Consultant Obstetrician/Gynaecologist, Dr B / Obstetrician/Gynaecologist, Dr C / Dr D / A Public Hospital

A Report by the

Health and Disability Commissioner

(Case 00HDC08633)

HDC
Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Complaint

The Commissioner received a complaint from the consumer, Mrs A, about the treatment she received from the providers, Dr B, Dr C, Dr D and a public hospital. The complaint is that:

- *Mrs A is concerned that delays by the public hospital in diagnosing and treating her ectopic pregnancy made it impossible for her to conceive.*
- *Mrs A seeks reimbursement of her expenses over the last two years as well as the costs of any future IVF treatment.*

Investigation process

The complaint was received on 28 August 2000 and an investigation was commenced on 12 September 2000. Information was obtained from:

Mrs A	Consumer
Dr B	Provider / Consultant Obstetrician/Gynaecologist
Dr C	Provider / Obstetrician/Gynaecologist
Dr D	Provider / Senior House Officer
Dr G	Clinical Director, Department of Gynaecology at the public hospital

Relevant clinical records from the public hospital's fertility service, Dr E and an Accident and Medical Centre were obtained and reviewed. Expert advice was obtained from Dr David Cook, an independent obstetrician/gynaecologist.

Information gathered during investigation

On 4 March 1997 Mrs A consulted Dr F, a GP registrar at a medical centre, because she thought she was having a miscarriage. Dr F performed a pregnancy test, which was positive. He referred her to the Gynaecology Department of the public hospital. Dr F's referral letter stated:

> "Dear Doctor
>
> Diagnosis: Inevitable M/C [miscarriage]
>
> Thanks for seeing this 37 year old, LMP [last menstrual period] uncertain ? [query] mid February who has a positive pregnancy test today and has had 6/7 [6 days] of dark PV [vaginal] bleeding – with associated painful abdomen. Currently the pain is mild – dull ache, not sided. Associated nausea and emotional lability.
>
> PHx [previous history]: 2 x TOP [terminations of pregnancy] – 1982
> Cervical dilation as teenager.
> Last smear one year ago – normal.

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No cyclical problems.

Surg/Medical: chronic pain syndrome
Cholecystectomy 10 years ago

Medications:
Surgam – pm
Codeine phosphate pm
Stemetil 10mg pm
No allergies known.

OE [on examination]: BP [blood pressure] 130/70 HR [heart rate] 75 regular

Abdomen: dull ache.
Vaginal exam deferred.
Pregnancy test positive.

Thanks for seeing this woman for further care."

First admission to the public hospital – 4 March 1997
Dr D, senior house officer, assessed Mrs A on her arrival at the public hospital. She advised me:

"On examination [Mrs A] was afebrile and her observations stable. Her abdomen was soft with some mild tenderness. There was a brownish discharge in the vagina and no adnexal masses were palpable. Following my examination I ordered initial investigations of a full blood count, a blood group and hold and a repeat urinary pregnancy test. This pregnancy test returned as a negative result.

Since this was my first week working in this department I was unaware of the exact procedures and protocols in the department therefore I made no clinical decisions without deferring to a more senior doctor in the department. I discussed my findings with [Dr B], the on call consultant who also saw [Mrs A] soon after I did and advised that a D&C should be performed."

Dr D's clinical notes recorded:

"Referred as a case of miscarriage 16-20 Feb heavy vaginal bleeding and terrible pain that woke this patient up from 20-26 Feb there was little pain on 26 till now. Having brownish discharge. Pregnancy test done today was positive. Now having mild pain and spotting. Ultrasound not done.

Obstetric history: G3 P0 with 2 terminations.
1. 1982 Clinic in […]
2. Before 1982 clinic in […].

Now having twinges and dark spotting.

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Gynaecological history: dilatation of cervix at 16 years of age.
Medical: None of significance.

Surgery: Cholecystectomy 10 years ago
Allergies: Nil
Social: smoker and drinker – living with a flatmate.

On Examination: Afebrile [without fever].
Abdomen soft
Vaginal Examination: mild tenderness
No adenexal masses.
Brownish discharge of examining finger.

Investigation:
- CBC
- Blood group to hold
- Consent
- Theatre booking."

Dr B, the on-call consultant obstetrician/gynaecologist, examined Mrs A at 7.50pm on 4 March 1997. He performed an EUA D&C (examination under anaesthetic dilatation and curettage) that evening. His clinical notes recorded:

"EUA D&C

Old blood ++
Cx firmish – easily dilated
Uterus bulky (10mm cavity)
- firm –
- Fornices clear
- Minimal curettings.

May possibly be ectopic. Keep overnight. Ultrasound in morning if persisting pain. Recheck BhCG in morning."

Dr B advised me:

"The [clinical] notes clearly state that I considered the history of her gynaecological problem, I examined her, I performed an EUA D&C and I commented at that time of the possibility of an ectopic pregnancy and suggested appropriate further investigation and management."

Mrs A advised me:

"I was admitted overnight and in the morning the pain had lessened. I was told not to go to the toilet as I was to have an ultrasound scan and it would be better if my bladder were full. By lunchtime I told the nurse I had to go to the toilet, as I couldn't hold on any longer. After this I was told that there would not be a scan done and I was going to

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> be discharged. An appointment would be made in a week's time for a follow-up, that they would contact me about. If any pain or bleeding occurred during this week, I should contact them."

Clinical notes dated 5 March 1997 recorded that, on examination, Mrs A experienced "lower abdominal tenderness on light palpation [touch]". The differential diagnoses were incomplete miscarriage and ectopic pregnancy.

The plan was for Mrs A to undergo a repeat pregnancy test. The pregnancy test, which was performed that day, returned a result of 295 U/L (which is, according to my expert advisor, a very low level of BhCG (blood pregnancy hormone), and which was reported as a negative pregnancy test in the discharge summary on 5 March 1997.

