Dr B – General Practitioner

A Report by the

Health and Disability Commissioner

(Case 03HDC16721)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Ms A	Consumer / Complainant
Dr B	Provider / General Practitioner
Dr C	General Practitioner
Dr D	Pathologist
Dr E	Obstetrician

Complaint

On 7 November 2003 the Commissioner received a complaint from Ms A about the services provided to her by Dr B, of a town health centre. The following issue arising from the complaint was investigated:

- *The circumstances surrounding the placement of an IUCD by Dr B on 29 May 2003.*

An investigation was commenced on 29 January 2004.

Dr B has not responded to the Commissioner's notification of the investigation and subsequent correspondence. Dr B gave a statement to the Police for the purposes of a Coroner's inquiry arising out of the same events. The Police forwarded the statement and Ms A's medical records to the Commissioner during the investigation. Dr B refused to sign the Police statement.

Information reviewed

- Dr B's medical records for Ms A
- Dr B's report to the Police
- Ms A's medical records from general practitioner Dr C
- Ms A's medical records from the Public Hospital
- Report to the Coroner prepared by the Police including report of pathologist Dr D
- ACC file in relation to medical misadventure claim.

Independent expert advice was obtained from Dr Helen Moriarty, general practitioner.

Information gathered during investigation

Overview

On 29 May 2003 Dr B fitted an intrauterine contraceptive device (IUCD) for Ms A (aged 23 years). Neither of them was aware that Ms A was pregnant at the time. On 18 June Ms A suddenly gave birth to a baby boy, who died shortly after birth. After Ms A had been admitted to hospital on 23 June, with severe infection caused by retained placenta on 23 June, her mother reported the matter to the Police.

Background
Ms A's first baby was born in 1998. Dr B was not involved with her care at the time and the first pregnancy is not relevant to this investigation.

Dr B's first consultation with Ms A was on 24 December 1998 for her first antenatal check for her second pregnancy. Ms A had been referred by her usual general practitioner, Dr C, as he does not practise obstetrics. The pregnancy and birth proceeded normally and the baby, born in April 1999, had no complications.

On 28 [June] 1999 Ms A saw Dr B for a postnatal check and contraceptive advice at which she requested an IUCD. Dr B referred her back to Dr C for ongoing care.

Dr B did not see Ms A again until 13 August 1999 when he inserted a copper multi-load 375 IUCD. Dr B also took a cervical smear and, as the result of the test was abnormal, he referred Ms A to a gynaecologist for a colposcopy. The gynaecologist recommended that Ms A have cervical smears every year thereafter.

On 31 May 2001 Ms A consulted Dr B for her first antenatal visit in her third pregnancy. Ms A was unaware that she was pregnant until late in the pregnancy. She believed she conceived this child while the IUCD was in situ, and Dr B reported that he did not find the device which he had fitted in August 1999. Dr B considered that, as Ms A reported feeling no foetal movements until about 29 weeks (usually movements would first be reported at about 19 weeks, especially in a second pregnancy), she was a person who was "relatively unaware of her pregnant state".

Ms A advised me that during her first and second pregnancies she ceased menstruating but during her third pregnancy she continued to menstruate every 27 to 29 days and felt no foetal movements until just before the baby was born. She recalled taking a pregnancy test, which was positive, before consulting Dr C, who thought she was four months pregnant. Dr B thought she was six and a half months pregnant but the scan showed her to be seven and a half months pregnant.

Dr B reported that although Ms A believed she had been menstruating throughout her pregnancy, it is possible for women to have vaginal bleeding or episodes of bleeding throughout pregnancy, which can be misconstrued as menstruation, although this is unusual. He felt that in this situation, Ms A may have believed that she was menstruating throughout her pregnancy when she was not.

The third pregnancy was relatively normal and the baby was born on 24 July 2001, following a natural birth with no complications.

On 6 August 2001 Dr B saw Ms A for her postnatal check. They again discussed contraception, including whether her partner should have a vasectomy. On 7 September 2001 Dr B discussed IUCD contraception, and they again discussed a vasectomy. Ms A had an IUCD fitted on 18 October, which fell out about ten days after placement. It was replaced on 6 December 2001. Ms A told me that this IUCD was not satisfactory; every period was quite painful and she could feel the device, and by December 2002 it felt as though it was in the wrong place or had fallen out.

Dr B explained in his statement to the Police that it is not uncommon for an IUCD to fall out, particularly if it is fitted after childbirth. This is because the uterus may still be enlarged after childbirth and, as it shrinks back to normal size, the IUCD can be expelled at the same time. The device is more likely to stay in place if it is fitted after a reasonable period of time after childbirth, when the uterus is at normal size.

