Gynaecologist, Dr B

General Practitioner, Dr C

General Practitioner, Dr D

A Medical Centre

A District Health Board

A Report by the

Health and Disability Commissioner

Case 08HDC07350

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Overview

On 18 April 2007, Mrs A (aged 39) presented to her GP, Dr C at a medical centre, reporting three separate episodes of postcoital bleeding. Over the next few months, Mrs A re-presented at the medical centre on a number of occasions, complaining of vaginal bleeding, discharge and other issues. A series of tests, including an X-ray, an ultrasound scan and a vaginal swab, were taken to find the cause of the vaginal bleeding. A cervical smear was not taken during this time period.

On 14 June 2007, Mrs A saw Dr B, a gynaecologist at the DHB, who conducted a physical examination and took a full history, but did not take a cervical smear or perform a colposcopy.

On 11 October 2007, Mrs A called the medical centre and requested a cervical smear, but her request was declined. Four months later, in February 2008, Mrs A had a cervical smear taken. Her results were returned as abnormal, and she was subsequently diagnosed with Stage 3B cervical cancer. Mrs A died in 2009.

Complaint and investigation

On 7 May 2008 the Health and Disability Commissioner (HDC) received a complaint from Mr and Mrs A about the care provided to Mrs A. The following issues were identified for investigation:

- *The appropriateness of the care provided to Mrs A by Dr B and a district health board, in particular the decision in June 2007 not to investigate further Mrs A's presentation with postcoital bleeding.*

- *The appropriateness of the care provided to Mrs A by Dr C, Dr D, and the medical centre from April 2007 to February 2008, in particular the treatment following Mrs A's presentation with postcoital bleeding.*

An investigation was commenced on 21 January 2009. The parties directly involved in the investigation were:

Mrs A	Consumer
Mr A	Complainant
Dr B	Gynaecologist
Dr C	General Practitioner
Dr D	General Practitioner
A medical centre	General Practice
A District Health Board	District Health Board

Also mentioned in this report:

Ms E	Nurse
Dr F	Obstetrician

General practitioner advice was obtained from Dr David Maplesden (Appendix 1). Gynaecological advice was obtained from Drs Ian Page and Mahesh Harilall (Appendices 2 and 3).

Information gathered during investigation

In 2005, Mr and Mrs A moved to New Zealand with their daughter. At this point, Mrs A became a patient at the medical centre. On 2 February 2007, she gave birth to their second child via Caesarean section. Although her recovery was delayed by a wound infection, she made a good recovery following antibiotic treatment.

Consultation on 18 April 2007
On 18 April 2007, at the end of a consultation in relation to the baby's health, Mrs A spoke to Dr C at the medical centre, reporting three separate episodes of postcoital bleeding. Mrs A also conveyed her husband's concerns that a swab may have been missed after her Caesarean section, and that the retained swab might be the cause of her bleeding.

Dr C noted that Mrs A had a clear cervical screen result from January 2005.[1] During the consultation, he spoke to a GP Obstetrician at the medical centre. He advised that surgical swabs have a radio-opaque marker, which allows them to be located by an abdominal X-ray. He suggested that Dr C organise an ultrasound scan and, if this did not reveal any uterine abnormalities, take a cervical smear.

Dr C did not conduct a vaginal examination at the 18 April consultation. He discussed obtaining an ultrasound, and advised Mrs A that if the ultrasound was abnormal, he would refer her to a gynaecologist.

A few hours after this consultation, Mr A called Dr C to express his concern that a swab might have been retained after his wife's Caesarean section. Dr C reassured Mr A that, if a swab had been retained, an X-ray and an ultrasound would uncover it. Both an ultrasound and an X-ray were ordered that day.

An abdominal X-ray was performed two days later on 20 April, and did not detect any swab markers.

Consultation on 7 May 2007
On 7 May 2007, Mrs A consulted Dr D at the medical centre, reporting continued postcoital bleeding, and smelly vaginal discharge. Dr D noted that Mrs A was 12 weeks post-partum, and had previously been treated for infection after the birth of the baby.

Dr D discussed taking a cervical smear and a vaginal swab, and began filling out the cervical smear form. She then took a vaginal swab and conducted a pelvic

[1] The smear had been taken on 24 January 2005 before Mrs A came to NZ. A copy of these clinical records was held at the medical centre.

examination, noting "lots of green smelly, not frothy discharge in high vagina" and "bleeding from [the] cervix".

The clinical records note that, following this examination, Dr D queried the presence of an anaerobic infection. After discussion with Mrs A, Dr D prescribed a two-week course of antibiotics and advised her to await the results of the swab. The decision was made to take a smear after any infection had cleared, so as to have a more accurate cervical smear result. The clinical notes indicate that Dr D advised Mrs A to "come back after two weeks", in order to have a smear taken, as she was "not for cx smear until after treatment". Dr D advised HDC that Mrs A "did not make a further appointment … for a cervical smear later in May as we had discussed". Dr D did not herself book an appointment for Mrs A for two weeks later, nor send herself a reminder to follow up the recommended appointment.

There is no evidence of any discussion at the 7 May consultation of the use of Liquid Based Cytology (LBC).[2] The medical centre advised HDC that LBC "did not form part of the current National guidelines[3] that the practice was following on smear taking". The medical centre noted that "LBC is not funded by government and in [this region] for a significant portion of the population the additional cost of LBC is prohibitive. As a result of this there was reluctance for GPs to use it and for women to opt for LBC even if it was suggested as an option". Consequently, "the use of LBC at the practice had been governed by patient request".

According to the medical centre, its policy in situations where it is "not possible on the day to perform a smear due to blood, mucous or discharge" is that "smear takers would treat any infection and ask women to return for smear at a later date".

