Obstetrician, Dr B

A Fertility Centre

A Public Hospital

A Report by the

Health and Disability Commissioner

(Case 02HDC10862)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Mrs A	Complainant / Consumer
Mr A	Complainant / Consumer's husband
Dr B	Provider / Obstetrician
Dr C	Obstetrician
Dr D	Clinical Director of the fertility clinic
Dr E	Obstetrician
Ms F	Consumer Liaison Team Leader for the hospital
A Fertility Clinic	Provider
A Public Hospital	Provider

Complaint

On 8 August 2002, the Commissioner received a complaint from Mr and Mrs A about services provided to Mrs A by Dr B and a fertility clinic. The complaint was summarised as follows:

Dr B/the fertility clinic
In June and July 2002, Dr B/the fertility clinic did not provide services of an appropriate standard to Mrs A. In particular, on 29 June 2002:

- *following an earlier ultrasound scan, Dr B/the fertility clinic staff incorrectly diagnosed Mrs A with an ectopic pregnancy*
- *without assuring herself/themselves that the pregnancy was in fact ectopic, Dr B/the fertility clinic staff advised Mrs A that she had two options: to terminate the pregnancy surgically, or with methotrexate*
- *without assuring herself/themselves that the pregnancy was in fact ectopic, Dr B/the fertility clinic staff arranged for the drug methotrexate to be administered*
- *Dr B/the fertility clinic staff arranged for methotrexate to be administered, without giving Mrs A sufficient time to reflect on whether she had made the right decision to terminate the pregnancy with the drug*

In June and July 2002, Dr B/the fertility clinic staff did not provide Mrs A with information that a reasonable consumer in Mrs A's circumstances would expect to receive. In particular, Dr B/the fertility clinic staff did not provide Mrs A with adequate information about methotrexate and the risks it posed to a potentially viable foetus.

An investigation was commenced on 6 January 2003.

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

Information reviewed

- Information from Mr and Mrs A
- Relevant medical records and information from the fertility clinic

Independent expert advice was obtained from obstetrician and gynaecologist Dr Peter Dukes, and a gynaecologist in infertility treatment, Dr John Hutton.

Information gathered during investigation

Background
Mrs A first attended the fertility clinic in June 2001, after she and her husband had experienced two and a half years of primary infertility (difficulty conceiving a first child).

Mrs A's general practitioner had earlier referred Mrs A to obstetrician Dr C for the initial investigation of a fertility problem. In October 1999, Dr C noted that Mrs A had a degree of oligomenorrhoea (infrequent periods) with variable cycle lengths. On ultrasound Dr C found no convincing evidence of polycystic ovary syndrome, a leading cause of infertility. He therefore planned to start Mrs A on clomiphene, a drug that stimulates ovulation. At that stage, however, Mrs A decided to continue trying to conceive naturally.

In March 2001, Mrs A's general practitioner referred Mrs A to the fertility clinic, where she was first seen on 7 June 2001. Mrs A's cycle length was again noted to be irregular. She was investigated again for polycystic ovary syndrome, but the results of tests were negative. The results of analyses of Mr A's semen on 24 August and 9 November 2001 demonstrated that he had oligospermia (low sperm count). It was therefore decided that the male factor was the primary cause of infertility, and that in-vitro fertilisation (IVF) with intracytoplasmic sperm injection (ICSI) was the most appropriate form of treatment. ICSI is a process whereby sperm are injected into eggs during a standard IVF cycle.

IVF / ICSI treatment
Mr and Mrs A were accepted as eligible for treatment on 30 November 2001. They attended the fertility clinic for orientation on 14 January 2002, and on 16 May 2002 the first phase of Mrs A's IVF plus ICSI cycle was commenced. The first phase involves hormonal stimulation of the ovaries to produce more than one mature oocyte (egg). During the stimulatory phase, Mrs A was assessed twice by ultrasound – by the Clinical Director of the fertility clinic, Dr D, on 22 May, and by obstetrician and gynaecologist Dr B on 26 May.

On 27 May, Mrs A telephoned the fertility clinic advising that she felt very breathless. She was advised to come to the fertility clinic to be assessed by a doctor. Mrs A telephoned the fertility clinic again shortly afterwards, and told a staff member she was going straight to another public hospital. The notes record that she sounded "very distressed and appeared very breathless".

Mrs A was assessed at the second hospital for lower abdominal pain and increasing breathlessness, and a diagnosis of ovarian hyperstimulation syndrome was considered. Following discussion with Dr D, Mrs A was transferred via ambulance to a ward at the first public hospital, where it was decided that ovulation triggering would be undertaken that night, with ovum pickup planned for 29 May. Mrs A was discharged from hospital on 28 May.

On 29 May, after a peak estradiol level of 5078 was reached, a registrar carried out the oocyte pickup (OPU). Four eggs were obtained, ICSI was undertaken, and all four eggs fertilised normally. On 1 June, an obstetrician/gynaecologist placed two embryos into the uterus and two embryos were frozen.

On 12 June, which was luteal day 14 (the number of days since the eggs were picked up), the fertility clinic staff carried out the first of a number of Beta hCG hormone assays (human chorionic gonadotropin, the 'pregnancy hormone') to assess the viability of the pregnancy. Mrs A's medical records include a logarithmic graph used by the fertility clinic staff to plot the progress of rising Beta hCG levels. The fertility clinic confirmed that the vertical axis represented the levels of Beta hCG, and the horizontal axis represented the luteal days.

On 12 June, Mrs A's Beta hCG level was 48.9 and on 14 June (luteal day 16), it was 57.8. On 17 June (luteal day 19) it was 95. Dr B advised me that the rate of rise in Mrs A's Beta hCG level was less than normal. On 17 June staff at the clinic advised Mrs A that the pregnancy was unlikely to be viable. In a viable pregnancy, it is usually expected that the hCG level would approximately double during each 48-hour period.

A further blood test was arranged for 21 June, but the test was deferred until 24 June as Mrs A's veins were in poor condition. By 24 June (luteal day 26), Mrs A's Beta hCG had risen to 1010, and she was suffering from some pelvic discomfort. On 28 June (luteal day 30), the Beta hCG had risen to 2972.

Ultrasound – 'probable ectopic pregnancy'
On Saturday 29 June 2002, Mrs A attended a clinic appointment at the fertility clinic and Dr B performed a transvaginal ultrasound scan on the fertility clinic' Siemens Omnia machine. A handwritten note in Mrs A's fertility clinic records states (in part):

> "USS Empty uterus
> Stimulated ovaries
> No separate tubal mass identifiable
> No free fluid …"

There is no other record of this ultrasound. Dr B advised me that although she felt she had a good view of the uterus, she did not identify an intrauterine sac. At six weeks' gestation (four weeks since the embryo transfer), she would have anticipated a gestational sac with an 11mm diameter and a foetal pole of 6mm.

Dr B advised me:

> "[Mrs A] had complained of nausea, but no pelvic pain. A speck of vaginal bleeding had been noted. Because no intrauterine sac had been identified, which should have been obvious at 6 weeks, and the abnormal early slow rise of Beta hCG, I thought that she had a probable ectopic pregnancy."

Dr B then discussed with Mr and Mrs A options for managing an ectopic pregnancy (a pregnancy outside of the uterus). The options discussed were expectant management of the pregnancy (waiting for the ectopic pregnancy tissue to undergo cell death and reabsorption) with continued hormonal monitoring; treatment with methotrexate (a chemotherapeutic drug which attacks and destroys fast-growing cells); and surgical treatment with laparoscopy. The possibility of a normal intrauterine pregnancy was not discussed.

Dr B discussed the possibility of rupture of the fallopian tube if the expectant management option was chosen, and the side effects and possible failure of methotrexate treatment. In relation to the complaint that she did not provide adequate information about the risks methotrexate posed to a potentially viable foetus, Dr B advised me:

> "I did not discuss the effect of methotrexate on a potentially viable pregnancy because in this situation it would not be offered or accepted. Literature research has shown the risk of methotrexate to the fetus is unknown."

Mr and Mrs A chose the option of methotrexate. Based on Dr B's advice, they advised me that they considered methotrexate would be the least invasive option, and that it should be effective given that the pregnancy was very early on.

Dr B advised me:

> "After the tension [Mrs A] had suffered when the Beta hCG levels had failed to rise in a normal fashion it was felt that the wait for possible spontaneous resolution would be difficult to tolerate. Methotrexate was felt to be the least invasive treatment option. Because there was no sign of intra-abdominal bleeding, the timing for admission for treatment was discussed, but they wished to have the treatment expedited."

No further checks of the ultrasound performed by Dr B were performed or arranged.