Fourth pregnancy
In January 2003 Dr B received a letter from Dr C asking if he would see Ms A again for an IUCD insertion. Dr C's letter, dated 8 January 2003, stated:

> "Would you kindly see [Ms A] for consideration of reinsertion of an IUCD. We have in the past discussed her barrier contraception and the possibility that her partner may well undertake a vasectomy. This however, has not happened and she would like to see you again."

Dr B explained to the Police that he thought Dr C's letter said that Ms A had been using a different form of contraception.

Ms A told me she made an appointment with Dr B in January 2003 but then "it [her pain] settled down", so she cancelled it. Ms A thought the IUCD had fallen out in April and a home pregnancy test, recorded at the time, was negative. By May she realised the device had definitely fallen out. She made an appointment with Dr B and an IUCD was fitted about ten days later, on 29 May 2003. It is this fitting that is the subject of Ms A's complaint and my investigation.

When Dr B fitted the IUCD on 29 May 2003 Ms A was approximately 33 weeks pregnant, although unaware of it. She advised me that she had been menstruating regularly every 27 to 29 days (as she did with her third pregnancy). No pregnancy test was carried out prior to the insertion of the IUCD and Dr B did not ask about her menstrual dates. She recalled that the consultation took a long time, perhaps 40 minutes, and she was worried because she had to collect her children from kindergarten. She said Dr B did not have a chaperone, which she thought unusual, and he kept leaving the room, interrupting the consultation.

Dr B examined Ms A and reported that she showed no outward signs of pregnancy, although she said she was a little overweight. He advised me that he does not carry out a pregnancy test as a matter of course unless there are reasons for believing that the woman

may possibly be pregnant. He told the Police that "to a certain extent we rely on the women telling us whether they suspect they may be pregnant". He said he performed "the normal checks and smears" and recorded that the uterine cavity measured 8cm, and chlamydia and vaginal swabs were normal. He also told the Police that he saw nothing from his examination to indicate pregnancy. Furthermore, in her previous pregnancies Ms A was not someone who looked outwardly pregnant until the latter part of her pregnancy.

Dr B advised me that when fitting an IUCD his normal procedure is to clean the inside of the vagina and make sure there are no signs of infection. The IUCD has strings attached at the bottom, which have to be trimmed after insertion. The strings are left long and trimmed to the appropriate length at another appointment about one month after insertion. This allows time for the string to adjust to movements within the uterus. It is usual for the patient to be seen again 12 months later for a general check-up and after five years for the device to be changed, as it would have passed its expiry date. Dr B also recommended that Ms A have 12-monthly cervical smears because of the earlier abnormal smear.

Baby's birth
On 18 June 2003 Ms A was at home when she experienced sudden abdominal pain and gave birth to a male baby on her bathroom floor. The baby died shortly after birth.

On Friday 20 June, Ms A went to another town to attend a family function. She became ill and was admitted to the town hospital, where she spent some time in the intensive care unit. She was treated for infection and required surgery to remove some retained placenta. The Medical Director at the town hospital, a consultant obstetrician and gynaecologist, informed the Police:

> "[Ms A] presented to the Emergency Department of [the town hospital] on the evening of Saturday, 21 June 2003. On first assessment by my Senior House Officer she was noted to be obviously septic with a temperature of 40°C. She gave a history of having an IUCD in situ for contraception until some six weeks previously when it apparently 'fell out'. Some three to four weeks after this my House Officer was informed that [Ms A] had another IUCD inserted by her General Practitioner. Four days prior to this admission [Ms A] developed abdominal pains, passed the IUCD and began bleeding. In addition she gave a history of passing a tissue like structure, at least the size of an egg. She had had bleeding since that time and had been feverish with shaking and rigors. However, she had come to [the town] for a family celebration.
>
> On initial assessment, apart from the fever, [Ms A] was very tachycardiac with a heart rate of 160 beats/minute and a degree of hypotension with her blood pressure 96/33 mm mercury. Her abdomen was non tender but vaginal examination revealed a purulent discharge from the cervix. The cervix was open and the uterus slightly tender and enlarged. She was treated with high dose antibiotics and intravenous fluids. She was found to be grossly anaemic with a haemoglobin of 63gm/l. In addition, her sodium and potassium levels were low. A diagnosis of a septic miscarriage was made and she was initially transferred to Intensive Care Unit for full support, transfusion, antibiotics, fluid management, and with a plan for probable evacuation of the uterus approximately 12 hours after admission. At approximately 0700 on the next day, 22 June 2003, [Ms A]

had a further very large vaginal bleed with further cramping pain, however her temperature had reduced markedly and she had been reasonably stable until this point.

It was decided to take her immediately to the Operating Theatre for a full evacuation of the uterus to remove any retained products of conception.

My operation note is enclosed, but in Theatre [Ms A] had a general anaesthetic whilst being further transfused with blood. There was a large piece of placental tissue recently expelled by [Ms A] and this was sent for examination. The uterus was explored but essentially there were minimal further products obtained and [Ms A's] bleeding had by this point come under control.