The swab results were received on 7 May, and did not report any evidence of infection.

9–21 May 2007

On 9 May, Mrs A took the baby to see Dr C. At the end of the consultation, she told Dr C that she was still experiencing vaginal discharge and bleeding. She also communicated her concern that the ultrasound scan date she had been given was three weeks away. In response, Dr C called the public hospital's radiology service to request a more urgent appointment for Mrs A.

On 10 and 11 May, Mrs A rang the medical centre and spoke to a practice nurse about her swab results, and her ongoing vaginal discharge and bleeding. She was told that her swab results were clear, and that she should continue with her course of antibiotics until she had undergone her ultrasound scan. She was also advised that a cervical smear could not be taken due to her ongoing vaginal discharge.

[2] Liquid-Based Cytology (LBC) is an alternative method to the conventional Pap smear for preparing cells from the cervix for cytology testing. Instead of the cells being smeared on to a glass slide, they are put in a liquid preserving solution. There may be situations where LBC offers some advantage over conventional smears, such as women with excessive cervical mucus, discharge or blood.

[3] Operational Policy and Quality Standards for the National Cervical Screening Programme.

On 14 May, Mr A contacted the medical centre to express concern that his wife had still not received an appointment for an ultrasound scan. On the same day, Dr C contacted the public hospital, and Mrs A had a transabdominal and transvaginal ultrasound. Mr A advised HDC that he spoke to Dr C on 14 May and expressed concern about his wife's health, specifically that she might have cervical cancer. Dr C responded that he is quite certain that he did not speak to Mr A on 14 May and so "is quite clear that Mr A did not express concern about his wife's health, specifically that she might have cervical cancer". His request to the public hospital for an urgent ultrasound was, he advised HDC, the result of the public hospital contacting him on 14 May to "complain that [Mr A] had appeared at their offices demanding an urgent ultrascan". The medical centre has no record of Mr A visiting or telephoning the practice or Dr C on 14 May.

The ultrasound scan did not detect evidence of a retained swab and, according to the clinical records, Mrs A was told this on 21 May. During this phone call, Mrs A also noted her concern that she might have thrush, and was advised to come back in to the medical centre if she had ongoing problems.

Specialist referral letter
On 26 May, Mr A contacted the medical centre and spoke to Dr C about his wife. Mr A advised Dr C that there had been no change in his wife's condition, and they discussed a gynaecological referral. Due to the long waiting times for specialist appointments at the public hospital, Dr C attempted to consult the obstetrician, Dr F, who had performed Mrs A's Caesarean section, to discuss her condition. Dr C knows Dr F through his practice at the Emergency Department at the public hospital.

Unfortunately, Dr C was unable to speak to Dr F. On 9 June, Dr C wrote to Dr F, asking that he see Mrs A regarding her ongoing problems with vaginal bleeding and discharge. The referral letter detailed that Mrs A had

> "presented a month or so ago concerned that she continued to bleed vaginally and had had an intermittent smelly discharge since the birth. The bleeding tended to be post coital and was not constant. Her husband who was present at the LUCS [Caesarean section] had concerns that a swab had been misplaced in the operation. I have undertaken both abdominal Xrays and an ultrasound and have seen no sign of a retained swab but [Mrs A] continues to bleed. She has seen other doctors and been treated with antibiotics without improvement. She has no hx [history] of abnormal smears."

Attached to the referral letter were the results of Mrs A's ultrasound scan, abdominal X-ray and vaginal swab.

Specialist consultation — Dr B
On 13 June, Dr C telephoned Dr B, a gynaecologist at the public hospital, about the possibility of seeing Mrs A urgently. During this discussion, Dr C emphasised the concerns about a possible retained swab, and an appointment was organised for 9am the next day.

On 14 June 2007, Dr B saw Mrs A at the public hospital. Mrs A was unaccompanied. Dr B made a note in the clinical records of Mrs A's recent Caesarean section and vaginal bleeding "especially postcoital". He also noted that the concern about a possible retained swab had been negated by a negative abdominal X-ray and ultrasound scan. After taking a full clinical history, he queried whether she was breastfeeding, and established that she did not have a regular menstrual cycle. He then conducted an abdominal and vaginal examination, but did not perform a cervical smear.

After this he discussed with Mrs A his diagnosis of anovulation, and suggested that use of the pill would stabilise her cycle. In response to Mrs A's concerns about whether it was safe to use the pill, Dr B reassured her that it was safe given that she was not a smoker, and that she was not at risk of a stroke.

Mrs A told Dr B that she had bleeding after sex and that "the bleeding was not at any other time". She said Dr B told her that the bleeding was "perfectly normal, caused by hormonal changes arising from breast-feeding". According to Mrs A, Dr B said "nothing about how long it would go on for, or at what point [she] should worry about it or consult a doctor". Mr A, who had not been present at the 14 June consultation, advised HDC that Dr B "did not even consider [Mrs A] should come back to him if her problems did not resolve in a limited period of time … He reassured my wife and her doctor that it was clearly anovulation and this would [resolve] if she gave up breastfeeding or went on the pill."

Mrs A left the appointment with the understanding that her bleeding would continue until she stopped breastfeeding.

She stated that she was "really upset because [she] felt that [she] had wasted [Dr B's] time, but was also reassured". As a consequence, "when the postcoital bleeding continued throughout 2007, [she] did not raise it with [her] GP or any other health professional [as] Dr B had told [her] it was normal".

