy. At this stage however I have recommended he continue with regular exercise and also wears warm socks to keep his feet warm. I have not made arrangements for further review but would be happy to do so should his situation change.'

[Mr A's] situation had dramatically changed by April 2002, at the beginning of the situation under discussion. [Mr A] had developed rest pain, and his foot pulses were not palpable. A case could be made for vascular referral before or at this time.

A clinical suspicion of osteomyelitis, marked arterial vessel calcification on a foot X-Ray, redness and pain of his ankle area, and a rapidly developing ulcer followed by cellulitis would definitely tip the balance toward referral.

In my opinion, [Dr C] should probably have decided on the need for a vascular surgeon's opinion well before [Mr A] was seen by the District Nurses and the specialist nurses.

I think referral to a diabetes specialist should have been made at the onset of [Mr A's] foot and leg problems, especially in view of his poor diabetic control.

I would in the first instance refer to these two specialists, but would also consider a dermatology referral once [Mr A's] legs had blistered and developed serous exudates. This would be especially so if prompted by a wound control specialist nurse.

In this situation I would not start steroid treatment before the patient had been seen by a specialist of any kind, and not unless it was recommended by the specialist, and arrangements were made for careful diabetic control.

9 Were [Dr C's] responses to concerns communicated by the district nurses appropriate and timely?

No. On 22 August 2002 the District Nurse reported to [Dr C] that [Mr A] had arterial problems, and suggested referral to a vascular surgeon. I think that when the District Nurse passed on her concerns, and given their severity, [Dr C] should have acted on them immediately, and made a referral to a vascular surgeon.

The District Nurse also reported further deterioration to [Dr C's] practice on 22 September 2002, 30 October 2002 and 1 November 2002, but again no referral was made.

A vascular surgical referral was still not arranged when it was later recommended by a wound specialist nurse on [12] September 2002, and by a diabetes nurse on 4 December 2002.

I think each of these contacts should have triggered [Dr C] to rethink the severity of the situation, and to act appropriately, including making a referral to a vascular surgeon.

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

Yes. I don't think [Dr C] understood the necessity of specialist management in ischaemic, neuropathic diabetic feet and legs.

I don't think he understood the seriousness of leg ulcers and cellulitis in diabetic patients.

When he was tactfully given prompts by the District Nurses to rethink his diagnosis and management, he did not follow up on this useful advice.

Opinion

Between April and December 2002 general practitioner [Dr C] did not provide services of an appropriate standard to [Mr A] in relation to the deterioration of a varicose ulcer on his right leg. In particular, [Dr C]:

– did not adequately consider the increased risk of harm to [Mr A] in view of his history of diabetes

In my opinion, [Dr C] did not adequately consider the increased risk of harm to [Mr A] in view of his long term diabetes. These risks included ischaemia and neuropathic changes. They would put [Mr A] more at risk from ulcers and cellulitis, and lead to delayed healing.

In my opinion, diabetes should be treated aggressively in the presence of infection and ulcers, so that there is the maximum chance that these can be brought under control. Similarly, the leg conditions should be treated aggressively, both so that the diabetes can be more readily controlled, and also so that the limb may have maximum chance of survival.

– did not provide appropriate clinical management/intervention to [Mr A] despite evident deterioration and concerns expressed by the district nurse.

In my opinion, [Dr C] should have arranged specialist referral for [Mr A]. This would be to a vascular surgeon and/or a diabetes specialist. (It is likely that each one would refer to the other.)

He was prompted on a number of occasions by the district nurse, but did not alter his management and intervention despite evident deterioration of the patient.

Nomenclature of Diabetes

Diabetes mellitus is no longer divided into insulin requiring diabetes (IDDM) or Juvenile Onset Diabetes, and non-insulin requiring (NIDDM) or Maturity Onset Diabetes.

Differentiation is based on age, rate of clinical onset, body weight, family history and urinary ketones.

The following explanation is from Diabetes In General Practice (appendix 3, page 6):

Once a diagnosis is made it is important to determine the type of diabetes. Usually there is clear clinical evidence and differentiation is easy.