You ask for particular comment about two matters. Firstly there is no doubt that [Ms A] suffered a significant infection as the result of her pregnancy and subsequent delivery. As noted above, we had no real idea of her gestation at this point and initially considered her to have had a septic miscarriage. However, given that she had in fact delivered a child consistent with a much later gestation I would now consider this a case of puerperal sepsis.

Your second query relates to the IUCD. This was not located or recovered as part of any medical treatment that [Ms A] received at [the town hospital]."

Ms A was discharged from the town hospital on 24 June 2003.

Autopsy findings

On 24 June pathologist Dr D conducted a post-mortem examination of Ms A's baby. In her report she stated that the baby's gestational age was 36 weeks at the time of birth and that he would have been alive for a short period of time after delivery.

Dr D stated:

" … The likely series of events in this case are that the amniotic cavity was infected and inflamed and this precipitated the unexpected delivery of the infant. The post-mortem findings suggest that the infant was likely to have been seriously ill with sepsis. Following birth he would have been shocked and may have indeed appeared to the inexperienced eye to be stillborn. Shocked infants usually appear pale and lifeless. Breathing movements may be shallow and a heart rate may not be observed by the inexperienced observer. Infants who are delivered in controlled settings with unsuspected sepsis have a significant mortality rate – even with expert neonatal care. It is unlikely that he would have shown signs of breathing or have a heart rate. On external examination there were no external injuries and the cause of his death was as a result of sepsis suffered prior to birth."

ACC report

ACC accepted Ms A's claim for medial misadventure. A finding of medical error against Dr B was based on an independent report from obstetrician Dr E. Dr E stated:

" …

Therefore a physical injury namely chorioamnionitis resulting in premature delivery and intrauterine pneumonia had occurred following the insertion of an IUCD to a pregnant woman. A registered health professional has been involved in the provision of treatment in that the IUCD was inserted by [Dr B] who was unaware of the fact that [Ms A] was in the advanced stages of pregnancy.

Medical Error

In this case the insertion of an IUCD was clearly not appropriate or correctly provided. I do feel that this is a failure of the registered health professional to observe a standard of care and skill reasonably to be expected in the circumstances. I cannot be sure of what history was provided to the doctor inserting the IUCD and whether any attempt was made by the patient to conceal the pregnancy or whether the patient was genuinely unaware that she was pregnant which seems more likely to be the case. However prior to the insertion of any IUCD especially where the previous IUCD has fallen out it would be standard practice to ascertain carefully the menstrual history and whether there was any possibility that the patient could be pregnant. [Ms A] gives a history of negative home pregnancy test which is clearly incorrect, however it is not certain whether this history was given to [Dr B] prior to insertion of the IUCD. Prior to any insertion of an IUCD it is mandatory to palpate the position of the uterus and to sound the cavity prior to the insertion. Record of the sounding of the cavity of 8cm was clearly incorrect and bimanual palpation of the pelvis could be expected to reveal that the patient was in the advanced states of pregnancy."

Independent advice to Commissioner

The following expert advice was obtained from Dr Helen Moriarty, an independent general practitioner:

"***Expert Advisor Report:***

Preamble:

I have received instructions from the Commissioner and Guidelines for Independent Advisors. I have read and followed these guidelines in preparation of this report. I am a New Zealand Registered Medical Practitioner with the following qualifications obtained at University of Otago: MB, ChB, MGP, DPH/P/G cert. Hlth Sci.

I have spent my medical career of over 27 years, working at the primary care–hospital interface. I am a Fellow of the Royal New Zealand College of General Practitioners, and also an Associate of the Australasian College of Sexual Health Physicians and Fellow of the Chapter of Addiction Medicine of the Royal Australasian College of Physicians. I have had experience of inserting IUDs since 1980. I inserted up to 5 IUDs per week

during my years working at the Hutt Health Service and Community Sexual Health Service.

I am currently a Senior Lecturer in General Practice at the Wellington School of Medicine and Health Science.

Instructions from the Commissioner were to prepare an expert medical advisor's report on case number 03/16721/WS. The purpose of this report is to advise the Commissioner whether [Ms A] received an appropriate standard of medical care from general practitioner [Dr B].

I received the following background information:

[Ms A] was referred to [Dr B] by her general practitioner, [Dr C], for obstetric and gynaecological care. [Dr B] first saw [Ms A] on 24 December 1998 for antenatal care. [Dr B] fitted an IUCD on 13 August 1999 (copper multi-load 375 IUCD).