Dr D discharged Mrs A on the afternoon of 5 March 1997 with an instruction to return immediately if there was any further pain or bleeding. No ultrasound examination was performed prior to discharge. Dr D recorded in the discharge form that Mrs A was to return for a repeat BhCG in one week's time. It was also recorded that she would have her stitches removed at a second medical centre on Sunday 30 March 1997.

Uterine curette results

The histology on the uterine curette (performed the previous evening), dated 5 March 1997, reported:

> "…
> There is no definitive evidence of gestation, current or recent, in the present material. Elevated hCG is not explained by the curettings, and the possibility of early extrauterine gestation is considered.
>
> Mid-secretory phase endometrium. No definitive evidence of gestation."

Dr B was asked when he saw the histology report and whether this altered his clinical management. He advised:

> "I first saw the histology report on the uterine curette, dated 5 March 1997, at the time I wrote my report to you following the complaint [19 October 2000]. The Registrars have the responsibility of checking the histology and they are expected to refer any unusual reports to the consultant concerned."

Dr D viewed the histology report. She advised:

> "I cannot recall whether I notified a senior colleague of this result, but this is highly likely to have occurred due to my practice at that time. It is also possible that I may not have even seen this result until about the time of Mrs [A's] second admission [on 25 March 1997] as it was not uncommon for results to take this long to be seen by the clinical team. This histology report was consistent with [Dr B's] intraoperative findings and no new arrangements were required since Mrs [A] had been instructed to return in one week's time for a repeat blood test."

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Dr D subsequently advised me:

> "As [Dr B] was only a visiting consultant at the time it was possible that he was not the person that I consulted as he may not have been present at the time that the result became available. But it would be very surprising to me if any of the seniors would recall specifically seeing [Mrs A's] result at this time given the number of results that were viewed each day at that time and subsequently.
>
> I would add that despite this result on the histology it would not have changed the management of [Mrs A] who had been informed to return in one week's time. It is likely that if I signed the report during the week following the admission, the advice received from whoever I consulted would have been in the context of knowing that this plan had been arranged.
>
> I apologise for being unable to provide specific answers in relation to the signing and viewing of the histology report but it is not possible to remember such specifics four years after the event. I find it surprising that [Dr B] can seem to recall this matter clearly for the same reason, but as stated earlier it is possible that he was not the senior colleague that I consulted."

Dr G, Clinical Director, Department of Gynaecology of the public hospital, advised me:

> "All histology is reviewed and signed by the Registrar and where appropriate the named Consultant is notified. The patient is recalled as required for further diagnostic procedures or treatment. This applies to all abnormal histology.
>
> This is the process for histology management now and would have been the process followed in 1997. However, in light of recent events, we are reviewing our histology follow-up protocols and in particular who signs these off."

Abdominal pain returns
Mrs A consulted Dr H, her general practitioner at the Accident and Medical Centre, on 6 March 1997 because she had a swelling on her face/neck. Dr H diagnosed an infection and prescribed antibiotics. He requested a review in one day's time. His clinical notes recorded:

> "1. In [the public hospital] past 3/7 [three days] had a miscarriage (went to [the public hospital] after 6/7 [six days] of PV [vaginal] bleeding. Is having an ultrasound in 1/52 [one week].
>
> 2. Has a swelling left side of face/neck past 1/52. Started as a small lump (submandibular) now ↑ swelling up to just below left ear."

As requested, Mrs A returned to see Dr H the following day, 7 March 1997. He recorded that the swelling in her neck had reduced and that he would review her again if necessary. He also recorded:

> "…

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2. Developed central lower abdominal pain, awaiting ultrasound to rule out ectopic
Plan: dipstick urine.

HCG +ve – recent miscarriage. Dipstick – blood

→ MSU [mid-stream urine]
→ Discuss with [Mrs A]. To contact [the public hospital] to rule out ectopic (may need urgent ultrasound)."

Mrs A advised that on Friday 7 March 1997 her abdominal pain again became severe. She said that when she saw Dr H that day, on an unrelated matter, she discussed the pain with him and he advised her to contact the hospital. Mrs A said:

"I rang the hospital mid afternoon and talked to a nurse in the Gynaecology Dept. I was very clear about the events of the week and that I had been told to ring if I was in any more pain. I told her that I was in pain and that it was as if my body was trying to bleed but there was nothing to bleed. She spoke with a doctor and then told me, I quote, 'women have miscarriages all the time and half of them don't realise it.' She said that I was probably fine, but an appointment would be made for me that day if I really thought it was necessary.

I was stunned by what she said and how she said it. She made me feel that I was over-reacting and wasting their time, so I declined the appointment. I was exhausted, ill and in pain. I couldn't face going all the way from […] to the hospital when nobody thought there was anything wrong with me. I just wanted to sleep. I suffer from chronic pain syndrome and thought I was just feeling more pain than other people, so decided to wait […] for the appointment from the hospital the following week."

On 8 March 1997 the report on the mid-stream urine sample requested by Dr H on 7 March recorded "no significant growth".

Mrs A consulted Dr H on 12 March 1997 in relation to her ongoing pain. Dr H's clinical notes recorded:

"Had D&C for TOP/miscarriage 5/3/97. Has had ongoing problems with pain and vaginal discharge since then. 1/7 [one week] ago passed dark/black blood. Has not had an ultrasound as yet.

Plan: arrange ultrasound. For review."

Mrs A underwent an ultrasound scan at a radiology. The radiology report dated 12 March 1997 reported:

"Obstetric Ultrasound 12 March 1997

Indications: Persisting bleeding following evacuation of incomplete miscarriage 1 week ago at [the public hospital]. Pain in the left iliac fossa.