Type 1
Young (generally), rapid onset, ketosis prone, insulin deficient, recent weight loss.

Type 2
Middle aged (generally), slow onset, not prone to ketosis, insulin resistant, overweight, strong family history.

At present there are no practical specific markers for either group. While type 1 diabetes occurs in the young it is by no means confined to that group. Similarly while many people with type 2 diabetes are overweight, some are a normal weight. In fact, most overweight people do not develop diabetes. ...

Someone treated with insulin does not necessarily have type 1 diabetes. In fact, if insulin is started several years after diagnosis, it is likely that the person has type 2 diabetes.

[Mr A] has type 2 diabetes.

Conflict of Interest Statement

I do not know [Mr A] or [Dr C], or anyone involved in this case.

I note from reading [Mr A's] hospital case notes that he is a participant in the FIELD (Fenofibrate Intervention and Event Lowering in Diabetes) study. This is a study based at the Clinical Trials Centre at the University of Sydney, and involving participants from Australia, New Zealand and Finland. (See Appendix 5)

The Lipid and Diabetes Research Unit in Christchurch is one of the centres involved. Two members of the Group are on the Management Committee, including one who is a Monitor for other centres in New Zealand.

I am not involved at all in the Field study, and have not seen any raw data from the study. The patients are followed up by their general practitioners, and I have no clinical or research contact with any participants in the study.

I do not consider myself to have any personal or professional conflict in this case.

List of Appendices

1. Curriculum Vitae. Dr Wendy Isbell, 2004.
2. Management of Type 2 Diabetes, Chapter on Diabetic Foot Disease, pages 67-73. Evidence-Based Best Practice Guidelines. Ministry of Health and New Zealand Guidelines Group, December 2003.
3. Diabetes Management in General Practice, Section on Foot Problems, pages 61-2, What Type pf Diabetes, page 6. Diabetes Australia and The Royal Australian College of General Practitioners, 2003/4.
4. Hospital Referral and Management Guidelines, A Guide for Canterbury General Practitioners, Section on Diabetes, pages 6-7, and Section on Arterial Vascular Disease, page 5. Canterbury District Health Board, April 2003.
5. The FIELD Study (Fenofibrate Intervention and Event Lowering in Diabetes). An International Study into Diabetes and Heart Disease. Pamphlet, endorsed by Diabetes Australia and Diabetes New Zealand, undated.

Response to Provisional Opinion

Dr C

Dr C made the following submissions in response to my provisional opinion:

> "Referral to a vascular surgeon or diabetic specialist would not have prevented his Bullous Pemphigoid disease nor altered its treatment. I note the expert opinion dismissed the diagnosis and significance of [Mr A's] Bullous Pemphigoid ('not enough evidence') despite the opinion of a GP, 3 Pathologists and a Dermatologist, (and the patient himself). As the Bullous Pemphigoid was difficult to control, so too was his diabetes; insulin increase was necessary and advised by me (and the diabetic nurse) but [Mr A] was at risk of hypoglycaemia also (even when on Prednisolone, when the Bullous Pemphigoid settled)."

Dr Kerr

Dr C provided a report from Dr David Kerr, general practitioner, in response to my provisional opinion. Dr Kerr stated:

"**Dr Wendy Isbell**:

Dr. Isbell has provided advice and it is of concern that her advice seems to be almost entirely the basis for the Health & Disability Commissioner's comments.

Dr. Isbell is not a typical General Practitioner, as evidenced by her extensive homeopathic practice and her Specialist clinic practice and her holding of the Degrees of MRCP FRACP. These are the qualifications of a physician and not a General Practitioner. In addition, her decade as a consultant physician at the Princess Margaret Hospital makes her knowledge base substantially different from that of a General Practitioner.

I have no difficulty with the guidelines that she has identified and I gather that pp.11 & 12 are copies from the Guidelines. In terms of the Ministry of Health Guidelines, it is recommended that if cellulitis is present hospitalisation is necessary. This, in its absolute terms, is an inflexible statement and usual practice would be that a general practitioner would be more cautious in managing any ulcer in the presence of diabetes and even more significantly cautious if there were any signs of cellulitis. If the cellulitis were limited in extent it would be reasonable to treat with antibiotics while observing progress. Dr. Isbell comments about the availability of parenteral or injected antibiotics in the community, but this is unusual to have access to such therapy, although it is available in Christchurch City.