On 31 May 2001 [Dr B] saw [Ms A] for the first antenatal check for another pregnancy when she was 31 weeks pregnant. [Ms A] told [Dr B] that she did not begin to feel foetal movements until she was 29 weeks' gestation. [Dr B] concluded that [Ms A] was 'relatively unaware of her pregnant state'. He examined [Ms A] but could not find the IUCD he fitted in August 1999. He was not concerned because devices fall out, or can be intentionally removed. The baby was born on 24 July 2001. [Dr B] saw [Ms A] for her postnatal checks on 6 August and 7 September, and they discussed contraception.

[Dr B] fitted [Ms A] with an IUCD on 18 October 2001. He saw her again on 6 December to refit the IUCD as it had fallen out about ten days previously. He warned [Ms A] that the device could again fall out.

On 8 January 2003 [Dr B] received a letter from [Dr C] asking him to see [Ms A] to have an IUCD fitted. [Dr B] said he understood from [Dr C 's] letter that [Ms A] was on some other form of contraception.

Although [Dr B] received [Dr C's] letter in January, [Ms A] did not have the IUCD fitted until 29 May 2003. [Dr B] said that [Ms A] did not have any outward signs of pregnancy and she did not say anything that led him to believe she could be pregnant. [Dr B] did the normal checks and smears and nothing suggested that [Ms A] was pregnant.

On 18 June 2003 [Ms A] gave birth to a baby boy at home which she believed to be stillborn. The baby was thought to be 38 weeks' gestation [the Police report indicated that the baby was at least 36 weeks' gestation].

[Ms A] went to a family gathering in [a town] on 20 June where she collapsed. She was taken to [the town hospital] where she was immediately admitted and subsequently taken to theatre with septic abortion.

[Dr B] has not responded to the Commissioner's investigation and we rely on his statement to the Police. [Dr B] indicated that it was not his usual practice to perform pregnancy tests before inserting an IUCD unless the woman leads him to believe that a pregnancy is possible.

I understand that the issue the Commissioner is investigating is summarised as follows:

The circumstances surrounding the placement of an IUCD by [Dr B] on 29 May 2003.

I have sighted the following documentation:

- [Ms A's] letter of complaint to the Commissioner dated 3 November 2003 and associated documentation (pages 1-2) marked 'A'
- Commissioner's letter to [Dr B] dated 29 January 2004 (pages 3-5) marked 'B'
- [Dr B's] statement to [the Police] on 9 July 2003 (pages 6-13) marked 'C'
- Report to the Coroner by [Dr D] identified 2003A/200 (pages 14-23) marked 'D'
- [Ms A's] medical records from [Dr B] (pages 24-47) marked 'E'
- A letter from [Ms A's] general practitioner [Dr C], dated 8 January 2003 (page 48) marked 'F'
- [Ms A's] records from [the town hospital] (pages 49-52) marked 'G'.

The Commissioner has requested advice as to whether, in my professional opinion, [Dr B] provided contraceptive care to [Ms A] with reasonable care and skill and, in addition, has requested an answer to the following questions:

1. What particular standards apply in this case?
2. Did [Dr B's] care comply with those standards? Please explain?
3. Was a pregnancy test warranted before [Dr B] inserted the IUCD on 29 May 2003?
4. Was a pregnancy test warranted given [Ms A's] history of unexpected pregnancies and uncertain contraception?
5. Is it usual practice to perform a pregnancy test before inserting an IUCD?
6. What, if any, other tests or questions should be performed or asked prior to inserting an IUCD?
7. Is there any other matter which, in my opinion, should be brought to the Commissioner's attention?

I have addressed these questions one by one below:

1. What particular standards apply in this case?

The standards to consider are: (a) specific standards for IUCD insertion and (b) general standards for GP care.

(a) Specific standards for IUCD insertion.

There are no national standards for GP insertion of IUCDs in New Zealand.

The New Zealand Family Planning [Association] issues a reference handbook for use by doctors and nurses working at Family Planning (FPA) Clinics. This handbook has a chapter on IUCDs.

The chapter on IUCDs outlines patients suited and least suited for IUCDs, lists the absolute contraindications to IUCD use, gives recommendations for a pre-IUCD insertion visit for counselling and health check, instructions for insertion and for follow-up care.

In the absence of any other national standard, the following advice has been based upon the 1999 edition of the FPA handbook.

The standards, as laid out in the FPA manual, most relevant to this complaint are the recommendations for:

(i) a pre-IUD insertion visit (one to two weeks before planning insertion) to discuss suitability, precautions, and possible problems, take a full history and do a pelvic examination and take the STI swabs.
(ii) testing before IUCD insertion for sexually transmitted infections (STIs) such as chlamydia, gonorrhoea, bacterial vaginosis.
(iii) performing a cervical smear before IUCD insertion (if a smear is due).
(iv) timing the IUCD insertion in relation to the woman's menstrual cycle and any history of unprotected sex.

(b) General standards for GP care

The general standards for GP care are outlined in a document published by the Royal New Zealand College of General Practitioners.