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Findings: The uterus lies anteverted in the midline and is empty. It measures 9.6 x 4.0 x 5.0cm. Endometrial complex measures 9-11mm in thickness, with no sign of a gestational sac or retained products. The ovaries are bulky (right 16ml, left 15ml), with the right ovary including a 20mm folicle. The right ovary lies normally in the adnexa, while the left is tucked behind the uterus.

There is no fluid in the pelvis and there is no hydronephrosis [obstruction to the free flow of urine from the kidney, causing distension and enlargement of the renal pelvis].

Tenderness in the left iliac fossa [concave depression on the inside of the pelvis] was maximal over the descending colon.

Comment: No sign of retained products of conception and no cause of pain has been found.

NOTE: one of the hard copy films was lost due to a technical fault."

Mrs A saw Dr H on 14 March 1997 for the results of the ultrasound scan. She said he told her that her left fallopian tube was behind her left ovary but that there were no signs of anything abnormal.

Dr H's clinical notes dated 14 March 1997 recorded:

"Ultrasound revealed no retained products or ectopic pregnancy.

Pain has decreased since passing BM [bowel motion] (? constipated). Review in the next 1/52 [week] if no improvement.

For FBC [full blood count] today."

Following this appointment Mrs A left the city to look after her ill father. She advised me that, although she still felt very unwell, she believed she must be overreacting. However, by 20 March 1997 Mrs A was feeling worse and sought medical assistance from Dr E at the medical centre. She explained the appointment on 20 March as follows:

"By now I was very ill, felt faint all the time and in so much pain that I could hardly walk. I went to see [Dr E] at [the medical centre]. She examined me and sent me for tests saying she thought I had an infection in my uterus. She gave me antibiotics and made a follow-up appointment for me the following Tuesday (I think Monday was a public holiday)."

Clinical notes record that Mrs A consulted Dr E on Friday 21 March 1997. Dr E noted:

"Had D&C on 4/3/97. Had USS on 14/3/97 – normal. Still very light PV bleeding.

O: abdomen medium tender. No rebound/guarding.
PV uterus very tender.
CX: exutation +ve

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Adnexae a. acute endometritis
Post D&C

Plan: check BhCG
Augmentin 1 tds [three times daily] 30
Doxycycline 1 BD [twice daily] 20

Review 5 days."

Mrs A described her condition on Tuesday 25 March 1997:

"I was still worse. I had been living on painkillers and laxatives. I had to get cold wet flannels, put them on my neck and forehead and lean against the wall of the toilet to stop me passing out. I now thought I must have bowel cancer. My glands were so swollen and I had so much swelling in my neck that I looked like I had the mumps. Again I went and saw [Dr E]. I was hysterical and told her I was physically, mentally and emotionally in crisis. I begged her for help. My father's health had been deteriorating and I was finding it very hard to look after him.

The test results again showed a positive pregnancy and again I was sent immediately back to [the public hospital]."

Dr E's clinical notes for that date recorded:

"Emotionally 'a mess' – has been taking antibiotics up till today but now stopped and has low abdominal pain +++ but no temperature. Now bleeding more heavily PV.

Observation: Abdomen tender ++ with rebound/involving guarding."

Dr E referred Mrs A immediately to the public hospital. Her referral letter stated:

"Many thanks for re-assessing [Mrs A] who was discharged on 5/3/97 following D&C for ? inevitable abortion. BhCG on 5/3/97 was 295, it was 537 on 20/3/97.

Seen on 20/3/97 with light PV [vaginal] bleeding (normal USS [ultrasound scan] on 14/3/97) with symptoms of endometritis – very tender uterus, cervical excitation but no adnexal tenderness.

Started on Augmentin and Doxycycline.

Today, pain worse. BHCG up. Heavier PV bleeding.

O/E: LIF [left iliac fossa] pain, rebound ++, involving guarding.

Impression:
? extension PID despite antibiotics
? Partial mole
?? ectopic pregnancy."

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Second admission to the public hospital – 25 March 1997

Mrs A was admitted to the public hospital on 25 March 1997 and an abdominal and pelvic ultrasound was performed. The ultrasound report recorded:

> "Indication: D&C on 5.3.97 for incomplete abortion. Has lower abdominal rebound tenderness and slightly increased BHCG. ? ectopic pregnancy. Approximal gestation by date would be nine and a half weeks.
>
> Findings: Uterus is normal in size with an overall length of 8.6cm. The uterine cavity is empty with no evidence of retained products or gestational sac. The endometrium is normal, reaching a maximum of 7mm. No fluid is evident in the uterine cavity.
>
> Both ovaries are normal in size, shape and position. No adnexal masses are detected. There is a small pool of fluid in the pouch of Douglas.
>
> Comment: Transabdominal and transvaginal scanning have revealed no evidence of pregnancy or hydatidiform mole. The tenderness and small amount of free fluid would be consistent with PID but no complications are detected."

Mrs A saw Dr C, obstetrician/gynaecologist, at 7.00pm on 25 March 1997. Dr C advised:

> "[Mrs A] first came to my attention and care on 25.3.97 having been referred to the gynaecological senior house officer (Dr I) by GP Dr E. … [Dr I] discussed [Mrs A] with me, as specialist on call, at approximately 1800 hours while I was in operating theatre and was seen by me and assessed pre-operatively at 1900hrs.
>
> …
>
> On examination, she was haemodynamically stable. T=36 BP=110/50 P=80/min. She was tender with rebound in the lower abdomen and a diagnosis of ectopic pregnancy was made and appropriate surgery arranged.
>
> [Mrs A] was fully informed regarding her surgery and her wishes to conserve her fallopian tube respected. At operation, she had evidence of extensive old pelvic inflammatory disease with old adhesions and a large ampullary ectopic …"

Dr C's clinical notes recorded:

> "Seen pre-op.
> 9½ weeks pregnant by certain conception date (one x intercourse 31.1.97).
> D&C 3/52 ago 5/3/97 – histology no products of conception.
> Been bleeding ever since, 3 pads/day and had 'awful abdominal pain' not responding to antibiotics. BHCG ↑ 250 → 589 and scan shows an empty uterus and fluid in pouch of Douglas.
>
> Impression: Ectopic pregnancy
> Plan: For laparoscopy and proceed if necessary."