Peripheral Vascular Disease:

The presence of peripheral vascular disease was already recognised by [Dr C] on the basis of the absent foot pulses. The patient had good popliteal pulses, which means that there was good circulation to the arteries behind the knees. The presence of calcification on the X-ray of the ankle is of relatively passing interest only, as is the outcome of any Doppler investigation. The Doppler investigation is a way of quantifying flow of blood in a more accurate means than assessment of pulses.

I understand that [Dr C] was not suspecting the presence of osteomyelitis and as a consequence the commentary of Dr Isbell relating to a bone scan would not seem to me to be relevant. Instead, I understand that [Dr C] was looking to exclude any possible bone fragment or bone damage in the vicinity of the affected area of skin. The Doppler investigation, as mentioned above, is of interest, but a clinician will always be guided most strongly by clinical findings, and the clinical findings in this patient were the absence of foot pulses.

Chest X-ray – 23rd July 2002:

The use of a chest x-ray to exclude heart failure was perfectly reasonable, given that the patient had a history of both ischaemic heart disease and peripheral vascular disease. A silent myocardial infarction could have induced heart failure, then fluid overload and peripheral oedema.

Any patient whose feet are frequently in a dependent position [hanging down], and who is not walking around, is always at risk of oedema, even without the presence of local pathology. In other words local pathology is not the only cause of oedema, e.g. immobility, poor venous or return circulation, dependent position, and poor nutrition.

Locum Consultations:

Locums assessed this patient on three occasions over two weeks. No reference was made to cellulitis being present and on 03.09.02 the wound was described as 'clean'. There is also a note that there is no cellulitis present or inflammation. These case notes are really an endorsement of the care provided to that time.

Nursing Inputs:

1. Considerable emphasis is placed on these inputs by both the Health & Disability Commissioner and the Reviewer.

   The first notable input was on 22.08.04. This note was clearly made by someone other than [Dr C], as evidenced by the handwriting. It comments that:

   > 'Doppler showed arterial problems. They are doing further tests and will get back to us. ? for referral to vascular surgeon'

The GP Reviewer interprets this as 'suggesting' a referral. This is not the same, and clearly one would be anticipating further information as a result of this file entry. I understand that [Dr C's] note of '? Sympathectomy OP' was made on 22.08.02, and this would also lend credence to the thought that [Dr C] was awaiting further advice. The comment '? Sympathectomy OP' was his thought on what may be required for the patient, but he was awaiting the 'further tests'.

2. The General Practitioner Reviewer comments that the wound specialist nurse recommended vascular surgical opinion on 09.09.02. I see the referral dated on 07.09.02 for 'ulcer dressings', but I see no reference to vascular surgical opinion.

3. The Diabetes Clinic initiated a vascular review on 06.12.02. This was presumably by the Diabetes Clinic nurse and such nursing staff have very high skill levels, and would be aware of dangerous diabetic situations. They also have ready access to specialist advice. It is of interest that the referral was not initiated until 06.12.02, despite the diabetes nurse having input prior to July 2002, as evidenced by [Dr C's] notes.

4. Diabetes nurse comments 04.12.02.

   This was a phone call, clearly not taken by [Dr C], as evidenced by the case notes. The comment is '? for referral'. There is a comment as a post-script question asking about whether the patient 'has been reviewed by a skin specialist and vascular surgeon – what was outcome'. The file entry in [Dr C's] case notes of 04.12.02 is not by himself and there is separate reference on the referral from the diabetes nurse, dated possibly 06.12.02, where the post-script is entered. This was clearly not received until 11.12.02 where [Dr C's] advice that the patient has been admitted to [the Public Hospital] is noted.

The essence is that the diabetes nurse did not drive referral and one presumes that this was because of relatively low levels of concern.