Administration of methotrexate

Mrs A was admitted to the ward at the first public hospital later that day, 29 June 2002. A handwritten copy of Dr B's referral note to the ward states:

> "Thank you for admitting this probable ectopic pregnancy.
>
> Hx [history] IVF + ICSI [due to] [male] factor
>
> OPU 29/5/02
> ER 1/6/02 2 embryos
>
> Abnormal rise of BhCG
> 12/6/02 49

14/6/02 57
18/6/02 95
24/6/02 1010
28/6/02 2972

Pt [patient] c/o [complaining of] nausea
no pelvic pain
speck of PV [per vaginal] bleeding

USS [ultrasound scan] empty uterus
stimulated ovaries
no separate tubal mass identifiable
no free fluid

Discussed options with patient
She would prefer Rx [treatment with] Methotrexate"

Upon Mrs A's arrival, blood tests were taken and then she was administered 85mg methotrexate intramuscularly. She was discharged later the same day, with instructions to attend a medical laboratory for follow-up blood tests on 2 July and 5 July 2002.

On 2 July 2002, an hCG laboratory result of 5915.7 was reported to the ward. The ward records note that it was the third day after methotrexate administration and state:

"If asymptomatic, can wait till rpt blds [repeat blood tests] and review on Day 7

[therefore] advise to return for review if develops abdo[minal] pain or any concerning [symptoms]."

Mrs A was contacted by telephone and the above information was relayed to her. She reported no pain or bleeding, so it was agreed that she would wait for her repeat blood test before any further action was decided upon.

Ultrasound – live foetus
However, on Thursday 4 July 2002, Mrs A experienced abdominal pain, backache and nausea, and was again reviewed at the ward. Her Beta hCG level was recorded as 5800 on 4 July, and a further ultrasound scan was carried out. The scan confirmed the presence of a single live intrauterine foetus in a small gestational sac. The crown/rump length was 4mm, which Dr D (the Clinical Director of the fertility clinic) advised me was smaller than the expected gestation. There was no evidence of ectopic pregnancy.

Mr and Mrs A recalled their horror at the new ultrasound results:

"[We] find it difficult to express in words the all-consuming sense of horror and grief that descended upon us, we were distraught beyond belief. On advice from [Dr B] our normal pregnancy had been mis-diagnosed and treated with a drug designed to end it. … Of course the main concern in our mind was what has this drug done to our unborn child?"

Mrs A was transferred back to the ward, where staff attempted to find out what effect methotrexate might have had on a viable foetus.

Dr B advised me that when she was notified of the result of Mrs A's 4 July scan, she immediately attended Mr and Mrs A in their hospital room and apologised for not having identified an intra-uterine pregnancy earlier.

In the meantime, obstetrician Dr E made an entry in the clinical notes on 4 July, recording that he had spoken to two medical oncologists who were unable to provide advice on the potential effects of methotrexate on a viable foetus, and who suggested contacting the pharmaceutical company and doing a literature search. Dr E recorded in the notes:

> "I've emphasized [to Mr and Mrs A] that this is a very unusual situation and very few people have experience in this clinical scenario. Given that fetus is viable, no urgency to make any decisions immediately."

Over the next four days the fertility clinic staff gathered information about the likely effects of methotrexate on the foetus. On 8 July, Dr E advised Mr and Mrs A that there was a significant risk of foetal malformation. An ultrasound scan on 8 July showed further growth (the crown/rump length was now 10mm), and Mrs A's Beta hCG had risen to 9100. There was a degree of oligohydramnios (reduced amniotic fluid).

Termination of pregnancy and aftermath
Mr and Mrs A decided to terminate the pregnancy. Mrs A underwent the procedure at the first public hospital on 12 July 2002.

Mr and Mrs A advised me that, given that the diagnosis of ectopic pregnancy had been made very early on in the pregnancy and had not actually been located, and that Mrs A was therefore in no immediate danger, they felt that Dr B should have offered them a "wait and see" option. They said:

> "[We] must reiterate at no time was the possibility of a normal uterine pregnancy discussed, the diagnosis was ectopic and the options given to us were based on the treatment of such."

Dr B advised me that the circumstances that led to the termination of a most desired pregnancy had deeply distressed her.

Mr and Mrs A subsequently met with the fertility clinic clinical staff and the first public hospital management to discuss the circumstances surrounding their care, and what action would be taken. In a letter to Mr and Mrs A dated 12 October 2002, the Consumer Liaison Team Leader for the hospital, Ms F, wrote:

> "After your initial positive pregnancy test, there was concern at the relatively slow increase in Beta hCG level over the first week but in the second week the level went up appropriately. An ultrasound scan done at [the fertility clinic] at approximately 6 weeks

gestation, did not identify an intrauterine sac and the likelihood of an ectopic pregnancy was raised.

The subsequent decision to administer methotrexate was based on this possibility. We acknowledge that [Mrs A] had no acute symptoms of an ectopic pregnancy, and a follow up ultrasound in the Radiology Department and a repeat Beta hCG the following week, would have been advisable to confirm the diagnosis. We also regret that you were not offered pregnancy loss counselling prior to administration of methotrexate.

…

The loss of your pregnancy has deeply distressed us. Please accept our deepest sympathy for your loss. Staff at [the fertility clinic] and [the first public hospital] apologise for all the events that led to the loss of your pregnancy."

Arrangements were made for Mr and Mrs A to undergo further fertility treatment with another fertility clinic. The two frozen embryos from the fertility clinic were transferred to the second fertility clinic, but neither survived the transfer process. However, Mrs A subsequently conceived in January 2003 following a further IVF plus ICSI cycle at the second fertility clinic.

Changes to procedures / policies since events

Since these events occurred, the first fertility clinic and the second public hospital have made a number of changes to their policies and procedures in relation to early pregnancy care for fertility patients, and the diagnosis of ectopic pregnancy and its medical management with methotrexate.

For fertility patients, the first fertility clinic now monitors the Beta hCG weekly, rather than twice weekly. Dr D advised me that the purpose was "to try and minimise the anxiety around the early stages [of pregnancy] when definitive diagnosis can be difficult". For early pregnancy care following fertility treatment, there is continuity of care where possible (several doctors were involved in reviewing Mrs A's results). A new form for plotting the serial assay readings has been designed.

The second public hospital's methotrexate administration policy in place at the time – "Methotrexate (IM) Administration for Persistent Ectopic Pregnancy" (dated September 1999) – has been updated to include the following requirements:

- if an ectopic pregnancy is diagnosed, an ultrasound must now be performed in the Department of Radiology on a high-resolution ultrasound machine by a certified sonographer or radiologist before methotrexate is administered;

- the policy now states that "a second opinion from another consultant is wise if diagnosis is not 100% clear"; and

- patients who are to be administered methotrexate are now offered pre-decision pregnancy loss counselling.

Ms F advised me that the above key aspects of the policy are reinforced by means of a sheet on the front cover of a specific folder containing the methotrexate policy and the clinical procedures protocol, "Ectopic Pregnancy". The two policies are currently being amalgamated so that complete information on diagnosing and caring for women with ectopic pregnancies will be available in one document.

Independent advice to Commissioner

Obstetric advice
The following advice was obtained from independent obstetrician Dr Peter Dukes:

> "Thank you very much for asking me to review the claim of [Mr and Mrs A] with regard to their care at [the fertility clinic] and in particular by [Dr B], an employee of [the first fertility clinic].
>
> As a couple [Mr and Mrs A] had had a fertility problem which was initially investigated by [Dr C] and he noted at the time that there was a degree of oligomenorrhoea with rather variable cycle lengths but, on ultrasound, no convincing evidence of polycystic ovary syndrome. In view of the irregularity of the cycles it was decided that Clomiphene treatment should be started to induce regular ovulation, but the notes do not suggest to what extent this was carried out.
>
> [Mr and Mrs A] subsequently sought assistance from [the fertility clinic] and a referral note was forthcoming from [Mrs A's general practitioner] and [Dr C] forwarded his notes to [the fertility clinic] from her original consultations.
>
> [Mrs A] was initially seen at [the fertility clinic] on 7 June 2001 with 2½ years of primary infertility. At this stage it was noted that she was fit and well but had previously been investigated for an eating disorder. Her height is 1.7 metres and her weight 75 kilograms with a BMI of 24. The irregularity of her cycles was again noted but, more particularly, in [Mr A's] investigations, he was found to be significantly oligospermic on two occasions. After a full work up on both [Mr and Mrs A] it was decided that the male factor was the main problem and it was felt that intracytoplasmic sperm injection (ICSI) would be the most appropriate management for their infertility. They were accepted as eligible for treatment on 30 November 2001.
>
> They were seen on 14 January 2002 by [Dr B] for orientation and it was decided that the treatment would start with the March cycle. In the event stimulation started on 16 May 2002. However, on 27 May [Mrs A] became unwell with breathlessness and pain and she phoned [the fertility clinic] but ultimately, because of her symptoms, took herself to [the second public hospital] where she was assessed and was transferred to [the ward at the first public hospital] after discussion with [Dr D]. During the stimulatory phase [Dr D] assessed her on 22 May by ultrasound and [Dr B] again on 26 May, the day prior to her admission with pain.