Mrs A said that after she was admitted and the ultrasound scan performed:

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"I was told I might have an infection. Yet again there was great confusion surrounding what exactly was wrong with me. The doctor said they would like to do a laparoscopy so they could 'look inside me' to see what they could find wrong.

I was sent up to [the] Ward to await the procedure. Suddenly a lot of doctors and staff arrived in a flap and said that I was pregnant and that it was ectopic. This was of no surprise to me. I told them it was in my left tube as I had felt it was ectopic weeks before.

My confidence with the hospital at this stage was non-existent. I was terrified they might perform the wrong procedure. The doctor explained what they were going to do and asked me to sign a form, (I think it was a surgical consent form). I insisted that if surgery was necessary, they make every effort to save my tube, as in the future I would like to conceive naturally. Under no circumstances did I want them to do a hysterectomy and made them sign these conditions on the same form."

Mrs A signed a 'consent to surgery/other procedure' form on 25 March 1997 after discussion with Dr I, gynaecological senior house officer. The consent form stated:

"I, [Mrs A] … request that laparoscopy – proceed to laparotomy and whatever else is necessary. ? D&C (please keep incision small) (patient wants children) be performed on me."

Clinical notes at 9.00pm on 25 March 1997 recorded:

"Operation

Diagnostic laparoscopy, minilaparotomy and left salpingostomy.

Findings: Evidence of old PID [pelvic inflammatory disease]
Periovarian adhesions bilaterally
Ovaries otherwise normal
Large left ampullary ectopic adherent omentum
200-300ml old blood in abdomen
Right tube relatively normal

Procedure:

Under GA diagnostic laparoscopy.
Left ectopic in pool of blood and surrounded by adhesions/bound by omentum.
→ minilaparotomy. Adhesions freed up and left salpingostomy."

The histology report on the contents of Mrs A's left fallopian tube, dated 1 April 1997, stated:

"Products of conception consistent with a tubal ectopic gestation."

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Mrs A said that post-operatively she was told that the surgery had been complicated but successful and that they had managed to save her left fallopian tube. She made an uneventful recovery and was discharged home on 28 March 1997.

Dr C advised me:

> "[Mrs A] was seen each day post-operatively by [Dr D] and by myself on 26 March 1997 and 27 March 1997. Her operation was fully explained and she made a good recovery apart from slight initial constipation.
>
> She was advised to go to her GP for removal of her stitches in a week. She informed us that she would go to [another] Accident Medical Centre to have the stitches removed. This conversation with [Mrs A] is fully recorded in the notes and also noted in the discharge summary. She was discharged on antibiotics at my advice (due to her old PID and the risk of a flare up post operatively) and given a script by [Dr D] on 28 March 1997. She was aware of the high risk of ongoing subfertility and risk of another ectopic pregnancy in the future. As it was her wish to conceive again, she was advised to record her period dates carefully and see a specialist immediately if she thought she may be pregnant again.
>
> The notes do not record any further contact with [the public hospital]."

Mrs A subsequently stated:

> "While it was made clear to me regarding high risk of ectopic pregnancies, I feel the full extent of the PID and subfertility was not."

Mrs A advised me:

> "If [the public hospital] had done the appropriate tests and listened to what I said, I would have been correctly diagnosed the first time and the procedure would have been a fairly simple one.
>
> I now feel that I will never recover completely from this treatment, both mentally and physically. It caused unnecessary suffering to both my family and myself. I am the only child living in New Zealand, of older parents, and have been taking care of them for a long time. My mother is 77 and very ill and my father was dying from cancer while I was going through my own suffering. I had to look after him 24 hours a day, but because I was so ill I was unable to be with them when we needed to be together. My father's health deteriorated rapidly when we were apart, but there was nothing I could do, as I was too sick and weak."

Since this episode Mrs A has tried unsuccessfully to conceive. In 1999 Mrs A had a diagnostic laparoscopy, which demonstrated some filmy adhesions but grossly normal fallopian tubes and ovaries. The right tube was patent to dye but the left filled only to the ampulla. Mrs A has had ongoing treatment for sub-fertility.

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Dr C advised me:

"It is my opinion that [Mrs A] developed pelvic inflammatory disease many years prior to her presentation to [the public hospital], resulting in chronic abdominal and pelvic pain. PID damaged her fallopian tubes resulting in a left ectopic pregnancy and subsequent secondary tubal infertility. IVF is the best treatment for most cases of tubal infertility. Unfortunately, publicly funded IVF has been restricted to women under the age of 38 years for at least 10 years and it is to be noted that on her first presentation, [Mrs A] was unfortunately only a few months from her 38th birthday."

Independent advice to Commissioner

The following expert advice was obtained from Dr David Cook, an independent obstetrician/gynaecologist:

"Date: 4/10/94 […]Accident & Medical Clinic:
Crush injury right foot. X-ray normal. No treatment.

Date: 27/11/95 R Quigley, Osteopath:
Painful neck. ? treatment.

Date: 19/2/96 […]Accident & Medical Clinic:
Chronic neck pain. Stopped work. ACC beneficiary. Referred to [Dr J] (Pain Relief Specialist).

Date: 13/3/96 […]Accident & Medical Clinic:
Chronic neck pain. Missed appointment with [Dr J]. Also failed condom and 'morning-after' pill prescribed. Referred to [Dr K] (Orthopaedic Surgeon).

Date: 19/3/96 [Dr K] (Orthopaedic Surgeon):
Known neck injury (whiplash). Limitation of neck movement but no significant x-ray abnormalities. 'Findings suggest a non-organic (i.e. psychological) magnification of her complaints.' Prescribed analgesia. Referred to [Dr L].