'Aiming for Excellence' RNZCGP Standards for General Practice Care, 2nd Edition, 2002. This document is available on:
www.rnzcgp.org.nz/PDF/aiming_for_excellence.pdf

In this document, standards for GP care are considered in three dimensions using indicators relating to: patients and their outcomes; the professionals and their professional development and quality of practice; and continuous quality assurance. The standards most relevant to this complaint are:

(i) Indicator 7.1 which specifies 'Records sufficient to meet legal requirements to describe and support the management of health care provided'.
(ii) Indicator D8.4, relating to continuity of care.
(iii) Indicator 10.1 which covers GP qualification and continuing education for their type of practice may also be relevant.

2. Did [Dr B's] care comply with those standards? Please explain?

The standards mentioned above are considered in sequence.

(a) Specific standards for IUCD insertion

(i) Regarding a pre-IUD insertion visit (*one to two weeks* before planning insertion):

FPA recommend this visit for 1-2 weeks pre-insertion to ensure that the tests for infection will be recent and that results will be to hand at the time of the insertion. The medical records confirm that [Dr B] and [Ms A] did discuss an IUCD prior to the insertion on 13th August 1999. This discussion took place at the postnatal check on 28th June 1999 approximately 7 weeks prior to the actual insertion (document E page 030). [Dr B] and [Ms A] also discussed an IUCD at the 7th September 2001 postnatal check. This was about 6 weeks prior to the insertion on 18th October 2001 (document E page 028).

None of the pre-IUCD consultations took place 1-2 weeks before each IUCD insertion, and there is no documentation of any prior consultation in association with the IUCD re-fit of 6th December 2001 or the IUCD insertion of 29th May 2003 (document E page 028).

(ii) Regarding testing *before IUCD insertion* for sexually transmitted infections (STIs) such as chlamydia, gonorrhoea, bacterial vaginosis:

The available documentation shows that STI screening was performed about the time that an IUCD was inserted on 13th August 1999 (document E page 030), as results reached the surgery, dated 16 August 1999 (document E page 036).

An IUCD was inserted on 18th October 2001 (document E page 028) and there is evidence that STI screening was performed about that time, as results reached the surgery dated 23rd October 2001 (document E page 031).

On 6th December an IUCD was re-fitted (document E page 028) because the previous IUCD had fallen out after only 10 days (more than 5 weeks earlier). There is no evidence to indicate that STI tests were ordered at this time, and no results corresponding to this IUCD insertion.

An IUCD was inserted on 29th May 2003 (document E page 028) and corresponding STI results are dated 30 May 2003 (document E page 031).

The timing of the entries of these STI screening results within the medical records indicates that the STI screening may not have been done until the day of IUCD insertion.

If that was the case, the results of the lab tests would not have been available at the time of insertion, and if so this would not have complied with the FPA protocol.

(iii) Regarding a cervical smear before IUCD insertion (*if a smear is due*):

A cervical smear was performed about the time of IUCD insertion in 1999, and results were dated 16th August 1999 (document E page 036). [Dr B] referred the patient for specialist review, due to abnormalities seen on this smear. As a result of the specialist referral colposcopy was performed on or about October 19th 1999 (document E page 046) and the precancerous cervix abnormality diagnosed and subsequently treated (document E page 044). A further cervical smear was reported on 23rd October 2001 and although this one was normal, annual smears were indicated because of the previous abnormality (document E page 031A).

There is no record of any cervical smear test associated with the May 29th IUCD insertion. At the time of IUCD insertion on 29th May 2003, the first annual smear would be overdue, unless this follow-up smear had already been performed elsewhere by another provider.

(iv) Regarding the timing of the IUCD insertion in relation to the woman's menstrual cycle and any history of unprotected sex:

The protocol recommended by FPA is that: timing of insertion can be at any time in the cycle if no unprotected sex is reported; otherwise (for a copper IUCD, such as multiload) IUCD insertion must be within 5 days of possible fertilisation or (for a Mirena IUCD) up to day 7 of the cycle.

FPA are very strict on the timing of IUCD insertion (Dr Christine Roke, National Medical Advisor, Family Planning Association Inc., personal communication June 11th 2004). The insertion of IUCDs after implantation carries known risks of infection and miscarriage ***('Emergency Contraception' by Christine Roke, New Zealand Family Physician, vol 31 no 1 pp33-35, February 2004)*** and IUCD insertion after this time this may contravene the provisions of the Contraception Sterilisation and Abortion Act 1997.

The available medical records for the four IUCD insertions do not contain any documentation of the timing in relation to the last menstrual period, or unprotected sex. It is unknown if [Ms A] had been asked for these details on any occasion, and in particular if she gave any information that would warn [Dr B] that she might be pregnant on 29th May 2003.

Therefore from the available documentation it is not possible to determine if [Dr B's] care did or did not comply with FPA standards in relation to the timing of the IUCD insertion.