During her admission it was decided that ovulation triggering should be undertaken on 27 May and ovum pickup planned for 29 May 2002.

By 28 May [Mrs A] was feeling much better as far as her pain was concerned and was discharged and she presented on 29 May, to [the fertility clinic], for ovum pickup as arranged.

At the time of pickup four eggs were obtained and ICSI was undertaken and two eggs replaced on 1 June 2002. At the time of pickup arrangements were made for follow up hormone assays to assess the viability of the pregnancy.

The first of these assays was on 12 June (luteal day 14) which was 48.9 and it was therefore arranged for this to be repeated on 14 June (day 16) when it had risen to only 57.8. The situation was discussed with [the obstetrician/gynaecologist] and he suggested a further repeat on 17 June 2002 (day 19). This result was only 95 and [the registrar] indicated that it was unlikely that this was going to be an ongoing pregnancy. A further blood test was arranged for 21 June but, as [Mrs A's] veins appeared to be the worse for wear, this was delayed, with [Dr D's] permission, until 24 June 2002 (day 26).

On 24 June Beta hCG was 1010 and [Dr B] requested that this be repeated on 28 June and for [Mrs A] to call if there was any worsening in her pain. On 28 June the Beta hCG was noted to be 2972 and it was arranged with [Dr B] to scan [Mrs A] the following day.

The only contemporaneous note from the 29 June is what I presume is [Dr B's] referral note from [the fertility clinic] to the Inpatient Department of [the first public hospital] for administration of Methotrexate. Unfortunately the photocopying has removed the signature from the bottom. However, in this note [Dr B] details the HCG rise together with her ultrasound impressions of empty uterus in association with stimulated ovaries, but notes that there was no separate tubal mass nor any free peritoneal fluid. The note starts by referring [Mrs A] because of a 'probable ectopic pregnancy'. It is clear that the options for future management were discussed at [the fertility clinic] by [Dr B] and the decision to proceed with Methotrexate was made at [the fertility clinic]. She was subsequently referred to [the first public hospital] for Methotrexate treatment to be actioned. The appropriate protocol was put in place for the administration and 85 mg of Methotrexate was given at 1615 hours on 29 June 2002. A further repeat HCG on the day of admission was 3100.

As part of the follow up protocol hCG estimations were undertaken on day 3 post Methotrexate at which stage the level was 5915 although this was done in the outside laboratory and there may be significant variation in the estimation of hCG between laboratories. However, the estimates of hCG from the […] laboratory, […], on 29 June, 4 July and 8 July were 3100, 5800 and 9100 respectively.

While the protocol did not call for further ultrasound examinations, I assume a further ultrasound was undertaken within [the first public hospital's] Ultrasound Department on 4 July because there was a significant rise in the hCG levels in the post-treatment follow

up. A scan showed that there was a live foetus with a crown rump length of 4 mm in a small gestational sac. This scan was repeated at 1700 hours the same day and the gestational sac was noted once again and cardiac activity was seen but there was some difficulty in visualising this. This scan was done by [a] sonographer and reported by [Dr …]. Thereafter [Mr and Mrs A] were seen by [Dr E] who discussed the difficult situation with them and over the next four days information was gathered about the likely effects of Methotrexate on the foetus. He saw [Mr and Mrs A] again on 8 July following a further scan which confirmed the viability of the foetus. It was noted at this stage that there was a degree of oligohydramnios. This scan was carried out by [another] sonographer and reported by [Professor …].

[Dr E] indicated that there was a significant risk of foetal malformation as a result of the administration of the Methotrexate and after discussion [Mr and Mrs A] decided that surgical evacuation of pregnancy should be undertaken. This was dealt with by [Dr E] on 12 July 2002 and this procedure was quite straightforward.

There was, very understandably, significant stress created by the whole situation and significant amounts of counselling were required over this period of time.

In recognition of the significant difficulties created by the erroneous diagnosis of ectopic pregnancy [the fertility clinic] have agreed to fund further cycles of ICSI and at [Mr and Mrs A's] request these were to be carried out at [the second fertility clinic]. There is nothing within the file to indicate that this has subsequently taken place.

REQUESTED ADVICE

WHAT PARTICULAR STANDARDS APPLY IN THIS CASE?

There are no National standards for the management of ectopic pregnancy and currently the Royal Australian and New Zealand College of Obstetricians and Gynaecologists does not have a position statement on ectopic pregnancy. However, the Royal College of Obstetricians and Gynaecologists published guidelines with regard to the 'Management of Tubal Pregnancy' in October 1999. These guidelines were, as the title suggests, for management rather than the diagnosis. In a different publication, 'The Obstetrician & Gynaecologist', the Royal College of Obstetricians and Gynaecologists have, this year, reviewed the current diagnosis and non-surgical management of ectopic pregnancy.[1] While these are not strictly College guidelines they were published in the journal which is concerned with continuing professional development and are therefore a significant contemporary summary of the management, both diagnosis and treatment, of ectopic pregnancy.

Many hospitals have either protocols or guidelines for the management of ectopic pregnancy because of the significant life threatening risk of ruptured tubal pregnancy and also for risk management because of the potential for misdiagnosis and medicolegal fallout where the diagnosis is not made at an early stage in the clinical picture. However, in this particular instance the situation was reversed in that the ectopic pregnancy did not exist but some of the parameters which might have indicated ectopic

pregnancy were present. In the event however, these were misleading. [The first public hospital] has a clinical procedures statement concerning the management of ectopic pregnancy and certainly a number of the diagnostic criteria were present. It should be stated at the outset that one of the confounding difficulties with the use of Beta HCG is that very early intrauterine pregnancies which will not proceed to term but are destined to end as a miscarriage may also show reduced levels of Beta HCG mimicking the changes which might be seen in ectopic pregnancy although generally HCG levels would be somewhat higher in failing pregnancies. Such pregnancies may also give rise to the presence of a foetal heart and early growth but be subsequently spontaneously lost in the 6 to 8 week period in spite of the presence of a foetal heart in the very early gestation. In this particular instance we can have no knowledge as to whether this pregnancy was going to be satisfactorily ongoing, as its development was clearly significantly outside the expected parameters for normal pregnancy, but already modified by Methotrexate at the time of diagnosis.

There are therefore, no direct standards which may be applied as a template, so to speak, to assess the adequacy of management other than the [first public hospital's] clinical procedures statement.

2. APPROPRIATENESS OF THE DIAGNOSIS

In this particular instance the only clinical criterion of significance was the fact that ectopic pregnancy is a recognised complication of assisted reproductive technology. [Mrs A] was asymptomatic as far as ectopic pregnancy was concerned but she had had quite a lot of pain surrounding her ovarian stimulation which might have heightened the suspicion concerning ectopic pregnancy.

Some of the hCG levels were significantly lower than would have been expected but the interpretation of these is difficult as many of the values on the hCG progress graph provided are plotted both at variance from the appropriate luteal day and level of hCG. The latter no doubt arises from the complete illegibility of the graph. Some of the luteal day plottings are more in relationship to the egg replacement day, but confirmation has been received from [the fertility clinic] that these should have been plotted in relationship to luteal days, i.e. from the day of egg retrieval. In fact there is variance from what appears to be appropriate in all plottings except for the level of 1010 on day 26. As an example, the first two hCG values of 48 and 57.8 on luteal day 14 and 16 respectively are plotted on day 12 and 14. Likewise, because of the construction of the graph, these results are plotted significantly lower than is appropriate. Much effort has been made on the part of the Commissioner's staff to acquire a graph which was legible but it appears that there are none available. I have plotted my interpretation of the results on the original graph provided and left the subsequent copy obtained from [the fertility clinic] in its pristine state. However, where decisions of significant import are being made from the graph the graph should be at least readable so that the plottings are accurate.

Whatever the situation is with regard to the graph, it is clear that the day 21, day 26 and day 30 levels represented an appropriate progression of hCG albeit below the 'lower

limit of normal' on the graph. It is uncertain from the graph whether this represents the lower two standard deviations or the 10th or 5th centile. However, whatever the interpretation, it should be stressed that normal pregnancy may occasionally be found outside the 'normal range'. Kadar et al showed that 85% of viable intrauterine pregnancies will show an increase of 66% in the hCG level in every 48 hour period up to 40 days of gestation.[2] Therefore, 15% of normal pregnancies will in fact be below this level of increase. The [first public hospital's] Protocol indicates that hCG levels will generally double in each 48 hour period and this is certainly the standard rule of thumb which is used for calculating the appropriateness of the rise. However it is clear, from Kadar's figures, that more than 15% of normal viable pregnancies will fall below this 'doubling' rise. In [Mrs A's] case there was certainly a 66% rise per 48 hour period from day 21 through to day 30, albeit that the latter two estimates were below the shaded 'normal' range. Although, as previously noted, it is difficult to know whether or not this pregnancy was an ongoing normal pregnancy or whether the intrauterine pregnancy might have been non viable, it should be noted that its development by 8 July was almost consistent with the expected gestation. The tables of Jeanty and Romero suggest a gestation of 7 weeks and 2 days for a crown rump length of 10 mm when [Mrs A] was in fact 7 weeks and 5 days.[3] However, [Professor …] noted that there was oligohydramnios present and the ultrasound appearances were likely to have been modified by the therapeutic dose of Methotrexate given some 9 days previously. This might have accounted for this abnormality of liquor production and reduction in hCG production following its administration.