In his response to the complaint, Dr B said that he is "sure that [he] advised [Mrs A] that if her symptoms persisted after discontinuation of breastfeeding, she should see her GP". He advised HDC that he "thought that common sense would prevail, and that persistent symptoms would lead to a follow-up evaluation by the GP, and a new referral". He also stated that "if taking the pill did not stabilise her cycle, and she continued to have irregular bleeding then I am surprised that she (or her husband) didn't consult her GP". His record of the consultation does not contain any reference to this advice and, in his referral letter back to Dr C, Dr B notes that he "reassured" Mrs A, and that "she needs no active treatment" and "will not require any further treatment". The referral letter back to Dr C also notes that "the clinical picture here is of anovulation, which is common while breast feeding".

Dr B advised HDC that he considered the possibility of cervical cancer and appreciates that it is the most serious cause of postcoital bleeding, where that is the primary presenting symptom. However, he emphasised that "postcoital bleeding (PCB) was *one* of the symptoms mentioned in the referral letter of [Dr C], not the primary reason for the referral" [my emphasis]. Dr B assessed the symptom of

postcoital bleeding in the context of the clinical presentation of a woman who was post-partum and still breastfeeding. He stated that having "considered all the options, the most likely explanation for her problems was of anovulation". He submitted expert advice provided to him by Drs Digby Ngan Kee and John Tait, who concurred that his management of Mrs A was appropriate.[4]

Further GP consultations
Mrs A attended the medical centre on four more occasions in 2007, on 3 and 9 July, and on 3 and 9 September. The appointment on 9 July was for a flu vaccination, and the other three related to skin complaints. The records indicate that Mrs A did not raise any concerns about vaginal discharge or bleeding at these consultations. Mr A advised HDC that his wife did not mention "she was having ongoing problems because she had been told that this was normal but knowing her past I would have thought that on these occasions the doctor may have asked how things were for her".

Request for a cervical smear
On 11 October 2007, Mrs A telephoned the medical centre to request a cervical smear. As she was not due to have her next smear taken via the National Cervical Screening Programme until January 2008, her request was declined. Ms E, the nurse who spoke to Mrs A, recalls that she "did not report any history of abnormality or abnormal bleeding … and seemed satisfied when she was told that her smear was not due until January 2008". In contrast, Mr A recalls that his wife specifically told the nurse of her ongoing postcoital bleeding and vaginal discharge.

The medical centre advised that its policy "has always been that if a woman rings up complaining of abnormal bleeding or discharge an appointment is made with her GP". This policy, the medical centre advised, was "formulated with the help of [Ms E]". The medical centre submitted that Ms E was "therefore fully aware of [the medical centre] policy in this area and would have ensured an immediate appointment was made".

On 23 January 2008, a letter was sent to Mrs A advising that she was due for a cervical smear. The letter requested that she contact the medical centre to book an appointment.

Re-presentation to the medical centre
On 22 February 2008, Mrs A consulted Dr D, complaining of heavy and erratic periods, and continued postcoital bleeding. Dr D prescribed iron supplements and took a cervical smear. The cervical cytology results were received on Monday 25 February, and stated that there were "atypical squamous cells present. A high grade … lesion cannot be excluded". The results also stated that "urgent referral for colposcopy and biopsy is indicated".

Dr D advised HDC that Mrs A's "smear result appeared in [her] inbox on the evening of Sunday 2nd March showing a high grade cervical abnormality and I wrote the

[4] The expert advice provided to Dr B by Drs Ngan Kee and John Tait is attached as Appendices 4 and 5.

referral for her to be seen at the Colposcopy clinic immediately". On the same day, Dr D wrote to Mrs A, advising that her "recent cervical smear showed some low grade changes", and that she had been referred to the public hospital's colposcopy clinic.

On 4 March 2008, Mrs A saw another GP at the medical centre, and was prescribed Celebrix for heavy bleeding and suprapubic ache. She returned again on 15 March, and saw another GP at the after-hours clinic. Later that day, Dr C documented in the clinical records that he had been to the outpatient department at the public hospital to seek a more urgent appointment for Mrs A's colposcopy, and had arranged for her to see a gynaecologist in two weeks' time.

Second specialist appointment
Mrs A was seen by an obstetrician on 28 March. The obstetrician performed a colposcopy examination, and took a cervical biopsy because abnormal changes were visible. Further diagnostic procedures were planned, depending on the result of the biopsy. The obstetrician believed that Mrs A's pelvic pain might be caused by adhesions following her Caesarean section, or by endometriosis, and explained that these conditions could be diagnosed with laparoscopy.

On 10 April 2008, the histology report was received. It described findings of HPV infection, CIN 3, and lymphovascular invasion consistent with invasive squamous cell carcinoma of the cervix. Dr C received a telephone call from Dr B, who explained the results and advised Dr C that "the problems with [Mrs A's] cervix wouldn't cause any of her other symptoms ie her abdominal pain and she still needs to be investigated to find out the cause of the pain".

On 11 April 2008, Mrs A saw a gynaecologist at the public hospital, and he explained the results to her and referred her to the Oncology Clinic at a public hospital in a main centre for assessment and further treatment.

Mrs A was subsequently diagnosed with stage 3B cervical cancer, and died in 2009.

Providers' responses

Drs C and Dr D
Drs C and D and other staff at the medical centre advised HDC that they were saddened to hear of Mrs A's diagnosis. The medical centre has reviewed practices in light of Mrs A's case and made the following changes:

1. The medical centre will cover the cost of LBC if:

    a. A standard smear test under the National Cervical Screening Programme cannot be performed on a woman on the day of her appointment, and there is any risk that she will not return for a smear at a later date, and she cannot afford LBC.

    b. A woman presents with postcoital bleeding, and a normal smear would not suffice because of infection or discharge, and the woman is unable to fund LBC herself.