Date: 11/4/96 [Dr J] (Pain Relief Specialist):
Limited assessment. Noted 'extreme antagonism towards medical profession'.

Date: 14/5/96 […] Accident & Medical Clinic:
Feeling much improved (? Treatment). Awaiting MRI approved by ACC.

Date: 5/7/96 […] Accident & Medical Clinic:
Attended for medical certificate. Urine culture, hepatitis serology, thyroid function, U&E's, liver function tests, B12 & folate, full blood count investigations all normal. Random sugar slightly elevated.

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Date: 19/7/96 Physiotherapy outpatients:
Initiated exercises for painful neck.

Date: 12/8/96 [Dr L] (Rheumatologist):
Patient has noted that pain is related to stress. Psychological counselling suggested. Also recommended B12 injections.

Date: 22/8/96 […] Accident & Medical Clinic:
Attended for B12 injection. Referral for counselling for childhood sexual abuse. Painful left breast. Referred to [Dr G].

Date: 2/10/96-20/11/96 […] Accident & Medical Clinic:
Sickness benefit approvals.

Date: 20/11/96 [Dr G] (Breast clinic):
No significant breast abnormality found. Mammogram normal.

Date: 27/11/96 [Dr M] (Psychiatrist):
Chronic pain syndrome. Significant stress issues and some problems with intimacy.

Date: 25/2/97 […] Accident & Medical Clinic:
Exacerbation of chronic neck pain. Analgesia & referral to pain clinic.

Comment
The above clinical information is not relevant to the current complaint although it does indicate that [Mrs A] was likely to have a greater than average familiarity with access to and procedures of both primary and secondary health care services.

Date: 4/3/97 […] Health & Medical Centre:
Positive pregnancy test, missed period, bleeding for last 6 days and painful abdomen. Referred to Gynaecology team at [the public hospital].

Date: 4/3/97 ([The public hospital]):
Admitted under care of [Dr B]. History of pain and bleeding noted. Also past history of two terminations of pregnancy. On assessment minor bleeding only and mild tenderness. Uterus slightly bulky and no masses apparent on internal examination.

Haemoglobin 145. Blood group O positive.

Examination under anaesthetic and D&C performed by Dr B 4/3/97 at 1950. Previous clinical findings confirmed and only 'minimal curettings obtained'. Noted: 'May possibly be ectopic. Keep overnight. Ultrasound in morning if persisting pain. BhCG in morning.'

Vital signs satisfactory overnight. Pulse rate 84 bpm and blood pressure 110/55. Minimal blood loss by 0630. Panadol only for pain.

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HX

Date: 5/3/97 ([The public hospital]):
'? Ectopic' BhCG organised. Result = 295. '? awaiting ultrasound' entry by nursing staff. No scan was performed before discharge. [An ultrasound scan result IS ERRONEOUSLY recorded in the case notes for 5/3/97. This was actually performed on 25/3/97.]

At 1415 there was 'no pain and no PV loss'. For review and repeat BhCG in one week. Advised to return if 'pain arises or vaginal bleeding resumes' (documented in notes and discharge summary).

Comment
A positive pregnancy test, vaginal bleeding and mild pain suggests miscarriage as the most likely (most common) diagnosis. [Dr B] adopted the most expedient method of addressing this by performing an EUA and evacuation of the uterus. This assists in making the diagnosis and treating the problem. The finding of only a small amount of material within the uterus suggested the possibility that most of the pregnancy had already been expelled or that the pregnancy was elsewhere (ectopic). [Dr B] clearly considered this diagnosis and recommended further investigation, primarily by assessment of the serum BhCG (blood pregnancy hormone) and ultrasound if ongoing symptoms suggested an ectopic pregnancy. The BhCG was very low at 295 not suggesting an ongoing ectopic pregnancy and since all the symptoms had subsided and the signs were normal, discharge without ultrasound scanning was undertaken. There was a very clear plan for follow-up with repeat BhCG to ensure that this was declining and clear instructions to return if there were problems. This management is entirely acceptable. The next step would be to review the histology result to ensure that placental tissue was present indicating that the pregnancy was located in the uterus rather than elsewhere. (The chances of natural pregnancies occurring in both the uterus and an ectopic site are about 1 in 30,000 thus the presence of placental tissue strongly suggests miscarriage whilst its absence suggests ectopic pregnancy.)

Date: 7/3/97 Lab result:
Uterine curettings mid-secretory phase with no evidence of pregnancy. 'Early extrauterine (ectopic) pregnancy is (viz. Should be) considered.'

Comment
The absence of placental tissue, particularly in the light of [Dr B's] comments following the surgery, would substantially increase the suspicion of an ectopic pregnancy. The report is slightly confusing as it fails to identify any sign of pregnancy either inside or outside the uterus and, but for the positive pregnancy test, might indicate that the bleeding and pain were actually related to menstrual problems rather than pregnancy. A complete miscarriage or an early 'tubal abortion' (where an ectopic, tubal pregnancy is expelled from the fallopian tube into the abdominal cavity) remain possibilities and are suggested by the low BhCG but the possibility of an ongoing ectopic pregnancy should be entertained. The generally accepted practice is for all histology reports to be reviewed by Gynaecology medical staff and to actively follow-up such results ensuring review

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of the patient and usually further investigation (ultrasound scan and/or repeat BhCG). The fact that this histology report explicitly alerted to the possibility of ectopic pregnancy and yet no active follow-up appears to have occurred suggests that such a review mechanism at [the public hospital] was unsatisfactory. A follow-up plan for repeat BhCG in one week or relying on the patient to return with increasing symptoms would not be regarded as satisfactory in this situation.

Date: 7/3/97 Patient complaint document:
The patient claims to have discussed her increasing pain with 'a nurse in the Gynaecology Department'. Apparently no special action was deemed necessary although an appointment was offered for that day. The patient declined as 'she (the nurse) made me feel that I was overreacting and wasting their time'.