Conversely Kadar also showed that 13% of ectopics will show a 66% rise in hCG production but that rises of less than 50% per 48 hours are almost invariably associated with non viable pregnancies whatever the site of the pregnancy.

It was against the background of these hCG levels [Dr B] scanned [Mrs A] on 29 June at 6 weeks and 1 day gestation anticipating a likely 11 mm gestational sac with a foetal pole of 6 mm and a foetal heart present. In the event no intrauterine pregnancy was visible suggesting the possibility of ectopic pregnancy, but there were no other positive confirmatory signs such as adnexal mass, gestational ring or free fluid in the pelvis. Although [Dr B] states that she felt the diagnosis was a 'probable' ectopic it is clear, from her actions, that she felt this diagnosis was fully sustained by the findings. The [first public hospital's] Protocol indicated that intrauterine gestations should be seen on vaginal ultrasound at levels of greater than 1500 milli units per litre. Stovall et al noted that 100% of viable intrauterine pregnancies could be demonstrated at levels greater than 2000 international units per litre.[4] The level noted on the day prior to the ultrasound was 2972. There remains a degree of controversy concerning the appropriate level of hCG at which intrauterine gestations should be seen, i.e. 1500 or 2000 international units per litre. However, in terms of the protocol [Dr B] appropriately felt that this criterion was satisfactorily fulfilled. However, while the hCG levels had initially not risen appropriately, there had been satisfactory rises over the 10 day period to the ultrasound on 27 June. Likewise there was no confirmatory clinical evidence for ectopic pregnancy such as pain or vaginal bleeding, the only other risk factor being the assisted reproductive technology. It was clear that the possibility that she was not visualising it

effectively or that the pregnancy might have been a lesser size than she had expected was not considered because of the 'certainty' of the dates. In the event one or both of these applied. Reliance on a single ultrasound on less sensitive equipment in such a critical situation was perhaps unwise in spite of the Clinical Procedures protocol. While the rapidly rising hCG might well have indicated a significantly advancing ectopic pregnancy, this was clearly not visible on ultrasound and there were no clinical signs which suggested the diagnosis. It would therefore have been appropriate to have reviewed this in two to four days time, as 100% reliance on a single ultrasound is unwise. This has been recognised in the further advice in that the new protocol requires a further ultrasound to be done by an appropriately qualified Sonographer or Radiologist on high resolution equipment. However, had a qualified Sonographer or Radiologist undertaken a further ultrasound on the same day, 29 June, it is possible that the same situation may well have pertained given that the foetal pole was only 4 mm one week later. However, we are not able to say how this measurement might have been modified by the Methotrexate. The increase in the crown rump length from 4 July to 8 July was appropriate for the period of time. However, as yet no satisfactory explanation has been advanced as to why there was a significant delay in the appearance of the foetal pole.

Within the handwritten notes there is an entry dated 25 June 2002 which indicates that the Beta hCG was 1000 and showed a slow rise, but also that the Progesterone was 250 which meant that ectopic was less likely. However, I cannot confirm this level of Progesterone by an actual result within the file. Progesterone is used as one of the markers for ongoing viability of IVF pregnancies and may also be used as a marker in the diagnosis of ectopic pregnancy. A level of 250 would certainly suggest a viable pregnancy and, as the note suggests, ectopic pregnancy less likely.

In summary therefore, in favour of the diagnosis of ectopic pregnancy was the ultrasound of Saturday, 29 June, where no sac or foetal pole were demonstrated within the uterus, which would have been quite unusual in an intrauterine pregnancy but not impossible. Together with this was the slow initial but subsequently satisfactory rise in the hCG levels, albeit at a lower level. However, against the possibility of ectopic pregnancy was the lack of clinical signs, the lack of any adnexal mass or free fluid on ultrasound in the presence of a reasonably high hCG, the likelihood that the Progesterone level was supportive of intrauterine pregnancy and the satisfactory rise in hCG levels in the 10 days prior to the ultrasound of 29 June 2003. Too much emphasis was placed upon the ultrasound findings to the exclusion of the rest of the clinical picture which indicated a significant degree of doubt with regard to the diagnosis of ectopic pregnancy, particularly when the diagnosis was made on less sensitive portable ultrasound equipment. Mol et al in their discussion of Beta hCG in relationship to transvaginal ultrasound indicated that a cut off level of 1500 units per litre would be appropriate where there was appropriate supporting adenexal abnormalities, but without these findings a cut off level of <u>at least</u> 2000 iu per litre would be appropriate. However, it should be said in [Dr B's] defence that the apparent significant delay in the appearance of the intrauterine pregnancy was very unusual and even when the intrauterine pregnancy was established by ultrasound it was about one week smaller than would have been expected for the gestation on certain dates.

3. [DR B'S] ADVICE ON MANAGEMENT OF ECTOPIC PREGNANCY

Given that [Dr B] felt that the diagnosis of ectopic pregnancy was confirmed and that treatment was required, the three options for management were appropriate. [Mr A] outlines in his letter the options discussed by [Dr B] which are clearly in line with those noted by [Dr B] in her report and in line with current management protocols for the established diagnosis of ectopic pregnancy. Option 1 of conservatism and awaiting the outcome was clearly discussed and excluded because of the life threatening possibilities of tubal rupture and given that the discussion was concerning ectopic pregnancy this was appropriate. Therefore, [Mr and Mrs A] made a decision between medical and surgical management and elected Methotrexate. [Dr B] notes that she did discuss the side effects and the possibility of failure of treatment and therefore it seems likely that this was quite adequately covered. The Clinical Procedures 'Protocol' notes that there was available an information sheet concerning Methotrexate but there is no indication as to whether this was given to [Mr and Mrs A].

However, there was no discussion about the possibility that the diagnosis was as yet not established. Conservative management of further ultrasound to confirm the diagnosis was not considered, as this appeared to be outside the range of possibility although even in her referral letter [Dr B] referred to 'probable' ectopic pregnancy.

4. ADMINISTRATION OF METHOTREXATE FORTHWITH

Given that [Dr B] felt that the diagnosis of ectopic pregnancy was established, then early treatment of this would have been appropriate because of the potential risk to [Mrs A] of tubal rupture in association with the ectopic pregnancy. The diagnosis was made at [the fertility clinic] and she was referred to the ward for treatment by [Dr B]. [Dr B] is a Specialist member of the staff of [the fertility clinic] and as such is on the staff of the [first public hospital] in the capacity of Obstetrician and Gynaecologist. The ward staff actioned the treatment as the diagnosis was felt to be established by [Dr B] and no further diagnostic procedures were undertaken. Once the diagnosis is established there is little point in not proceeding with the treatment forthwith. If the treatment were to have been surgical then this should also have been carried out forthwith because of the risk to the patient of rupture of a tubal ectopic pregnancy.

5. 1999 ECTOPIC PREGNANCY 'PROTOCOL' WHICH WAS IN PLACE AT THE TIME

This protocol was designed to be used in situations where symptomatic patients presented complaining of abdominal pain plus or minus vaginal bleeding and in whom there was a positive pregnancy test. It is likely that these patients would already be inpatients or have been seen in the Gynaecological Assessment Unit and have been scanned within the ultrasound services of the Obstetrical and Gynaecological Service by a qualified scanner. However, the policy did not specify this directly and it may be that diagnoses were made on ultrasound examinations undertaken by less formally trained staff with less sensitive equipment. Where there is room for doubt then all of these scans would need to be confirmed by the Ultrasound Service, whether the treatment was

to be medical or surgical. In this particular instance had surgical treatment been elected then a laparoscopy would not have demonstrated an ectopic pregnancy but intrauterine cannulation at the time of the laparoscopy may well have disrupted a developing intrauterine pregnancy. It may be that the Clinical Procedures statement on ectopic pregnancy assumed high resolution ultrasound in the Ultrasound/Radiology Department, but clearly this did not always happen.

While the hCG 'doubling' protocol is widely used, it should be noted that some patients with normal intrauterine pregnancies may fall below this 'doubling' regime and this perhaps should have been drawn attention to in a positive way in the protocol. However, if the whole clinical picture is taken into consideration then the risk of misdiagnosis would be minimal. From the point of view of an ectopic it is exceptionally unlikely that a developing ectopic would exceed this 'doubling' regime, but it will be noted that if a 66% regime had been used then in excess of 10% of ectopics might have exceeded this regime. There is therefore no entirely satisfactory regime which will cover all possibilities and the 'doubling' regime will virtually exclude ectopic pregnancy and is mathematically easier.