2. The electronic record recall system at the medical centre now allows for smear recalls outside those set by the National Cervical Screening Programme.

3. When nurses answer telephone calls, they now record the questions asked and information given. When a cervical smear is requested, nurses are prompted to ask the caller if she has experienced "any bleeding? any pain? any unusual discharge? any other concerns?".

Dr D advised HDC that she has reviewed her follow-up of patients recommended to return for a procedure, and that appropriate follow-up "would now happen".

Dr B
Dr B advised HDC that "being diagnosed with cancer is a devastating experience" and noted that if he "could turn back the clock, [he] would gladly undo what has happened". Nevertheless, Dr B maintains that he thoroughly examined Mrs A and "considered all possibilities, including cancer of the cervix" before deciding that "the most likely explanation for her problems was anovulation, given her history of a normal smear and normal findings on examination".

As a direct result of this complaint, Dr B noted, "I have since made a point of not only outlining a clear plan of action for each patient that I see (as I routinely do), but also of documenting it in the notes and in my reply to the referring colleague."

Dr B noted that he is now "much more liberal in doing cervical smears and colposcopies, regardless of the screening status of the patient when ... presented with [postcoital bleeding]".

Relevant standards

National Screening Unit, Ministry of Health, *Guidelines for Cervical Screening in New Zealand* (1999).

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists, *Guidelines for referral for investigations of intermenstrual and postcoital bleeding,* (July 2004).

Opinion: No breach — Dr C and Dr D

I have analysed below the standard of care at each of Mrs A's relevant consultations with GPs Dr C and Dr D and then considered the overall picture of care.

18 April 2007
On 18 April 2007, at the end of a consultation with Dr C about her son's health, Mrs A reported three episodes of postcoital bleeding. My general practitioner advisor, Dr Maplesden, noted that postcoital bleeding "is not an unusual experience in the first three months post-partum".

In deciding not to take a smear, Dr C clearly took this fact into account, along with the fact that Mrs A's previous cervical smears had not raised any concerns. I also note that the possibility of a retained swab was raised at this stage, and that Dr C initiated the appropriate procedures to rule this out as a possible cause of Mrs A's bleeding. In my opinion, it was appropriate to defer obtaining a smear until other investigations in relation to the possibility of a retained swab had been undertaken, or Mrs A's bleeding had ceased.

7 May 2007
On 7 May 2007, Mrs A presented to Dr D with complaints of postcoital bleeding and vaginal discharge. After examining Mrs A and taking a vaginal swab, Dr D decided not to take a smear, as she suspected the presence of an anaerobic infection. She prescribed antibiotics and discussed deferring the smear until any infection had cleared. Dr D recommended that Mrs A come back in two weeks' time for a smear, but did not follow this up.

Dr Maplesden commented that it was "reasonable for [Dr D] to assume that local infection was a likely cause for [Mrs A's] symptoms at this stage" and that the "appropriate swabs were taken and antibiotics prescribed". Dr Maplesden advised that the decision to defer taking a cervical smear was "reasonable given that local infection can cause inflammatory changes to the cervix and lead to a suboptimal smear result". I note that Dr D failed to follow up the recommendation that Mrs A come back two weeks later, and did not recall Mrs A, or have any system in place to ensure that the management plan was completed — something she says "would now happen".

9 May 2007
On 9 May 2007, at the end of a consultation with Dr C about her son's health, Mrs A again advised Dr C of her vaginal discharge and bleeding, and stressed her concern that the ultrasound scan date she had been given was three weeks away. At this stage, Dr C was aware of the negative result of Mrs A's vaginal swab, but he chose to wait for the results of the ultrasound scan before taking further action. Dr Maplesden considered that Dr C may have "failed to consider alternative diagnoses (most importantly a cervical lesion — either benign or malignant) as a cause for [Mrs A's] symptoms having effectively excluded infection as the cause".

Nonetheless, Dr Maplesden advised that Dr C appropriately referred Mrs A to a specialist and "it was reasonable ... for [Dr C] to expect that all outstanding relevant

investigations would be undertaken by the specialist ([Dr B]) or that [Dr C] would receive direction from the specialist regarding follow-up investigations". While Dr Maplesden concluded that "management of [Mrs A] to this point was still consistent with accepted practice", ideally Dr C should have included the actual date of Mrs A's last smear in the referral letter to Dr B.

22 February 2008
At the consultation on 22 February 2008, when Mrs A complained of heavy and erratic periods, and continued postcoital bleeding, Dr D took a cervical smear. When abnormal results were returned a few days later, Dr D referred Mrs A to the public hospital's colposcopy clinic. When the colposcopy results were also returned as abnormal, Mrs A was then referred to a larger public hospital for further management.

Dr Maplesden advised that the management of Mrs A's abnormal smear result was consistent with recommended guidelines.

RANZCOG guidelines
The Royal Australian and New Zealand College of Obstetricians and Gynaecologists *Guidelines for referral for investigations of intermenstrual and postcoital bleeding* (July 2004)[5] are "to assist general practitioners to decide when it is necessary to refer women with intermenstrual or postcoital bleeding for further tests or to a specialist gynaecologist, and to assist gynaecologists in formulating management plans".

The RANZCOG guidelines state that when presented with a patient with intermenstrual and/or postcoital bleeding, providers should take a Pap smear if the patient has not had one within the previous three months. The guidelines also state that "women with persistent intermenstrual bleeding and/or postcoital bleeding … should be referred for specialist opinion".