Comment
This discussion is not documented in the case notes. An urgent outpatient appointment was an appropriate suggestion in the circumstances.

Date: 12/3/97 […] Accident & Medical Clinic:
Reviewed with pain and discharge. An ultrasound demonstrated an empty uterus with no adnexal masses or fluid in the pelvis: 'No sign of retained products of conception and no cause of pain has been found'.

Date: 14/3/97 […] Accident & Medical Clinic:
Ultrasound result reviewed. 'Pain has decreased.' Advised to return if no better by one week.

Comment
The unspectacular clinical course and negative ultrasound scan are common features of ectopic pregnancy which is often a difficult diagnosis to confirm without surgical intervention.

Date: 20/3/97 […] Health & Medical Centre:
Presented with light PV bleeding and marked tenderness on examination. BhCG = 537 (increased). Endometritis (infection) was suspected and antibiotic therapy commenced.

Date: 25/3/97 […] Health & Medical Centre:
Pain worse and bleeding heavier. BhCG = 537 noted to be increased from previously. Referred to Gynaecology Registrar at ([the public hospital]).

Date: 25/3/97 ([The public hospital]):
Ultrasound demonstrates empty uterus and no adnexal masses. There is a small amount of fluid in the pouch of Douglas. 'No cause for pain detected.'

1900 [Dr C] assessed and advised urgent laparoscopy. Haemoglobin 135.

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<u>Comment</u>
The persistent symptoms and investigation results, though inconclusive, were promptly interpreted as indicating a possible ectopic pregnancy and the laparoscopy was entirely appropriate.

2100 [Dr C] performed a diagnostic laparoscopy which demonstrated adhesions from previous (old) pelvic infection and a large left tubal pregnancy adherent to the omentum. A mini-laparotomy was performed and a left salpingostomy was undertaken without complications.

<u>Date: 26/3/97 – 28/3/97</u> ([The public hospital]):
There were no significant complications following the operation. She was noted to be 'quite emotional' at one point and was upset about the 'shape of her stomach' but this was thought to be consistent with normal healing. On discharge a script for completion of the antibiotic course and clear instructions regarding removal of the sutures were provided and documented on the discharge summary.

<u>Comment</u>
The post-operative management was uncomplicated and discharge advice very clear, specifically with regard to suture removal.

Since this episode [Mrs A] and her partner have been investigated and treated for subfertility. A diagnostic laparoscopy on 7/9/99 demonstrated some filmy adhesions but grossly normal fallopian tubes and ovaries. The right tube was patent to dye but the left filled only to the ampulla. The last dated entry indicates ongoing treatment for subfertility with ovulation induction therapy.

<u>Comment</u>
It is very possible that the tubal surgery has compromised the left fallopian tube however the previous evidence of (old) pelvic inflammatory disease is a more likely cause of tubal factor infertility especially as this was the probable cause of the ectopic pregnancy.

What are the specific standards that apply and were they followed?

For the diagnosis of ectopic pregnancy a high index of suspicion and use of ultrasound, BhCG, exploration of the uterus, laparoscopy or laparotomy would all be well recognised standards. If a clear diagnosis is not established clinical review with repeat BhCG, review of any histology and repeat ultrasound would be warranted. In addition to general standards of patient care the management was entirely satisfactory with a good objective and clinical outcome.

How is an ectopic pregnancy diagnosed?

Common indicators are:

i. The clinical history is often the most accurate means of suspecting ectopic pregnancy.

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HDC

ii. Examination findings are often unhelpful.

iii. A high or rising hCG level with ultrasound evidence of an empty uterus.

vi. Ultrasound findings of an empty uterus, fluid in the pelvis (blood) and a complex mass lateral to the uterus.

v. Decidua (pregnancy-altered lining of the uterus) from a D&C specimen without evidence of trophoblast (placenta).

vi. Laparoscopic or open visualisation of the ectopic pregnancy.

The most common first line approach when suspecting the diagnosis is a careful history, serum BhCG and ultrasound assessment.

How difficult is it to diagnose at [Mrs A's] stage of pregnancy?

The diagnosis is notoriously difficult and it is not uncommon for the condition to be diagnosed only at the second or even third admission. This is because the symptoms and signs are highly variable and will often suggest some form of miscarriage. Easily available tests such as serum BhCG and ultrasound are not usually diagnostic but contribute to the general picture.

What did the pregnancy test on 5 March 1997 show?

A very low level of BhCG. This would commonly indicate:

1. A very early, viable pregnancy in either the uterus or fallopian tube.

2. A miscarriage within the last 2-3 weeks. Such a miscarriage might be complete, requiring no further treatment, incomplete where some pregnancy tissue is left inside the uterus or missed where the entire (non-viable) pregnancy is still within the uterus. In these cases an evacuation of the uterus is usually required.

3. A tubal miscarriage where an ectopic has been naturally extruded from the fallopian tube into the abdomen.

Was it reasonable in the circumstances for [Mrs A] to be discharged home on 5 March 1997?

Yes. Symptoms and signs had completely subsided and a very low serum BhCG did not suggest the presence of a viable, ectopic pregnancy. Nevertheless a clear plan for follow-up was explained and documented with the advice to return if there was increased pain or bleeding.

Was the information provided to [Mrs A] on discharge sufficient?

Some of this advice would have been verbal. The written discharge summary (it is unstated whether a copy was given to the patient but this is usual) states:

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1. 'To come if pain arises or vaginal bleeding resumes.' Grammatically uninspired but an unambiguous recommendation to return if further problems arose.

2. 'To come 1/52 to repeat BhCG.' The plan to review the blood test in one week was presumably verbally discussed i.e. where to go, what to do.

As a synopsis of the (presumed) verbal advice this was sufficient.