6. COMMENT ON CHANGES

The most important change with regard to the use of Methotrexate has been to ensure that all women who are to receive Methotrexate have a scan on the day of the Methotrexate administration by a certified Sonographer or Radiologist. While this will clearly ensure that the risk of Methotrexate being administered to a patient with an intrauterine pregnancy is reduced to an absolute minimum, one would hope that the diagnostic ultrasound examination used to make the diagnosis initially was of an equal calibre, whatever the ultimate treatment used. The stringency with regard to diagnosis of ectopic pregnancy should be applied at the diagnostic level and no different diagnostic criteria should be applied just because the ectopic is to be dealt with medically by Methotrexate.

The second significant change in the protocol is to ensure that pregnancy loss counselling takes place before Methotrexate is administered. It is suggested that this would have allowed a further review of the situation although I am not sure how the pregnancy loss counselling might have modified the diagnostic process in [Mrs A's] case. The diagnosis of ectopic pregnancy is a medical concern and until the diagnosis is made there is no certainty that there is any 'pregnancy loss'. In terms of pregnancy loss it is difficult to see how the patient who has an ectopic which is dealt with by surgical means has any lesser 'pregnancy loss'. There is of course a longer period of waiting following the treatment, which may be stressful, but nevertheless the loss will be similar. The availability of pregnancy loss counsellors is not stated within the protocol, but one would be surprised if they were consistently available seven days a week and one might envisage a situation where the 'need' for pregnancy loss counselling might delay the treatment process unnecessarily. Once the diagnosis of ectopic pregnancy is made then the treatment should be expeditious, be it medical or surgical. It may be that in the case of [Mrs A] the pregnancy loss counselling was omitted as the diagnosis was made on a

Saturday and [Dr B] felt the need to expedite the treatment as the ectopic was clearly not degenerating as far as the hCG levels were concerned.

The protocol also now suggests, rather than requires, that a second Consultant opinion be obtained unless the diagnosis is 100% clear. The difficulty with this, of course, is that it may only be in retrospect that it was not '100% clear'.

[Ms F], in her letter concerning the changes to the policy reiterates the changes noted above and also indicates pre-decision counselling from a pregnancy loss counsellor and further team discussion prior to proceeding with any formal treatment. This situation should of course apply to both surgical and medical management.

There have been other minor changes to the protocol which will improve the flow and understanding for those using it, but in general they are mainly procedural. It is clear that a review of the ectopic pregnancy protocol is underway to combine the ectopic protocol with the Methotrexate protocol to make them a single document and this will certainly streamline its use. I suspect that the existing Methotrexate protocol was added to the ectopic pregnancy protocol as an addendum as this is a relatively recent form of treatment and that the original protocol was developed before it was an established management. Nevertheless, I would feel that the protocols that were in position at the time were appropriate, but probably needed to be more specific in the directions with regard to the ultrasound diagnosis.

I would however, suggest that wherever ectopic pregnancy is contemplated and that the patient is clinically stable, then the patient be afforded, as far as possible, the benefits of high resolution ultrasound so that inadequacies of diagnosis by lesser trained operators using less sensitive equipment are avoided. Inadequacies around the diagnosis of ectopic pregnancy remain one of the high generators of medicolegal dispute.

I would also suggest that if pregnancy loss counselling is to be introduced following the diagnosis of ectopic pregnancy, then consideration should be given to pregnancy loss counselling in all cases. It is of course probable that those to be treated surgically are more likely to be in a group in which deterioration because of intraperitoneal bleeding will occur and require more urgent attention. Nevertheless their pregnancy loss is ultimately no different, only the management differs.

[Dr D] has also noted that policies with regard to the hormonal monitoring of early pregnancy progress in assisted reproductive techniques will be modified so that hormonal assays will only be done on a weekly basis. I would agree with him that this is likely to reduce the level of tension around the assay situation in a group of patients where there is often a significant degree of anxiety. He also notes that [the fertility clinic] will ensure that high resolution ultrasound in the Department of Radiology will be undertaken before Methotrexate is administered. I would suggest that the same proviso applies here, that the quality of the original diagnostic ultrasound needs to be of an equivalent calibre whether the treatment is ultimately medical or surgical.

In summary, [Dr B] was unfortunately caught in a situation where pregnancy development was significantly outside the norm and, although some criteria of ectopic pregnancy were present, there was a minimum of other supporting evidence. Her concern with regard to the possibility of a rupturing ectopic and its potential consequences for [Mrs A], overrode the appreciation of the fuller picture. However, as noted previously, the development did appear to be very significantly delayed and a further ultrasound on the same day under ideal circumstances may well still have not confirmed the intrauterine nature of the pregnancy.

Finally I would note, from recently forwarded information, that a new legible graph is now available for plotting the hCG levels.

I would be very happy to discuss or review the situation should you have any further queries. I will include copies of the RCOG Guideline and Review Statements.

REFERENCES

1. Sau A, Hamilton-Fairley D. The Obstetrician & Gynaecologist 2003; 5: 29-33. Non Surgical Diagnosis and Management of Ectopic Pregnancy.

2. Kadar N, De Vore G, Romero R. Obstet Gynaecol 1981; 58: 156-61. Discriminatory HCG Zone: Its Use in Sonographic Evaluation for Ectopic Pregnancy.

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5. Mol BWJ, Hajenius PJ, Engelsbel S, Ankum WM, van de Veen F, Hemrika DJ, Bossuyt PMM. Fertil Steril 1998; 70: 1972-81. Serum Human Chorionic Gonadotrophin Measurements in the Diagnosis of Ectopic Pregnancy when Transvaginal Ultrasonography is Inconclusive."

Gynaecology advice

The following expert advice was obtained from Dr John Hutton, an independent gynaecologist with experience in infertility treatment:

"Thank you for forwarding me relevant documents from this complaint file.

You have asked me to provide additional advice to the Commissioner about services provided to [Mrs A] by [Dr B] and [the fertility clinic] (Case Number 10862/…). I have read and agree to follow the Commissioner's guidelines for Independent Advisors.

My qualifications are:

M.B., Ch. B	University of Otago	1968
MRCOG	Royal College of Obstetricians and Gynaecologists	1974
Ph D	University of London	1979
FRANZCOG	Royal Australian and New Zealand College of Obstetricians and Gynaecologists	1982
FRCOG	Royal College of Obstetricians and Gynaecologists	1986
CREI	Royal Australian and New Zealand College of Obstetricians and Gynaecologists	1998

I believe I am able to be an objective peer reviewer of this case because I am the Medical Director of a Fertility Clinic in New Zealand, and involved in the management of cases such as this for at least the last ten years. Although I do not have a specialist ultrasound qualification, I, like [Dr B], undertake many vaginal ultrasound examinations and am involved, almost on a weekly basis, [in] managing women during the early stages of a pregnancy that is consequent upon IVF – including abnormal pregnancy. The current practice of an IVF pregnancy that is associated with a slow and late rise of HCG levels is today no different than it was in June or July 2002.

In agreeing to follow the guidelines for Independent Advisors, my advice to you is based on the standards within an IVF clinic practice in a major centre in New Zealand. I have maintained some professional contact with [the first public hospital], and know the broad arrangements within [the fertility clinic] for the management of their patients. I am also associated with the care of IVF patients at [a city hospital].

I have known [Dr B] in only a professional capacity, and for at least 20 years – we meet and have discussions at meetings of professional organisations with which we are both associated. I do not have any conflict of interest although I am a Director of [a fertility clinic], and therefore know that [the two fertility clinics] share the public contract for publicly funded tertiary fertility services in [a city]. I note also in the letter of complaint that the couple have elected to a 'further round of IVF treatment … with [the second fertility clinic]' (should they have one …).

I note you have stated the complaint to me as '*That in June and July 2002, [Dr B]/[the fertility clinic] did not provide services of an appropriate standard to [Mrs A]. In particular, on 29 June 2002:*

- *following an earlier ultrasound scan, [Dr B]/[the fertility clinic] staff incorrectly diagnosed [Mrs A] with an ectopic pregnancy*
- *without assuring herself that the pregnancy was in fact ectopic, [Dr B]/[the fertility clinic] staff advised [Mrs A] that she had two options; to terminate the pregnancy surgically, or with methotrexate*

- *without assuring herself that the pregnancy was in fact ectopic, [Dr B]/[the fertility clinic] staff arranged for the drug methotrexate to be administered*
- *[Dr B]/[the fertility clinic] staff arranged for methotrexate to be administered, without giving [Mrs A] sufficient time to reflect on whether she had made the right decision to terminate the pregnancy with the drug.*

In June or July 2002, [Dr B]/[the fertility clinic] did not provide [Mrs A] with information that a reasonable consumer in [Mrs A's] circumstances would expect to receive. In particular, [Dr B]/[the fertility clinic] staff did not provide [Mrs A] with adequate information about methotrexate and the risks it posed to a potentially viable foetus.