Mrs A had not had a cervical smear since January 2005, and had vaginal discharge at the consultation of 7 May (with Dr D) and 9 May (with Dr C). This appears to have influenced their decision not to take a Pap smear, nor to recommend an LBC smear (which in any event was not offered because of cost) at that time.

Dr Maplesden advised that "even though a cervical smear had not been taken at this point it had been recognised that this was an expected part of the investigation of PCB and it was reasonable, in my opinion, for Dr C to expect that all outstanding relevant investigations would be undertaken by the specialist". Furthermore, I note that there is no evidence of how widely the RANZCOG guidelines are followed in general practice.

Conclusion

In most respects, Dr C and Dr D provided appropriate care to Mrs A from April 2007 to February 2008. Counsel for Dr C and Dr D also noted that "without [Dr C's] efforts and personal connections with those persons at [the public hospital] neither [Mrs A's] Radiological nor her Specialist referral would have happened as quickly as it did". I

[5] The RANZCOG Guidelines are attached as Appendix 6.

note that Mr A initially stated that he did "not feel let down by the GPs". Furthermore, the information gathered during this investigation indicates that Dr C and Dr D endeavoured to provide appropriate care in the circumstances.

I am, however, critical of the slight delay in Dr C's referral of Mrs A for a specialist opinion, the fact that the possibility of an LBC smear was not discussed by either doctor, and the failure of Dr D to follow up the recommendation that Mrs A return for a smear two weeks after the consultation of 7 May 2007.

Timing of specialist referral
Dr C did not contact a specialist until 26 May (when prompted to do so by Mr A). Counsel for Dr C and Dr D submitted that "at all times, [Dr C] considered that the possibility of a retained swab being the issue to be remote. However, he was trying to manage and eliminate this as an issue as the family, particularly [Mr A], remained convinced that a retained swab was the problem." It was submitted that the referral was made on 26 May partly because "[Dr C] considered he had exhausted all ways of reassuring [Mr A] that there was no retained swab in his wife's uterus". Furthermore, "it was only [Dr C's] efforts in contacting [Dr B] directly that [resulted in] a more urgent appointment".

In my view, Dr C should have referred Mrs A for a specialist opinion once he knew that the bacterial swabs were clear, antibiotics had not alleviated her symptoms, the ultrasound results did not show a retained swab, and Mrs A was still complaining of postcoital bleeding. In these circumstances, a specialist opinion was necessary to establish a cause for Mrs A's ongoing gynaecological symptoms.

LBC smear
I also consider that both Dr C and Dr D should have discussed the possibility of an LBC smear with Mrs A, rather than assuming that their patients would be unable to pay. I discuss this issue further below, at page 18.

Follow-up of 7 May 2007 appointment
Finally, I am critical of Dr D's failure to actively recall Mrs A after the consultation on 7 May 2007. At this consultation, Dr D clearly considered the need for a smear, but decided to defer taking the smear until after Mrs A's infection cleared. In my opinion, after a GP has identified that a woman needs a smear, and documented that the woman is "not for cx smear until after treatment", the GP has a responsibility to follow up the recommended smear. Dr D "accepts that in retrospect she could have booked an appointment for [Mrs A] two weeks henceforth or sent herself a reminder to follow-up with an appointment for [Mrs A]". She advised that "this is what would now happen".

Final comment

Despite the criticisms noted above, I accept the advice of Dr Maplesden that the overall standard of care provided by Dr C and Dr D was "consistent with expected standards". I conclude that Dr C and Dr D did not breach the Code of Health and Disability Services Consumers' Rights (the Code).

Opinion: Breach – Dr B

Discussion

Management
On 14 June 2007, Mrs A was assessed and examined by Dr B. She had had a history of postcoital bleeding, and an unexplained vaginal discharge since the birth of her baby in February 2007. In addition, there had been concerns raised about the possibility of a retained swab. An abdominal X-ray, an ultrasound, and a vaginal swab had been performed, and had not revealed the cause of Mrs A's vaginal discharge and bleeding. Antibiotics had also been prescribed and had not improved her symptoms.

Dr B apparently did consider the possibility of cervical cancer, but made a conscious decision not to perform a cervical smear or colposcopy. Following his examination, he concluded that Mrs A's symptoms were the result of anovulation, related to her breastfeeding. He reassured her that she needed no further treatment.

My gynaecologist advisors, Drs Page and Harilall, both considered that the clinical history taken by Dr B and the physical examination he performed were appropriate. In relation to the diagnosis of anovulation, Dr Page advised that "it was quite appropriate for [Dr B] to reach the diagnosis he did".

Dr Page noted that "had a smear been taken or colposcopy performed … they *might* have indicated the presence of the cancer". However, Dr Page also advised that many of Dr B's peers, if faced with a similar clinical presentation, would have adopted the same approach, and not performed a smear or colposcopy. Dr Harilall advised that Dr B's decision to "not perform a cervical smear test was not unreasonable", and he "would not be over-critical of a colleague's decision not to perform a colposcopy examination".

I also note the opinion of Dr B's gynaecologist advisors, Drs Tait and Ngan Kee. Dr Tait stated his opinion that Dr B's management was "appropriate" and that "with the clinical scenario [Mrs A] presented with, it would not have been [his] practice to perform a smear either". Dr Ngan Kee's opinion is that Dr B's management was "consistent with current professional standards", and that he could "find no fault in the standard of care given to [Mrs A] by [Dr B]".

Advice re follow-up
Dr B advised HDC that he is "sure" that he told Mrs A to consult her GP if her symptoms persisted, which is his standard advice to patients. He thought that "[Mrs

A] would have understood, and there would have been no doubt in her mind, that if her symptoms continued after she stopped breast-feeding then she should seek further advice." He thought this was "common sense".