(b) General standards for GP care

(i) Indicator D7.1 'Records sufficient to meet legal requirements to describe and support the management of health care provided'.

Important detail about the IUCD insertions has not been recorded in the medical notes.

The available medical records for the four IUCD insertions do not contain any documentation of details about the timing of insertion in relation to the last menstrual period, or unprotected sex. It is unknown whether or not [Ms A] had been asked for these details at the time of any of the IUCD insertions, and in particular if she gave any information to [Dr B] on May 29th 2003 that may have indicated to him the possibility of pregnancy.

Some other information also appears to be omitted. [Dr C] mentions: 'from his records 07-12-02 IUCD annual check' (document F page 048), referring to [Dr B's] records. This annual check would have been for the IUCD re-inserted on 6 December 2001. Dr [B's] records do not indicate whether or not an IUCD annual check did take place on that date, since there is no corresponding entry in [Dr B's] medical records for the date December 7th 2002 (document E page 028).

(ii) Indicator 8.4 Continuity of care.

Failures in continuity of care were a contributing factor in the health problems experienced by [Ms A]. [Dr C] was the family GP for Ms A (document C page 007). His letter of referral of [Ms A] for an IUCD insertion was written on January 8th 2003 (document E page 043) and was scanned into the notes at [Dr B's] surgery on 18th January 2003 (document E page 028, but [Dr B] has stated that [Ms A] did not attend for the IUCD insertion until 29th May 2003 (document C page 010). There is no documentation to indicate whether [Dr C] had been notified that his patient had not attended promptly for the procedure. To the contrary [Dr C] has indicated that he did not receive communication from [Dr B] about the care of this patient: 'I have no documentation what so ever from [Dr B] about the insertion of an IUCD' (document F page 048).

[Dr C] has indicated that he was unaware of the details of other IUCD insertions by [Dr B] for this patient. He states 'I believe there was one inserted in late May or June 2003 although I have no confirmation of this'.

After an IUCD insertion [Dr B] usually saw the woman again in one month (document C page 010), but from his past experience he was aware that [Ms A] 'was a patient who never returned for the follow-up check a month after'. A follow-up was particularly indicated at the time of the December 2001 IUCD, given that it was a re-insertion and a 'rather voluminous uterine cavity' had been noted, and the patient had been warned that it might fall out again (document E page 028). However, there is no documentation to indicate whether or not [Dr C] was informed about the risk of loss of this particular IUCD so that he would know to expect an IUCD expulsion. [Dr C] refers only to an 'IUCD annual check' for December 2002 which may or may not have taken place (as mentioned in indicator 7.1 above). The available records carry no indication whether or not [Ms A] had been instructed on how to check regularly for IUCD strings, to ensure the device was still present, or what to do if she could not feel the strings herself.

Without a plan to ensure continuity of care, no doctor checked that the IUCD was still in situ and consequently [Ms A] was at risk of an unplanned pregnancy, which occurred in late 2002.

(iii) Indicator 10.1 Qualification and continuing education for the type of practice.

As [Dr B] has not replied to the Commissioner's enquiry directly, the extent of his expertise in IUCD insertion is not declared. In the statement for [the Police], [Dr B] has mentioned that he obtained the qualification of DRCOG in 1984. It is not known whether [Dr B] was trained to insert IUCDs at that time or later. Similarly it is not known how many IUCDs [Dr B] might expect to insert in the normal course of a year and if this is sufficient to keep up his expertise with this procedure. FPA has just agreed that their clinic doctors should insert 25 IUCDs per year (or equivalent in endometrial sampling) to keep up their expertise (Dr Christine Roke, personal communication). It is not known if Dr B participates in quality assurance activities such as audit of his contraceptive practice, or if he attends for continuing education and meets regularly with peers who also perform IUCD insertion to keep abreast of changes in this field.

Therefore it is not known if [Dr B] was compliant with RNZCGP Indicator 10.1.

3. Was a pregnancy test warranted before [Dr B] inserted the IUCD on 29 May 2003?

[Dr B] has stated that he would 'rely on the woman telling us whether they suspect they may be pregnant' (document C page 008), and that he would not do a pregnancy test 'unless there are reasons for believing that the woman may possibly be pregnant' (document C page 008). [Dr B] has stated that there was nothing on examination that indicated to him that [Ms A] was pregnant (document C page 010).

In order to judge if there is any risk of pregnancy certain details of the medical history are necessary, as mentioned in response to question 2; information about the last menstrual period and last unprotected sex. These details are not documented in the medical records relating to the IUCD insertion of May 29th 2003 (document E page 028).

If [Ms A] had been asked for these details, and if she had given an indicative reply, then a pre-insertion pregnancy test would have been indicated. There is no comment documented in the records about these two aspects of the consultation. Therefore it is not possible to judge, from the available documentation, if a pregnancy test would have been deemed to be warranted at the time that [Dr B] inserted the IUCD on May 29th 2003.