Should an ultrasound scan have been performed prior to discharge?

Ultrasound scans are a cornerstone in the management of ectopic pregnancy and are frequently performed, with BhCG, as the first line of investigation. In this instance the rapid resolution of all symptoms, the absence of any strong signs suggesting ectopic pregnancy and the very low BhCG (suggesting a non-viable pregnancy) were sufficient to allow management without ultrasound assessment at this point. There was a clear expectation to review the clinical situation in one week when an ultrasound might prove to be a useful next step depending on the clinical scenario.

What role would an ultrasound scan have played in diagnosis at this stage?

In view of the result of the scan performed on 25/3/01 which was essentially normal and stated that there was 'no evidence of pregnancy' it is unlikely that a scan would have altered the management in any way.

How significant is pelvic inflammatory disease in relation to ectopic pregnancy?
How significant is ectopic pregnancy in relation to subsequent infertility?
In your opinion what roles, if any, have PID, the ectopic pregnancy, and the subsequent surgery played in [Mrs A's] infertility?

Pelvic inflammatory disease (PID) is the most common cause of ectopic pregnancy due to damage of the endosalpinx (the lining of the fallopian tube). This leads to abnormal tubal function when the early fertilised egg is present and predisposes to implantation within the tube. There was of course no previous history or suspicion of PID to guide the Gynaecologists at the initial presentation. This was only diagnosed at laparoscopy. In hindsight PID was the probable cause of the ectopic and has the future implications of increased risk for repeat ectopic pregnancy, reduced fertility, chronic pelvic pain and recurrent infection. Surgery to the affected tube may affect subsequent function although every effort was made to minimise damage. The pre-existing PID is the most important fertility issue.

Are there any other matters you consider relevant in relation to the standard of care provided to [Mrs A]?

Diagnosis and management of ectopic pregnancy is notorious for its many pitfalls. The management in this case was, in all but one regard, entirely satisfactory and of a generally high standard.

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The apparent failure to highlight and act upon the histology report which clearly stated the possibility of ectopic pregnancy delayed definitive management by about 18 days during which time the patient was subject to continuing and worsening symptoms. On the other hand the patient failed to observe the clearly provided advice for follow up and/or return if symptoms were worsening.

Thankfully the delay did not substantially alter the final outcome in this case. Nevertheless, ectopic pregnancy is a potentially life-threatening condition and any contributors to delay in diagnosis should be addressed. It may be timely for [the public hospital] Gynaecology team to review their processes for histology review and active follow-up for non-attenders in such sub-acute situations."

Response to Provisional Opinion

The General Manager of the public hospital responded to my provisional opinion as follows:

"[Dr B] has pointed out that it is documented on the total histology sheet that the specimen was mid-secretory phase with an approximate date of 6/9 days post ovulation. This would make the risk of ectopic pregnancy minimal according to the information the patient provided as to when intercourse last took place.

We attach for your information a copy of our 'Clinical Result/Report – handling process'. By the end of this year we also anticipate that all laboratory results will be made available and accessed electronically. This should allow better tracking and follow-up of all laboratory results.

We are also attaching our letter of apology to [Mrs A]. We would be grateful if you would forward this to her, if you think it is appropriate."

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Code of Health and Disability Services Consumers' Rights

The following Rights in the Code of Health and Disability Services Consumers' Rights are applicable to this complaint:

RIGHT 4

Right to Services of an Appropriate Standard

1) *Every consumer has the right to have services provided with reasonable care and skill.*

…

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

Opinion: No breach – Dr B

In my opinion Dr B did not breach Right 4(1) in relation to the initial diagnosis and treatment.

Right 4(1)

Mrs A was concerned that if the appropriate tests had been performed, and she had been correctly diagnosed at the first admission, she would not now be unable to conceive.

I accept the advice of my independent expert that Mrs A's presenting symptoms, on 4 March 1997, suggested miscarriage as the most likely (and most common) diagnosis and that Dr B appropriately performed an examination under anaesthetic and evacuation of the uterus. In light of the findings of this procedure my advisor said that Dr B appropriately addressed the possibility of ectopic pregnancy by suggesting a repeat BhCG and ultrasound if symptoms persisted. My advisor noted:

> "The BhCG was very low at 295 not suggesting an ongoing ectopic pregnancy and since all the symptoms had subsided and the signs were normal, discharge without ultrasound scanning was undertaken. There was a very clear plan for follow-up with repeat BhCG to ensure that this was declining and clear instructions to return if there were problems. This management is entirely acceptable."

In my opinion Dr B provided clinical services with reasonable care and skill and did not breach Right 4(1) of the Code.

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Opinion: No breach – Dr D

In my opinion Dr D did not breach Right 4(1) of the Code in relation to her involvement in the diagnosis and treatment of Mrs A, for the reasons set out below.

Right 4(1)

Dr D admitted Mrs A on 4 March 1997, took a history and appropriately contacted Dr B. She also gave Mrs A her discharge instructions the following afternoon.

My independent expert noted that the next step in Mrs A's clinical management was to review the histology results "to ensure that placental tissue was present indicating that the pregnancy was located in the uterus rather than elsewhere". My advisor also noted:

> "The generally accepted practice is for all histology reports to be reviewed by Gynaecology medical staff and to actively follow-up such results ensuring review of the patient and usually further investigation (ultrasound and/or repeat BhCG). The fact that this histology report explicitly alerted to the possibility of ectopic pregnancy and yet no active follow-up appears to have occurred suggests that such a review mechanism at [the public hospital] was unsatisfactory. A follow-up plan for repeat BhCG in one week or relying on the patient to return with increasing symptoms would not be regarded as satisfactory in this situation."