However, Dr B did not document any advice to Mrs A about persistent symptoms. Mrs A did not recall such advice, and her actions in not raising her ongoing symptoms with her GPs again until February 2008 are consistent with her no longer being worried about the postcoital bleeding (which, according to her husband, she had been told was "normal"). Dr B also did not refer to this advice in his letter to Dr C. Dr B advised Dr C that Mrs A "needs no active treatment … [and] will not require any further treatment".

In the absence of documentation, I am left in significant doubt that the advice was in fact given to Mrs A. This is a critical point. I note that my experts qualified their advice (about the reasonableness of Dr B not performing a smear) by stating that Mrs A needed to be told to return to her GP if her symptoms persisted. Dr Page noted, Dr B "does not appear to have given a likely timeline for resolution of the symptoms". Dr Harilall stated, "I trust that [Dr B] really did advise [Mrs A] to re-present to her primary care-giver should there have been ongoing or worsening symptoms."

In an earlier case involving a delay in diagnosing a woman's invasive squamous cell carcinoma of the cervix,[6] I highlighted the importance of communication in relation to follow-up arrangements between specialists and general practitioners. I noted that "appropriate follow-up care and review are essential following hospital admissions and outpatient clinics. It is critical that general practitioners receive all the necessary information about their patients, so that they can appropriately follow up matters identified at hospital. The reviewing doctor is responsible for ensuring that this information is communicated."

RANZCOG guidelines

As noted above, the RANZCOG guidelines state that when presented with a patient with intermenstrual and/or postcoital bleeding, providers should take a Pap smear if the patient has not had one within the previous three months. The guidelines also state that "in women with PCB or IMB a negative smear does not rule out the possibility of pathology" and "colposcopy should be the primary procedure with persistent PCB". In relation to follow-up advice, the guidelines clearly state that providers should consider informing women who present with symptoms of PCB "when to return for routine review if symptoms persist". Dr B advised HDC that he was not aware of these guidelines at the time he saw Mrs A, but that he recognised the "importance of the symptom of post-coital bleeding (PCB) as cardinal in the context of cervical carcinoma".

I specifically asked both my advisors to comment on Dr B's decision not to perform a smear, in light of the RANZCOG guidelines. Dr Harilall noted that the RANZCOG guidelines provide "a guide to recommended best practice, and do not replace the full history and clinical assessment". Dr Page noted that the RANZCOG guidelines were

[6] Opinion 03HDC15479, 19 October 2005, page 24, available from www.hdc.org.nz.

"produced to guide the management of these symptoms in women without the confounding effect of the hormonal changes that follow pregnancy and persist during breast-feeding". He stated that "the section [in the RANZCOG guidelines] about hormonal therapy could be viewed as applicable in the post-natal period. Irregular bleeding, due to hormonal changes, is a common problem at that time." Dr Page also advised that "where a reasonable alternative diagnosis is reached then the guideline need not be followed", and he believed that "this was the situation here".

Conclusion

Management

The key question is whether Dr B acted with reasonable care and skill when he saw Mrs A. Dr B made a diagnosis of anovulation and advised Mrs A that she did not require further treatment. He considered but discounted the possibility of cervical cancer, and did not perform a smear or colposcopy.

An assessment of Dr B's management relates to a matter of clinical judgement, which goes to the heart of medical practice. The adequacy of a doctor's clinical judgement is assessed substantially by reference to usual practice of comparable practitioners. However, even in relation to diagnosis and treatment, medical opinion is not necessarily determinative.[7] I am not bound to accept expert opinions uncritically.[8] It is open to HDC to hold that the standard acceptable to the profession was nonetheless not reasonable. Ultimately the reasonableness of any standards adopted by the medical practitioner is for the Commissioner to determine, taking into account usual practice, as well as patient interest and community expectations.[9]

In the leading decision of *Bolitho v City and Hackney HA*, the House of Lords stated:[10]

> "If, in a rare case, it can be demonstrated that the professional opinion is not capable of withstanding logical analysis, the judge is entitled to hold the body of opinion is not reasonable or responsible."

It is clear that Mr and Mrs A and the general practitioners involved in her care considered the possibility of cervical cancer, and the need for a smear to exclude this possibility. The RANZCOG guidelines state that when presented with a patient with postcoital bleeding or intermenstrual bleeding, a Pap smear should be taken.

Dr B accepts that persistent postcoital bleeding is "cardinal in the context of cervical carcinoma". However, he submits that postcoital bleeding was only one of the symptoms mentioned in the referral letter, not the primary reason. I find this curious, since there were only two symptoms mentioned by Dr C in his referral letter: the postcoital bleeding and "intermittent smelly discharge". The concerns about the retained swab were not a symptom, and seem to have been a distracter.

[7] *B v Medical Council of New Zealand* 8/7/96, Elias J, HC Auckland HC11/96.
[8] Skegg and Paterson, *Medical Law in New Zealand* (Brookers, Wellington, 2006), ch 4, p 114.
[9] *Lake v Medical Council of New Zealand* 23/1/98, Smellie J, HC Auckland, HC123/96.
[10] [1977] 4 All ER 771, 779 (HL).

Nevertheless, Dr B concluded that Mrs A's symptoms were the result of anovulation, related to her breastfeeding. I understand that recurrent PCB without bleeding at other times is *not* characteristic of anovulatory bleeding, but that it may also have causes other than cervical cancer. Dysfunctional uterine bleeding, including anovulatory bleeding, is a diagnosis based on the exclusion of other organic and structural causes for abnormal vaginal bleeding.