4. Was a pregnancy test warranted given [Ms A's] history of unexpected pregnancies and uncertain contraception?

Even with [Ms A's] unexpected pregnancies and uncertain contraception, the protocol recommended by FPA for timing IUCD insertion, if applied, would have indicated the risk of pregnancy without the need for pregnancy testing. This is because the protocol takes into consideration any unprotected sex in relation to the menstrual cycle.

If the protocol recommended by FPA cannot be followed for any reason, for instance if the woman cannot rely upon her bleeding pattern to indicate the menstrual cycle or is unable to give an accurate history of unprotected sex, then a pregnancy test is prudent.

The consumer advocate has stated that [Ms A] 'has periods during her pregnancy' (document A page 001). If [Dr B] had known this, then a pre-insertion pregnancy test would have been warranted.

5. Is it usual practice to perform a pregnancy test before inserting an IUCD?

As indicated in the response to question 4, the protocol recommended by FPA takes into account the risk of pregnancy according to the menstrual cycle and unprotected sex. A pregnancy test is not necessary if this protocol is followed in timing the IUCD insertion.

If the protocol recommended by FPA cannot be followed for any reason then a pregnancy test would be prudent. A standard urine pregnancy test may not be reliable for indicating pregnancy within the first few days of fertilisation. This is because the levels of pregnancy hormone may not be established sufficiently to turn the urine test positive. Therefore a negative urine pregnancy test result cannot always be taken for granted, and under some circumstances it may have to be repeated after 7-10 days without unprotected sex to ensure that it truly is negative before an IUCD is inserted.

If there is an urgency to insert an IUCD immediately and uncertainty exists about periods or unprotected sex, then a blood test with a same-day result is warranted to exclude early pregnancy before insertion.

6. What, if any, other tests or questions should be performed or asked prior to inserting an IUCD?

As indicated in the response to question 2, the recommended practice is to test for sexually transmitted infections (STIs) such as chlamydia, gonorrhoea, and bacterial vaginosis before inserting an IUCD, and to perform a cervical smear if due. It is also important to take a good medical history to ensure that there are no contraindications or relative contraindications to IUCD use. In addition, as mentioned above, specific questions about the menstrual cycle and unprotected sex should be asked in order to time the insertion of the IUCD.

7. And any other matter which, in my opinion, should be brought to the Commissioner's attention?

[Dr B] has indicated (in document C page 007) that he is a member of the British College of General Practitioners (MRCGP). [Dr B] has not mentioned any affiliation with the Royal New Zealand College of General Practitioners (RNZCGP). The advice

on general standards of GP care is taken from an RNZCGP document. [Dr B] may not be familiar with this document if he is not affiliated to RNZCGP.

The specific advice about standards for IUCD insertion given above is based upon the 1999 FPA handbook. This FPA manual has been used as a reference in the absence of any national standards for IUCD insertion. Although this handbook is widely used, nationally, in Family Planning Clinics, it is not generally available and is not readily accessible to doctors who do not work for Family Planning Clinics. [Dr B] may not be aware of the handbook, or the FPA protocol, if he does not have collegial contact with local FPA services.

Collegial contact with local peers is important for reflective medical practice, peer review for quality assurance, and continuing education. In this instance, relevant peers are other GPs who also insert IUCDs, or doctors who work at FPA or sexual health clinics or in gynaecology clinics. Standard techniques for IUCD insertion do change with time, as awareness of the risks and benefits evolves and as new IUCD models are introduced. Medical knowledge in contraceptive practice changes over time, and the 1999 FPA chapter on IUCD insertion has just been updated to include new information, although not yet printed (Dr Christine Roke, personal communication). It would be important that [Dr B] engage in such peer activities, if he does not do so already. The experience and insights he has gained from his involvement with this case should be shared with his peers, so that they might also learn from his experience."

Code of Health and Disability Services Consumers' Rights

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

RIGHT 4

Right to Services of an Appropriate Standard

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

Opinion: Breach – Dr B

Under Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code) Ms A was entitled to have general practitioner services provided with reasonable care and skill by Dr B.

Ms A attended Dr B for obstetric care and contraceptive advice, in particular IUCD insertion, on a relatively regular basis over a number of years. Ms A had devices inserted in August 1999, October and December 2001, and 29 May 2003. Dr B did not see Ms A between December 2001 and May 2003. Ms A's fourth baby was born on 18 June 2003, estimated at between 36 and 38 weeks' gestation. Therefore, the date of conception was between the last week of September and the second week of October 2002 and Dr B had only one opportunity to assess whether Ms A was pregnant before he fitted the IUCD on 29 May 2003.