I have also read the following supporting documents you forwarded, namely:

- *Letter of complaint to the Commissioner from [Mr and Mrs A], dated 5 August 2002, marked 'A' (pages 1-2A).*
- *Copies of notification of investigation letters to [Dr B] and [the fertility clinic], dated 6 January 2003, marked 'B' (pages 3-8).*
- *Letter to the Commissioner from [Dr B], dated 31 January 2003, marked 'C' (pages 9-10).*
- *Letter to the Commissioner from [Dr D], Clinical Director [of the fertility clinic], dated 4 February 2003, marked 'D' (pages 11-12).*
- *Letter to the Commissioner from [Ms F], Consumer Liaison Team Leader, [for the first public hospital], dated 14 February 2003, and attachments, marked 'E' (pages 13-17).*
- *[Mrs A's] clinical records, including scan results, received under cover of letter dated 26 February 2003, marked 'F' (pages 18-196).*
- *Letter to the Commissioner from Ms F, dated 13 March 2003, and attachments, marked 'G' (pages 197-220).*
- *Email to HDC Investigation Officer from [the] Quality Manager [of the first public hospital], dated 7 April 2003, attaching September 1999 policy 'Ectopic Pregnancy', and copy of HDC administration action note dated 9 April 2003, marked 'H' (pages 221-234).*
- *Letter from [Dr B] dated 5 December 2003 and attachment, marked 'I' (pages 235-236)*
- *A full copy of the previous advice provided by Dr Peter Dukes, with enclosures, marked 'J' (pages 237-260)*
- *Copy of finalised ectopic pregnancy document from [the first public hospital], marked 'K' (pages 261-270)*

You have summarised the facts as:

[Mrs A] underwent an IVF plus ICSI cycle at [the fertility clinic], because of oligospermia. Two embryos were placed into her uterus on 1 June 2002. [Mrs A's] Beta hCG levels were recorded as follows:

- *12 June (day 14)* *48.9*
- *14 June (day 16)* *57.8*
- *19 June (day 21)* *95*
- *24 June (day 26)* *1010*
- *28 June (day 30)* *2972*

On 29 June 2002, [Dr B], Obstetrician and Gynaecologist, performed a transvaginal ultrasound scan at [the fertility clinic]. Although she felt she had a good view of the uterus, she did not identify an intrauterine sac. [Dr B] thought [Mrs A] had a probable ectopic pregnancy.

[Dr B] discussed with [Mrs A] and her husband [Mr A] management options for ectopic pregnancy. Medical treatment with methotrexate was decided on. [Mrs A] was admitted to [the first public hospital] that day, 29 June 2002, and 85mg of methotrexate was administered.

On 4 July 2002, [Mrs A] was reviewed at [the first public hospital] because her Beta hCG levels had continued to rise. An ultrasound scan confirmed the presence of a single live intrauterine fetus in a small gestational sac, and no evidence of ectopic pregnancy. The crown/rump length was 4mm. A subsequent ultrasound scan showed further growth.

As the effect of the methotrexate on the fetus was unknown, [Mr and Mrs A] decided to terminate the pregnancy.

Since these events, a number of actions have been taken by [the first public hospital]. This includes a new requirement that an ultrasound be performed on a high resolution ultrasound machine at the hospital on the day of the methotrexate administration, by a certified sonographer or radiologist.

I would agree with your summary.

I now respond to your questions of me:

1. Is it usual practice for obstetricians working in a fertility clinic to perform transvaginal ultrasound scans?

Yes – gynaecologists with the experience and expertise that [Dr B] has perform transvaginal ultrasounds all the time, including during early pregnancy.

2. If so, are the results of those scans checked by another person? Who?

The results of scans are not normally checked by another practitioner at the time of an examination of follicle size, endometrial thickness or intrauterine pregnancy viability. However, there is an indirect check by way of blood tests usually done concurrently. When there is an abnormal or incongruous finding and particularly if there is an intervention planned, (such as D and C, or methotrexate therapy) then the findings are

always checked in some way. One common way of doing this is for the person conducting the scan to repeat the examination at a later date, say three days – more usually this is 7 to 14 days but this depends on the abnormality and the doctor or patient anxiety factor. If the patient (or doctor) wishes the repeat examination immediately because, say, they are wishing early/immediate intervention, then another doctor in the clinic would be called in to conduct a separate examination, or, more usually, the patient is sent to a more specialist ultrasound facility. Thus, the results are always checked in some way, and especially before any intervention.

I note that in this case there was no check scan – however, the standard practice in fertility clinics in [Mrs A's] case would have been to adopt a normal cautious non-interventionist approach, especially as the rate of HCG rise was occurring normally, albeit to the 'right' of normal intrauterine pregnancies (ie the levels were below the limit regarded as being in the normal range (90^{th} per centiles). (In other words, in 5% of pregnancies where there is a normal outcome/birth, the levels can be expected to be below the 5^{th} percentile line). Only if the patient demanded immediate intervention (such as by going overseas or into the backblocks in a couple of days) would the patient be referred to a specialist ultrasound facility. Indeed, there was the perfect excuse not to rush into intervention with this asymptomatic patient because it was a Saturday, and to wait at least until Monday at the earliest for the check scan.

3. The only record of the ultrasound performed by [Dr B] on 29 June 2002 is the note she recorded in [Mrs A's] clinical notes on this day (copy attached with [Dr B's] letter of 5 December 2003). Is it usual that this would be the only record? Is this an adequate record?

I can accept that the only record of the ultrasound performed by [Dr B] that Saturday in June 2002 was the note in [Mrs A's] clinic notes. However, there would normally also be an additional record in the referral note to the hospital if there was one written at the same time. I believe the record made is adequate by the standards then occurring, and this was a Saturday. Incidentally at [the second fertility clinic in another city], an additional form/record for early pregnancy scans was introduced in about March 2003, and all doctors are required to complete it after every early pregnancy scan – a copy of the result is then sent with any letters. However, I do not think having a form such as is current in [the second fertility clinic in the other city] (Appendix 1) would have made any difference here – the problem was the incorrect decision and management was made with the information!

4. Please comment on the ultrasound machine that was used by [Dr B] on 29 June 2002. Is it possible that a higher calibre machine could have detected an intrauterine pregnancy? Was the machine used by [Dr B] of a sufficiently high calibre to diagnose an ectopic pregnancy?

I do believe the ultrasound machine used by [Dr B] was of a high enough calibre to detect an intrauterine pregnancy, provided it is done when an intrauterine sac can be expected to be seen, and this depends on the HCG levels (always remembering that the blood level is only an indirect measure of the amount of HCG being produced), on the

gestation and the number of sacs. Whilst Stovall and Ling (1993) have an algorithm that suggests a **viable** intrauterine pregnancy sac should be visible with an HCG level of 2000+ iu/l, the HCG levels already showed that this was not a normal pregnancy and may not have been viable – hence caution in interpreting the result was required. I agree with Dr Dukes' report outlining the rationale and reliability of scanning machines in early pregnancy.

I believe that it very likely that [Dr B], using the fertility clinic ultrasound, would also have been able to diagnose the intrauterine pregnancy when the more high calibre machine did so a couple of days after the methotrexate injection – the reason she did not see the sac was that the sac was not yet big enough, and this was reflected in the HCG levels (assuming a single sac!). It is possible that [Dr B] or another operator using a higher calibre machine could have detected an intrauterine pregnancy on the 29th June 2002 but a better management would have been to simply wait a few days and repeat the scan on the fertility clinic scanner, and this would probably also have then detected an intrauterine pregnancy. Having a higher calibre scanner would probably not have made any difference here – the unfortunate outcome was consequent only on the interpretation and decisions made with the information!

5. Please comment on the current 'ectopic pregnancy' document in place at [the first public hospital].

The June 2003 policy manual is an excellent document from the medical viewpoint, and, like Dr Dukes, I agree that the rationale for counselling with medical treatment should also occur with surgical treatment, and is simply not feasible, especially as the management of many abnormal pregnancies occurs after hours. I attach (Appendix 2) the recently completed [second fertility clinic's] protocol about Early Pregnancy Monitoring – we have not previously had a written protocol.

6. Please comment on any other matter which, in your opinion, should be brought to the Commissioner's attention.

No further comment. Indeed, I agree with the judgments and opinions of Dr Dukes, and his report is a very fair review of the situation. Furthermore, all the references he uses, I would have used as well! [Dr B] was lulled by the HCG levels into making this tragic mistake, and there was then no 'systemic' protection that might have avoided the very tragic consequences. Unfortunately, there were many reasons for her to have stalled the treatment but conversely, the consequence of a ruptured ectopic pregnancy may, very occasionally, seriously compromise the mother's health, even in an urban environment – fortunately however, this is rare, especially when the level of HCG is low (as in this case). I have graphed the HCG results on the HCG chart used by [the second fertility clinic], and the interpretation of the levels and trends is the same (Appendix 3) as that which would have occurred with the chart used within [the fertility clinic].