Being confident in his diagnosis, Dr B did not consider it necessary to undertake any further investigations, including a smear. His management is supported by four of his peers, including two of my independent advisors. I accept the existence of a significant body of opinion supportive of Dr B's management, and that such an approach may be the usual practice.

I am conscious that decision-makers are generally reluctant to probe the reasoning for clinical decisions and undertake their own clinical risk/benefit assessment. However, I am left in significant doubt whether Dr B's management was reasonable.

I acknowledge that a smear is a screening procedure rather than a diagnostic procedure, but it was a simple and obvious precaution to take, and may have detected abnormal cells. I also note that viewing the cervix as part of a routine speculum examination and determining it to be normal does not by itself obviate the need for a smear or other relevant diagnostic process when dealing with a patient with a clear history of PCB.

Dr Ngan Kee submitted, on Dr B's behalf, that a breach finding by HDC in relation to Dr B's management might lead to defensive medicine:

> "Gynaecologists may well infer from this opinion that it is medico-legally indefensible not to investigate every episode of abnormal bleeding to the 'nth' degree. This may result in a raft of unnecessary interventions including cervical smears, colposcopy, hysteroscopy and cone biopsies. The latter has the potential to significantly compromise future pregnancy outcomes. This approach may well increase the income of Gynaecologists but also has the potential to create unnecessary anxiety amongst women, increase intervention rates and ultimately to increase consumption of scarce resources."

Dr Ngan Kee also commented that "'persistent' is open to much interpretation and debate. I believe that many Gynaecologists will determine that the safest medico-legal interpretation of 'persistent' is 'any' and that intervention rates may rise as a result."

I do not suggest that every episode of abnormal bleeding requires investigation to the "nth" degree, nor that a single episode of PCB requires intervention. I note the statement in the RANZCOG guidelines that "if the patient has not had a Pap smear within the previous three months, take a Pap smear".

There is no avoiding the fact that, as Dr Page notes, "there was a missed opportunity for the possible earlier diagnosis of [Mrs A's] cervical cancer" when she consulted Dr B. To quote Dr Page again, "Had a smear been taken or colposcopy performed at her visit to him in June 2007, they might have indicated the presence of the cancer." But

as Dr B submitted in his own defence, the tragic outcome for Mrs A must not colour the assessment of the adequacy of his actions at the time. I conclude that Dr B did not breach the Code in his management of Mrs A on 14 June 2007.

Advice re follow-up
It is also important to approach the adequacy of Dr B's advice (to Mrs A and her referring GP) about follow-up based on the objective evidence, without hindsight or outcome bias. Dr B omitted to advise the referring GP of the need for further evaluation if Mrs A's symptoms persisted. He did not document any advice to Mrs A about when to re-present to her GP if her symptoms persisted, or any clear plan of action.

General practitioners refer patients to specialists to obtain expert opinion about the patient's condition, with the expectation that the specialist will assess the patient and perform any necessary tests. The opinion of a specialist carries significant weight. If the specialist provides a benign explanation for worrying symptoms, that is naturally reassuring for the patient (and their referring GP). I am not convinced by Dr B's submission that "common sense" would lead a patient to return to their GP if the symptoms persisted — particularly where the proffered explanation (breastfeeding) is continuing, as in the case of a mother with a new baby. These factors highlight the need for clear, documented advice to the patient and their GP about follow-up (including a plan of action in the event of persistent symptoms).

Baragwanath J stated in his decision in *Patient A v Nelson-Marlborough District Health Board*[11] that it is through the medical record that health care providers have the power to produce definitive proof of a particular matter (in that case, that a patient had been specifically informed of a particular risk by a doctor). In my view this applies to all health professionals, who are obliged to keep appropriate patient records. Health professionals whose evidence is based solely on their subsequent recollections (in the absence of written records offering definitive proof) may find their evidence discounted.

As noted above, in the absence of any documentation, I am not convinced that Dr B gave follow-up advice to Mrs A, and none was included in his letter to Dr C. I conclude that Dr B breached Right 4(1) of the Code[12] by his failure to provide specific follow-up advice to Mrs A and her referring GP.

Opinion: No breach — The medical centre

11 May 2007
Mrs A called the medical centre on 11 May 2007 and mentioned that she had ongoing symptoms of vaginal discharge and bleeding. The nurse noted that ultrasound scan

[11] *Patient A v Nelson-Marlborough District Health Board* (HC BLE CIV-2003-204-14, 15 March 2005).
[12] Right 4(1) of the Code states: "Every consumer has the right to have services provided with reasonable care and skill."

results were still pending and that Dr D was "unable to do smear cos of discharge etc". The nurse advised Mrs A to continue with her course of antibiotics. By this stage, infection and retained swabs had been effectively ruled out as possible causes. Although the ultrasound scan results were still pending, this was at least the fourth time Mrs A had noted her concerns about vaginal bleeding, and I have been provided with no evidence that the nurse relayed these concerns to Mrs A's general practitioners.

21 May 2007
Mrs A called the medical centre on 21 May to discuss her ultrasound results. This telephone conversation occurred exactly two weeks after her consultation with Dr D on 7 May, where it was agreed that Mrs A would "come back after two weeks" to have a smear taken.

The clinical record of the telephone conversation on 21 May does not indicate that Mrs A requested a smear or made an appointment for a smear. She was advised to come back in to the medical centre for review if she had ongoing problems.

11 October 2007
Mrs A clearly requested that a smear be taken when she called again on 11 October 2007. This request was declined by the nurse, Ms E, because Mrs A was "not due til January 2008".