In my view, Dr B ought to have been aware about Ms A's uncertain contraceptive history, and this should have aroused his suspicion that she might be pregnant. Dr B needed to be especially vigilant when assessing her pregnancy status. When he examined Ms A on 29 May 2003 he found no outward signs of pregnancy and relied on her to tell him if she had had unprotected sex or believed that she could be pregnant. However, he was aware that she did not always rely on contraceptive measures. Dr B also knew that Ms A had felt no foetal movements until much later in her pregnancies, had conceived her last child with an IUCD in situ, had reported menstrual bleeding throughout her third pregnancy, and that he had assessed her in the past as "relatively unaware of her pregnant state".

Dr B did not usually perform a pregnancy test before inserting an IUCD. According to my advisor it would not have been necessary to take a pregnancy test if Dr B had ascertained whether Ms A had had unprotected sex since her last menstrual period and, if that was the case, only inserted the IUCD within five days of possible fertilisation.

If a device is fitted after implantation a woman is exposed to an increased risk of infection and miscarriage. Therefore, it was important that Dr B took a comprehensive history, particularly in relation to when Ms A had her last menstrual period and whether pregnancy was a possibility, before he inserted the IUCD in May 2003.

The ACC advisor, Dr E, stated that it is mandatory to palpate the position of the uterus before inserting an IUCD and it is standard practice to ascertain carefully the menstrual history and the possibility of pregnancy, especially where a previous IUCD has fallen out. Dr B failed to take these steps and in Dr E's opinion failed to observe the standard of care and skills reasonably expected in the circumstances.

My GP advisor, Dr Moriarty, suggested that Dr B had three options: eliciting information from Ms A about unprotected sex and the risk of pregnancy, a pre-placement pregnancy test or, if uncertain, a same day blood test. Dr B relied on his physical examination only, which he later acknowledged was unreliable, before placing the IUCD.

If Dr B had taken a contraceptive history from Ms A to remind himself of her previous experiences with contraceptive measures, she could have told him that the IUCD inserted in December 2001 was "never satisfactory" and by December 2002 she felt it was in the wrong place and she thought it had fallen out several weeks before. This might have alerted him to the possibility that she could be pregnant.

In my opinion Dr B failed to meet his duty of care to Ms A. It is not the patient's responsibility to guess what information her general practitioner requires to make good clinical decisions. Dr B did not provide services with reasonable care and skill. He did not take a comprehensive history or appropriately assess whether Ms A was pregnant during the 29 May 2003 consultation, and thereby exposed her to the risk of infection and premature delivery of a baby with sepsis. In these circumstances, for these reasons, Dr B breached Right 4(1) of the Code.

Other comments

My advisor has raised a number of aspects of Dr B's previous care for this patient. Although these issues were not the subject of this investigation, they warrant comment in my report.

The Family Planning Association recommends a pre-insertion consultation to ensure that tests for infections, particularly sexually transmitted infections (STIs), are recent and available at the time of IUCD insertion. My advisor said that Dr B should have seen Ms A about two weeks before he inserted the IUCD on 29 May 2003, and taken swabs so that the results would have been available and infections treated beforehand. Dr B took cervical and vaginal smears on the same day he inserted the IUCD, and the results were not available until the following day. It seems this is his usual practice as on two of the previous four placements STI results were also not available when the IUCDs were inserted.

My advisor criticised Dr B's medical records, indicating that important details of IUCD insertions had not been recorded. Although Ms A was due for an annual IUCD check on 6 December 2002 there is no record that this occurred.

My advisor identified a breakdown in co-ordination of services because Dr B failed to keep her usual general practitioner, Dr C, informed. There is no evidence that Dr B informed Dr C about the IUCDs he inserted. In particular, Dr C should have been notified that the December 2001 placement was a re-insertion and that with a "rather voluminous uterine cavity", IUCD expulsion was a real risk. Dr C referred Ms A to Dr B for a re-insertion of an IUCD on 8 January 2003, and the referral was scanned into his notes yet there was no further communication from Dr B to Dr C. Dr C was therefore not aware that Ms A had not attended her appointment and could be exposed to an unwanted pregnancy.

Dr B has been inserting IUCDs for Ms A since 1999. I am concerned that Dr B provided contraceptive services to Ms A over a period of years, without keeping adequate records or properly informing her usual GP.

I also note my significant disappointment that Dr B has failed to reply in any way to my investigation. An explanation and an apology would have gone a long way to address Ms A's legitimate concerns and to help her and her family come to terms with this tragic loss of the baby.

Follow-up actions

- A copy of this report will be sent to the Medical Council of New Zealand with a recommendation that the Council review Dr B's competence to practise.

- A copy of this report will be sent to the Royal New Zealand College of General Practitioners.

- An edited copy of this report, with details identifying the parties removed, will be sent to Women's Health Action and the Family Planning Association, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.