More than five years have passed since Mrs A's first admission and Dr D's recollection of events has dimmed. She was clear that she did view Mrs A's histology results, which were dated 5 March 1997. However, she was unsure whether they were available to her on or about this date, or whether she viewed them during Mrs A's second admission on 25 March 1997. If she did see the results before the second admission, she could not categorically state that she notified Dr B, or another senior colleague, of the results but advised that it was "highly likely to have occurred due to my practice at that time". Dr B said that the results were not brought to his attention in March 1997.

What is clear is that the process of recalling a patient with uncertain histology findings failed Mrs A on this occasion. There is not sufficient evidence for me to conclude that Dr D saw the results before Mrs A's second admission and failed to advise a consultant. I also note Dr D's advice that her usual practice would have been to refer the results when she saw them. Accordingly, in my opinion, Dr D did not breach Right 4(1) of the Code in relation to this issue.

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Opinion: No breach – Dr C

In my opinion Dr C did not breach Right 4(1) of the Code in diagnosing and treating Mrs A.

Right 4(1)

Mrs A was re-admitted to the public hospital on 25 March 1997. She saw Dr C for a pre-operative assessment at 7.00pm and underwent a diagnostic laparoscopy, minilaparotomy and left salpingostomy later that evening. Mrs A was concerned that the surgery rendered her left fallopian tube "completely useless" and that the right fallopian tube was not checked for infection, "leaving it to scar so badly that it blocked".

I note the advice of my independent expert that Dr C promptly interpreted Mrs A's symptoms as indicating a possible ectopic pregnancy, and that the laparoscopy Dr C performed was entirely appropriate, as was the necessary minilaparotomy and left salpingostomy performed when Dr C discovered the ectopic pregnancy. The surgery was undertaken without complications. During the operation evidence was found of old pelvic inflammatory disease. My advisor explained the significance of this finding:

> "Pelvic inflammatory disease (PID) is the most common cause of ectopic pregnancy due to damage of the endosalpinx (the lining of the fallopian tube). This leads to abnormal tubal function when the early fertilised egg is present and predisposes to implantation within the tube. There was of course no previous history or suspicion of PID to guide the Gynaecologists at the initial presentation. This was only diagnosed at laparoscopy. In hindsight PID was the probable cause of the ectopic and has the future implications of increased risk for repeat ectopic pregnancy, reduced fertility, chronic pelvic pain and recurrent infection. Surgery to the affected tube may affect subsequent function although every effort was made to minimise damage. The pre-existing PID is the most important fertility issue."

In my opinion Dr C provided services with reasonable care and skill when she diagnosed and treated Mrs A's ectopic pregnancy, and did not breach Right 4(1) of the Code.

Opinion: Breach – The Public Hospital

In my opinion the public hospital breached Right 4(5) of the Code as follows:

Right 4(5)

Histology review
A histology report dated 5 March 1997 explicitly raised the possibility of ectopic pregnancy. My advisor has stated that generally accepted practice is for gynaecology medical staff to review all histology reports and actively follow up abnormal results, ensuring review of the patient and usually further follow-up. This did not occur. Dr D, a senior house surgeon, was not clear at what point she saw the report. Dr B was clear that he did not see it before

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reviewing Mrs A's clinical notes for the purposes of this investigation. Dr G, the Clinical Director of Gynaecology, advised that for all abnormal histology the practice was to recall the patient for further diagnostic procedures or treatment. The system in place to trigger such a recall was for a registrar to review the results and, where appropriate, notify the named consultant. The system failed in this case. I note the advice of my independent expert that this failure suggests that the review mechanism at the public hospital was not satisfactory:

> "Diagnosis and management of ectopic pregnancy is notorious for its many pitfalls. The management in this case was, in all but one regard, entirely satisfactory and of a generally high standard.
>
> The apparent failure to highlight and act upon the histology report which clearly stated the possibility of ectopic pregnancy delayed definitive management by about 18 days during which time the patient was subject to continuing and worsening symptoms. ...
>
> Thankfully the delay did not substantially alter the final outcome in this case. Nevertheless, ectopic pregnancy is a potentially life-threatening condition and any contributors to delay in diagnosis should be addressed. It may be timely for [the public hospital's] Gynaecology team to review their processes for histology review and active follow-up for non-attenders in such sub-acute situations."

In the circumstances I conclude that the public hospital failed to have a system for reviewing histology reports and acting on abnormal results that ensured quality and continuity of care for Mrs A. In my opinion, therefore, the public hospital breached Right 4(5) of the Code.

Action

- In my provisional opinion I requested that the public hospital apologise in writing to Mrs A. The public hospital forwarded a letter of apology to me when responding to my provisional opinion. The letter of apology has been forwarded to Mrs A.
- In my provisional opinion I noted Dr G's advice that "in light of recent events we are reviewing our histology follow-up protocols and in particular who signs these off". I requested that the public hospital advise me of the outcome of that review. When responding to my provisional opinion the public hospital forwarded a copy of its "Clinical Result/Report – handling process" documentation and noted that it is anticipated that all laboratory results will be accessible electronically by the end of the year. In the circumstances I do not consider any further follow-up is necessary.
- A copy of this opinion will be sent to the Medical Council of New Zealand.

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- A copy of this opinion, with identifying details removed, will be sent to the Royal Australasian College of Obstetricians and Gynaecologists and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Other comment

Discharge instructions

The discharge summary completed on 5 March 1997 recorded, under 'Follow-up arrangements made', that Mrs A return in a week to repeat the BhCG. Dr D was clear that Mrs A was to return for a further blood test and that there was no need for an appointment to be made as Mrs A could have the blood test done at Accident and Emergency. Mrs A said to me that she was waiting for an appointment card.

To ensure patients are clear about what is required by way of follow-up, I recommend that they receive written instructions, particularly where no appointment is necessary and, therefore, no appointment card is sent.

IVF treatment

Mrs A seeks reimbursement of her expenses over two years and the costs of any future IVF treatment. I am unable to deal with this matter as it is not within my jurisdiction.

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