Other Medical/Surgical lnputs:

In the face of what has been described as a 'critical situation' the patient was admitted to hospital and no doubt seen by a trainee intern, house surgeon, registrar, and possibly consultant orthopaedic surgeon. This was at the time of his shoulder surgery. None of these practitioners felt that immediate admission was appropriate for his diabetes and lower limb status.

He was also seen by [Dr F] and [Dr G], and by the consultant dermatologist on two occasions. The same observation applies to these practitioners.

[Dr G] makes reference in his case notes to vascular insufficiency and that he would discuss the situation with [Dr C]. I understand this did not take place, and would therefore construe that [Dr G] did not have a particularly high level of concern as to the degree of vascular insufficiency.

Bullous Pemphigoid is a benign condition seen in older people. One of the differential diagnoses is of Pemphigus and biopsy is one of the only ways to differentiate these, the latter condition being much more serious. Treatment of both conditions will usually involve the administration of Prednisone in high dose and the usual mechanism for differentiation of the conditions is biopsy.

With regard to the biopsy that was done, according to the case notes, it was on the posterior aspect of the calf. This is not traditionally an area where circulatory function is critical. The popliteal pulses were palpable and this is not in dispute and so one would anticipate reasonable blood flow to the site of biopsy.

In the context of clarifying the diagnosis I believe it was a reasonable decision. In this era of punch biopsies the wound is very small and such procedures are undertaken not infrequently in General Practice.

[Dr C] was very aware of the implications of the fragile state of his patient and the implications of steroids, and this is clearly evident in his referral letter.

It is of interest that the patient was referred to the Dermatology Department on 13.09.02 by [Dr F], a follow-up letter was sent on 16.10.02, and the patient was seen on 23.10.02. This is a delay of nearly six weeks between referral and assessment. [Dr C] covered this public hospital system inadequacy by writing again and by advising that he felt he needed to initiate therapy.

Dr. Isbell 'doubts the diagnosis of Pemphigoid'. I would suggest the diagnosis is highly likely and her comments at best are unhelpful in making such a statement.

Ulcer:

There seems uncertainty in Dr. Isbell's report with regard to the location of the wound that is often discussed.

In her 'Factual Summary' on 15.07.02, she notes the right medial malleolus [inside of ankle] – and yet the case notes refer to the right lateral malleolus [outside ankle].

In her 'Opinion' on p. 19 she describes it as a 'varicose ulcer on his right leg'. This is a very specific type of ulcer that is not mentioned as far as I could see.

Review of the hospital notes at the time of his having surgery identify that he actually had a necrotic area on the plantar surface [sole] of the right foot and that he had a gangrenous right toe.

Some clarification of the relevance of these different sites might be helpful.

I hope these comments are of assistance in preparing a response on behalf of [Dr C]."

Further independent advice

Dr Isbell provided the following further advice in response to additional questions and Dr Kerr's opinion dated 6 August 2004.

"In my Advice on this case, I drew conclusions from the material provided to me. The content of the District Nurse notes were a factor I considered when making my comments that Dr Kerr has questioned in his section on **Nursing Inputs.**

I would like to make four points of clarification:

1 The wound care nurse rang [Dr C's] practice on 12 September 2002, not 9 September 2002, as mentioned in my report.
2 The ulcer was over the right lateral malleolus, not the medial malleolus. This was mentioned in [Dr C's] case notes on 15 July 2002. I apologise for this minor error in my report, but it does not alter my opinion or advice.
3 The references to 'varicose ulcer on his right leg' are a direct quote from the Complaint. I may have not made this clear in my report.
4 Necrotic and gangrenous areas on the foot are entirely consistent with complications in a neuropathic diabetic foot."

Code of Health and Disability Services Consumers' Rights

The following Right in the Code of Health and Disability Services Consumers' Rights is 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.

Opinion: No Breach – Dr C

Complaint
Under Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code) patients are entitled to services provided with reasonable care and skill.

Mr B's complaint centres on the care Dr C provided to his father (Mr A) for a persistent leg condition between April and December 2002 and alleges that as his father was a diabetic, he should have been treated with more care. Mr B has also expressed concern that Dr C did not follow up issues raised by the district nurses who were caring for his father. Mr A's son believes that if appropriate treatment had been provided earlier, his father may not have had his leg amputated.