…

Stovall TG, Ling FW (1993) Ectopic pregnancy. Diagnostic and therapeutic algorithms minimizing surgical intervention. J Reprod Med. 1993;38(10):807-12."

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.

RIGHT 6
Right to be Fully Informed

1) Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including –
(a) An explanation of his or her condition; and
(b) An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; …

Opinion: Breach – Dr B

Right 4(1)
Right 4(1) of the Code of Health and Disability Services Consumers' Rights states that patients have the right to services provided with reasonable care and skill. On Saturday, 29 June 2002, Dr B performed a transvaginal ultrasound scan on Mrs A at the fertility clinic, and made a diagnosis of an ectopic pregnancy. It is not disputed that the diagnosis of an ectopic pregnancy was incorrect. An incorrect diagnosis does not in itself amount to a breach of the Code. Rather, I need to form an opinion on whether Dr B acted with reasonable care and skill in reaching her diagnosis, on the basis of the information that was available to her at the time.

Diagnosis of ectopic pregnancy
Although Dr B advised me that she thought Mrs A had a "probable" ectopic pregnancy, and when she referred Mrs A for the administration of methotrexate she described the pregnancy as a "probable ectopic pregnancy", I note her advice that methotrexate would not be offered in the case of a potentially viable pregnancy. I also note the following comment from Dr Dukes:

> "Although [Dr B] states that she felt the diagnosis was a 'probable' ectopic it is clear, from her actions, that she felt this diagnosis was fully sustained by the findings."

I agree with Dr Dukes that given Dr B's actions, it is reasonable to assume that she actually made a definitive diagnosis of an ectopic pregnancy. I have therefore assumed a definitive diagnosis in forming an opinion on the first aspect of the complaint, that Dr B incorrectly diagnosed an ectopic pregnancy.

My obstetric advisor, Dr Dukes, summarised the relevant factors to be taken into account in reaching a diagnosis. First, there was no visible intrauterine sac when Dr B performed the ultrasound on 29 June 2002. The day before the scan Mrs A's Beta hCG level was 2972. Dr Dukes noted that the "Ectopic Pregnancy" clinical procedures protocol indicates that intrauterine gestations should be seen on transvaginal ultrasound when the Beta hCG level is greater than 1500, and that Dr B therefore appropriately felt that the protocol criterion was satisfactorily fulfilled. In addition to the lack of an identifiable intrauterine sac, Dr B was influenced in reaching her diagnosis by the abnormal early slow rise of the Beta hCG levels. Dr Dukes agreed this was a relevant factor.

However, according to Dr Dukes, these two factors were not representative of the full clinical picture. Dr Dukes pointed out that there was a lack of clinical signs of an ectopic pregnancy, and a lack of adnexal mass or free fluid in the presence of a "reasonably high" hCG. In addition, a note on file reported a progesterone level of 250 (although this was not confirmed with a copy of the actual test result). Dr Dukes advised this level of progesterone is supportive of an intrauterine pregnancy. He also noted the satisfactory rise of hCG levels in the ten days prior to the ultrasound. Dr Dukes advised me that even if the results (which were below the lower limit of the usual "doubling rise") were not interpreted as satisfactory, research shows that up to 15% of "normal" pregnancies may show increases below this usual range. He stated:

> "Too much emphasis was placed upon the ultrasound findings to the exclusion of the rest of the clinical picture which indicated a significant degree of doubt with regard to the diagnosis of ectopic pregnancy …"

My gynaecological advisor, Dr Hutton, suggested that extra caution was required in interpreting Mrs A's results. This was because it is expected that a *viable* intrauterine pregnancy should be detectable at an hCG level of 2000+iu/l. However, in Mrs A's case, the hCG levels that had been obtained showed that the pregnancy was not normal, and may not have been viable, hence the need for caution in interpreting results.

Checking of the ultrasound results

Both my advisors agree that it would have been prudent for Dr B to have repeated the scan in several days' time. Dr Hutton advised that the standard practice of fertility clinics (both in 2002 and currently) is always to perform some form of check "when there is an abnormal or incongruous finding and particularly if there is some form of intervention planned", as in Mrs A's case. A common form of check is by a repeat examination performed by the same practitioner after an interval – which may be at around three days, but is usually longer. Dr Hutton noted that Mrs A was asymptomatic. In her case, it would have been appropriate to

have waited at least until Monday for the check scan. If for any reason immediate treatment is required, another doctor is called to perform a repeat check or (more usually) the patient is sent to a more specialised ultrasound facility. In Dr Hutton's words: "[T]he results are always checked in some way, and especially before any intervention." In Mrs A's case no check occurred. There was therefore a deviation from standard practice.

I accept the advice of my independent experts. In my opinion, in relying on the ultrasound findings to the exclusion of other factors, and in deviating from standard practice by failing to arrange any form of check of the results when intervention was planned, Dr B did not provide services to Mrs A with reasonable skill and care. In the circumstances, Dr B breached Right 4(1) of the Code.

Explanation of condition and options
Under Right 6(1) of the Code, every patient has the right to information that a reasonable patient, in that patient's circumstances, would expect to receive, including an explanation of his or her condition and the available options.

In my opinion, Dr B's most significant omission in this case was her failure to explain to Mr and Mrs A the limitations of a diagnosis of ectopic pregnancy on a single ultrasound, in a woman in Mrs A's circumstances. There is no evidence that Dr B explained that a repeat scan, to check the diagnosis of ectopic pregnancy, was possible. As noted by Dr Hutton, Mr and Mrs A were not told that "the standard practice in fertility clinics in [Mrs A's] case would have been to adopt a normal cautious non-interventional approach".

Patients are critically dependent on doctors for information. Even if a doctor is confident in her diagnosis, she needs to provide contextual information. A reasonable couple, devastated by the news that IVF/ICSI treatment has resulted in an ectopic pregnancy, would expect to be told that such a diagnosis is not 100% certain and that many clinicians would undertake a second scan in a couple of days. As Dr Hutton commented, "[T]here was the perfect excuse not to rush into intervention with this asymptomatic patient because it was a Saturday, and to wait at least until Monday at the earliest for the check scan."

Mr and Mrs A were deprived of this information. They assumed that Dr B had given them the full picture, and made the decision to proceed on that basis. In these circumstances Dr B provided insufficient information, and breached Right 6(1) of the Code.

Opinion: No breach – Dr B

Interpretation of ultrasound results and sensitivity of ultrasound machine
My gynaecological advisor, Dr Hutton, commented that it is common practice for an obstetrician working in a fertility clinic to perform transvaginal ultrasound scans. It was therefore appropriate for Dr B to interpret Mrs A's results.

My obstetric advisor, Dr Dukes, stated that Dr B was "perhaps unwise" to rely on a single ultrasound on less sensitive equipment "in such a critical situation". This raises the issue of whether the particular machine used by Dr B was appropriate for the diagnosis of a suspected ectopic pregnancy. The machine used was a Siemens Omnia.

I requested further advice about the appropriateness of this machine from my gynaecological advisor. Dr Hutton advised me that this machine should have been able to detect a viable pregnancy if the scan was performed when a sac could be expected to be visible, which in turn is dependent on the hCG levels. Both my advisors acknowledge that it is possible that even a higher calibre machine may not have been able to detect Mrs A's pregnancy on 29 June. In relation to this, Dr Dukes pointed out that the foetal pole was only 4 mm one week later, although admittedly it could have been modified by the methotrexate by this stage.

Dr Hutton stated that although it is possible a higher calibre machine could have detected an intrauterine pregnancy on 29 June, better management would have been simply to repeat the scan on the fertility clinic's machine in a few days' time; he believes the pregnancy would also have been visible on the fertility clinic's scanner. Dr Hutton pointed out:

> "Having a higher calibre scanner would probably not have made any difference here – the unfortunate outcome was consequent only on the interpretation and decisions made with the information."

There is no evidence to suggest that Dr B made an inappropriate decision to perform Mrs A's scan using the scanner at the fertility clinic. I agree with Dr Hutton that having a higher calibre scanner would not have made a difference in this case. The problem resulted from a failure to arrange any form of check of the results before proceeding with an intervention.

Record-keeping
The only record of Dr B's scan on 29 June 2002 was a handwritten note in Mrs A's clinical records. Dr Hutton advised that he can accept that this is the only record, bearing in mind the standards in 2002, and the fact that it was a Saturday. He does not believe that having a form would have made any difference. Again, the problem was the incorrect decision, and the management decided upon with the information.

Management decisions for an ectopic pregnancy
The second and third bullet points of the complaint were notified as follows:

- without assuring herself that the pregnancy was in fact ectopic, Dr B advised Mrs A that she had two options: to terminate the pregnancy surgically, or with methotrexate

- without assuring herself that the pregnancy was in fact ectopic, Dr B arranged for the drug methotrexate to be administered.