History
Mr A first described pain and inflammation in his right ankle at his consultation with Dr C on 26 April 2002. At his next consultation on 15 July 2002 Mr A complained of rest pain. The rest pain continued and Mr A developed an ulcer on his right ankle, and oedema, erythema, crusting and blistering lesions on both legs. Mr A's blood sugar levels over this period also indicated that his diabetes was difficult to control. At various times he was seen by district nurses, a diabetic nurse, a wound care specialist nurse, and a dermatologist – but not by a vascular surgeon (as he had been in July 2000).

On 9 December Mr A was admitted to the Public Hospital with erythema, tissue ooze and bullae. His clinical situation deteriorated and he was transferred to another Public Hospital and underwent a right below-knee amputation on 31 December 2002.

Dr C stated:

> "At all times I was duly cognizant of the fact that diabetes increased the risk of progression of the condition of his legs and would reduce the rate of healing. It is for this reason that we kept [Mr A] under close scrutiny during this time. When it was apparent that vascularity was compromised, the appropriate referral was made."

Specialist referral
My independent advisor, Dr Isbell, considered that Dr C should have arranged a referral to a vascular surgeon and/or a diabetes specialist for Mr A as early as July 2002. By that time there were a number of important indicators suggesting Mr A had a serious condition warranting referral to a specialist and/or to hospital. They included rest pain, which is suggestive of serious arterial insufficiency; arterial calcification, an alert to the presence of severe peripheral vascular disease; pitting oedema, which in the absence of fluid overload is suggestive of significant local pathology; and cellulitus, which is of serious concern in an uncontrolled diabetic. Dr Isbell considered that Dr C should have made an immediate referral to a vascular surgeon when the district nurses raised concerns in late August 2002.

Summary
Dr Kerr, a general practitioner, made submissions on behalf of Dr C and criticised Dr Isbell's advice as coloured by her specialist background as a consultant physician and as setting an unrealistically high standard that is not reflective of general practice.

Dr Kerr suggested that Dr Isbell had over-interpreted the suggestion from the district nurse in August 2002, "? For referral to vascular surgeon", pointing out that further tests were awaited. Dr Kerr noted that the diabetic nurse did not suggest vascular review until December 2002, and that none of the other medical practitioners (Dr C's locum, the dermatologist, and medical staff at the Public Hospital during Mr A's admission for shoulder surgery in September 2002) showed particular concern about Mr A's lack of diabetic control and vascular insufficiency.

Dr Isbell was unpersuaded by Dr Kerr's advice, and maintained her opinion that earlier specialist referral was warranted. The vascular surgeon who advised ACC, considered that "it would have been appropriate to refer [Mr A] for vascular assessment given his non-healing and pain in August". However, the vascular surgeon found no evidence of a failure by Dr C to observe a standard of care and skill to be expected in the circumstances. The vascular surgeon noted that, sadly, amputation is a common end result of diabetes.

In the face of this conflicting advice, it would be unreasonable to find Dr C in breach of his duty of reasonable care and skill (under the Code). However, I do not find Dr Kerr's submissions entirely convincing. The fact that "[Dr C] was very aware of the implications of the fragile state of his patient" does not establish that he responded adequately. Nor does the fact that other health professionals exhibited "relatively low levels of concern". This misses the point that Dr C , as Mr A's long-standing general practitioner, was the health professional best placed to oversee and co-ordinate his care. Dr C was on notice (from the district nurses) that a referral to a vascular surgeon might be indicated. In my view, any competent general practitioner should be especially vigilant in light of the risk of infection and tissue destruction, leading to leg amputation, in a diabetic patient with peripheral vascular disease.

If Dr Isbell's advice is too 'gold standard' and exceeds the accepted practice standards for general practitioners in New Zealand, that suggests the need for further education, particularly in light of the current diabetes epidemic.

In summary, despite my misgivings about aspects of Dr C's care, I find that he did not breach the Code.

Follow-up actions

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

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