These points both relate to the management decisions that Dr B made, and conveyed to Mr and Mrs A, on the basis of her diagnosis of an ectopic pregnancy. Dr B in fact discussed

three options. In addition to the options of methotrexate or surgery, "expectant management" of the pregnancy (with the associated risk of rupture of the fallopian tube), was discussed. According to Dr Dukes, the three management options Dr B discussed were appropriate options for managing a diagnosis of ectopic pregnancy. The information conveyed to Mr and Mrs A therefore would have been appropriate, had the diagnosis of an ectopic pregnancy been correct.

In relation to the second point, there is no evidence to indicate that the administration of methotrexate is an inappropriate management decision for an ectopic pregnancy. Again, the problem was the incorrect diagnosis, not the advice to administer methotrexate.

Accordingly I do not find Dr B in breach of the Code in relation to these matters.

Insufficient time to reflect on decision to terminate pregnancy

Mr and Mrs A complained that Dr B arranged for methotrexate to be administered, without giving Mrs A sufficient time to reflect on whether she had made the right decision to terminate the pregnancy. Dr Dukes commented that "once the diagnosis is established there is little point in not proceeding to treatment forthwith because of the risk to the patient of rupture of an ectopic pregnancy". However, Dr Hutton noted (in the context of the wisdom of checking the original ultrasound scan) that "there was the perfect excuse not to rush into intervention with this asymptomatic patient because it was a Saturday, and to wait at least until Monday at the earliest for the check scan".

Unless, in clinical terms, it is absolutely necessary to proceed to an intervention, it is wise practice to allow a patient (and family) time to reflect on the proposed treatment rather than consent immediately. This is especially the case if the patient is grieving or in shock (as was Mrs A after the diagnosis of an ectopic pregnancy), and the decision is an emotional one (such as termination of pregnancy).

In light of Dr Dukes' comments, it would be unfair to find Dr B in breach of the Code in this respect. I suspect that many obstetricians would, with their patient's consent, arrange immediate intervention in similar circumstances. However, I recommend that Dr B carefully reflect on Mr and Mrs A's complaint that they were given insufficient time to reflect on the decision to terminate the pregnancy.

Information about risks of methotrexate

Under Right 6(1)(b) of the Code, every patient has the right to the information that a reasonable patient, in that patient's circumstances, would expect to receive, including information about the risks and side effects of proposed treatment options. Mr and Mrs A complained that Dr B did not provide Mrs A with adequate information about the risks methotrexate posed to a potentially viable foetus.

Dr B advised me that she discussed with Mr and Mrs A the side effects and possible failure of methotrexate treatment. She did not discuss the effects of methotrexate on a potentially viable pregnancy, because if a pregnancy were potentially viable, methotrexate would not be offered or accepted.

In my opinion, Dr B did not breach Right 6(1) of the Code by not informing Mr and Mrs A of the risks methotrexate posed to a potentially viable foetus. I accept that if Dr B had considered the pregnancy to be potentially viable, she would not have offered methotrexate. The aim of taking methotrexate is to terminate a pregnancy. Therefore, information about the risks posed to a potentially viable foetus is not information a reasonable patient would expect to receive.

Opinion: No breach – The First Public Hospital

Administration of methotrexate
On 29 June 2002, after diagnosing Mrs A with an ectopic pregnancy, Dr B referred her to the ward of the first public hospital for methotrexate to be administered.

Mrs A was admitted and administered 85mg methotrexate intramuscularly. Ward staff did not undertake any further diagnostic procedures. My advisor explained that staff followed the methotrexate administration protocol in place at the time. I note that since these events the protocol has been updated to include the requirement that all women having methotrexate undergo an ultrasound scan by a certified sonographer or radiologist on the day of methotrexate administration.

My advisor noted that ward staff actioned the treatment on the basis of a diagnosis of ectopic pregnancy, which Dr B felt was established. The decision to administer methotrexate was made by Dr B at the fertility clinic, before Mrs A went to the hospital for the treatment to be undertaken. As stated by Dr Dukes, "[T]he ward staff actioned the treatment as the diagnosis was felt to be established by [Dr B] and no further diagnostic procedures were undertaken." Dr B is a specialist obstetrician and gynaecologist, employed by the hospital as a member of the staff of the fertility clinic.

In my opinion, the hospital staff who carried out the methotrexate administration did not breach the Code. They followed the protocol in place at the time and were appropriately guided by Dr B's diagnosis and decision to administer methotrexate.

Opinion: No breach – The First Public Hospital / The Fertility Clinic

Vicarious liability
Employers are responsible under section 72(2) of the Health and Disability Commissioner Act 1994 for ensuring that employees comply with the Code. At the time of the events complained about, the first public hospital employed Dr B as a specialist obstetrician and gynaecologist at its fertility clinic.

Under section 72(5) it is a defence for an employer to prove that it took such steps as were reasonably practicable to prevent the employee from doing or omitting to do the thing that breached the Code. The hospital provided me with the protocols in place at the time for diagnosing ectopic pregnancies and administering methotrexate in the event of an ectopic pregnancy.

I note that the protocol in place at the time did not specify that an ultrasound was to be carried out by a certified sonographer or radiologist on a high-resolution machine before methotrexate was administered. However, in response to my provisional opinion, the hospital advised me that this was consistent with the standards prevailing in the sector in 2002. It suggested that subsequent changes to the policy, as part of a process of continuous improvement, should not be taken to imply that the previous policy was inappropriate. The policy was intended as a clinical guideline (recommended best practice) rather than mandatory policy.

I also note Dr Dukes' advice:

> "The protocols that were in place at the time were appropriate, but probably needed to be more specific in the directions with regard to the ultrasound diagnosis."

The hospital has made appropriate changes to the policy in light of these events. I am persuaded by the argument that it is only with the benefit of hindsight that the need for changes to the policy became apparent.

Accordingly, in my view the hospital/the fertility clinic took reasonable steps to prevent Dr B's breach of the Code, and is therefore not vicariously liable.

Other comments

The First Public Hospital

Pregnancy loss counselling
I also note that under the "Medical Treatment of Ectopic pregnancy" section of the ectopic pregnancy document, it is stated:

> "Pre-treatment counselling by the pregnancy loss counsellor / on call social worker should be offered at all times."

I agree with Dr Dukes that it is unclear how pre-treatment pregnancy loss counselling might have changed the outcome for the couple. However, both my advisors, while noting the difficulties that may arise in making pregnancy loss counselling continually available after hours, recommended that the updated protocol offering counselling to people for whom medical management is being contemplated be amended to extend to people for whom surgical management is being contemplated. As stated by Dr Dukes, "[I]t is difficult to see

how the patient who has an ectopic which is dealt with by surgical means has any lesser 'pregnancy loss'."

Actions taken

I note that the following actions have already occurred:

- Dr B and the first public hospital have apologised to Mr and Mrs A for the incorrect diagnosis of an ectopic pregnancy.

- In response to my provisional opinion, Dr B confirmed she has reviewed her practice as a result of this incident. She advised me: "Such an event has a significant impact which provokes a revision of one's practice."

- The first public hospital has updated its policies and procedures in relation to early pregnancy care for fertility patients, the diagnosis of ectopic pregnancy, and medical management with methotrexate. I note my advisor's comments that the changes should reduce to an "absolute minimum" the risk of methotrexate being administered to a patient with an intrauterine pregnancy. Specifically, its "Methotrexate (IM) Administration for Persistent Ectopic Pregnancy" policy now requires that an ultrasound be performed in the Department of Radiology on a high-resolution ultrasound machine by a certified sonographer or radiologist before methotrexate is administered. The hospital has also confirmed that the policy now requires pregnancy loss counselling both before administration of methotrexate, and in cases of surgical management when it is appropriate because the woman is asymptomatic. It has been pointed out that ectopic pregnancy is a potentially lethal abnormality and there may be some cases where a delay to facilitate counselling could prove fatal. I recommend that the hospital consider further amendment of the policy to include an explicit statement about the requirement to check ultrasound findings, in the manner outlined in Dr Hutton's advice.

- I note Dr Dukes' comments about the illegibility of the logarithmic graph that was used by the fertility clinic staff to plot the Beta hCG levels. Since these events a new (and legible) form for plotting the serial assay readings has been designed.

- The fertility clinic has changed its policy with regard to hormonal monitoring of early pregnancy to a weekly reading rather than more frequent readings. I agree with Dr Dukes that this is likely to reduce the level of tension connected with the assay reading for patients, such as Mr and Mrs A, who may be experiencing a significant degree of anxiety about the results.

I commend the hospital and the fertility clinic on these changes.

Follow-up actions

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

- A copy of this report, with all identifying features removed, will be sent to the Royal New Zealand College of Obstetricians and Gynaecologists, and Fertility New Zealand, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.