According to Ms E, Mrs A did not report any history of abnormal bleeding and was happy to wait. This is in direct contrast to Mr A's recollection that his wife specifically told the nurse of her ongoing postcoital bleeding and vaginal discharge. Dr Maplesden advised that "on the face of it this action to decline a smear in a patient who is symptomatic is a departure from accepted practice and would garner the disapproval of a majority of providers". Dr Maplesden also noted that "in retrospect, the decision not to perform a smear at this stage resulted in further delay of [Mrs A's] eventual diagnosis".

However, Dr Maplesden also advised that "smeartakers are generally aware that the national guidelines discourage screening smears being undertaken at sooner than the recommended interval and Mrs A had had a previous negative smear history and had been presumably fully assessed and reassured by a specialist five months previously".

It is impossible to reconcile the conflicting accounts of whether postcoital bleeding was discussed with the medical centre nurse on 11 October 2007. It seems likely that Mrs A's ongoing bleeding prompted the call, so it is curious that she would not have mentioned it — though she may have been reassured by her specialist consultation with Dr B some months previously.

In hindsight, it is regrettable that the nurse did not elicit further information to find out why Mrs A wanted to bring forward her smear. I note Dr Maplesden's advice that in the absence of ongoing symptoms, declining Mrs A's request would not have been a departure from accepted practice.

I note that since these events, nurses at the medical centre have been instructed to elicit further information from women who call to request smears before they are due under the National Cervical Screening Programme.

MOH Guidelines
Dr Maplesden advised that, in line with the MOH guidelines, an asymptomatic woman with a normal smear history would be recalled for a routine smear at a three-yearly interval. In Mrs A's case, this was in January 2008.

However, he also advised that "this recommendation does not apply if the patient is symptomatic (as [Mrs A] was) … the Guidelines for screening for cervical cancer state that if a woman is symptomatic or there is concern about the clinical appearance of the cervix, she should be referred for colposcopic assessment as per the RANZCOG Guidelines". Mrs A was appropriately referred to a specialist in May 2007.

Dr Maplesden noted that the "recommendations contained in the cervical smear screening programme guidelines may not have been followed in that there appeared to be no consideration that Mrs A remained symptomatic when the decision was made to decline her smear in October 2007 because the standard screening interval had not elapsed". My advisor did not see this as "a significant departure from accepted practice", since the smeartaker does not appear to have been aware of Mrs A's ongoing symptoms.

Availability of LBC
The medical centre advised HDC that, due to the cost of LBC, its use at the time of the events in question "had been governed by patient request", and that there was reluctance for staff to use it and for women to opt for LBC "even if it was suggested as an option". There is no evidence that the option of LBC was suggested to Mrs A.

I acknowledge that LBC was not covered by the National Guidelines on smear taking that were followed by the medical centre. Furthermore, I accept that even if a smear had been taken using LBC, it would not necessarily have detected Mrs A's early cervical cancer. However, the Code states that every consumer has the right to information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including an explanation of the options available and costs of each option.[13]

In my opinion, a reasonable consumer in Mrs A's circumstances would have expected alternative smear taking options to be discussed with her. She was clearly very concerned about her postcoital bleeding and vaginal discharge, and the option of a smear had been discussed when she saw Dr C on 18 April 2007. She should have been told about the option of having her smear taken using LBC, if not on this occasion, then on the subsequent occasions when she reiterated her concerns about postcoital bleeding.

[13] Right 6(1)(b) of the Code.

It is possible that, if the option of LBC had been suggested to her, Mrs A would not have opted to use it. That is not the point. I do not accept that it is appropriate to have a policy of not offering the option of LBC simply due to the cost associated with this alternative smear taking procedure. While I commend the medical centre on the steps it has now taken to make LBC more available to women in the area, I consider that Mrs A should have been given the option of having her smear taken using LBC.

Conclusion

While I consider that the medical centre should have suggested the possibility of an LBC smear to Mrs A, Dr Maplesden has advised that the overall care provided to Mrs A by the medical centre was "consistent with expected standards". I accept Dr Maplesden's advice and conclude that the medical centre did not breach the Code.

Opinion: No breach — The DHB

Dr Page advised that the times taken to perform radiological tests for Mrs A at the DHB were "perfectly reasonable, and reflect the public health system in many parts of New Zealand". He also advised that "the availability of gynaecological services to Mrs A appears to have been adequate, as where a more urgent assessment was requested it was provided".

In my opinion, the care provided to Mrs A by the DHB was appropriate in the circumstances. I conclude that the DHB did not breach the Code. I note, however, that both Drs Page and Harilall identified issues in relation to the DHB's role as Dr B's employer, particularly with respect to his familiarity with the RANZCOG guidelines.

In response, the DHB advised HDC that "enabling clinicians to be aware of relevant college guidelines is an issue the DHB needs to address for all disciplines. The DHB will ensure that current clinicians are aware of college guidelines and … DHBs will need to work with colleges to ensure robust mechanisms are in place to inform the DHB and clinicians when college guidelines are updated or new guidelines are available."

Recommendations

I recommend that Dr B:

- apologise to Mrs A's family for his breach of the Code. This apology is to be sent to HDC and will be forwarded to Mrs A's family; and
- review his practice in light of this report.

I recommend that Dr C and Dr D review their practice in light of this report.

Follow-up actions

- A copy of this report will be sent to the Medical Council of New Zealand.
- A copy of this report, with details identifying the parties removed (but naming Dr B, and advisors Drs Maplesden, Page, Harilall, Tait and Ngan Kee) will be sent to the Royal Australian and New Zealand College of Obstetricians and Gynaecologists.
- A copy of this report, with details identifying the parties removed (but naming advisors Drs Maplesden, Page, Harilall, Tait and Ngan Kee) will be sent to the Director-General of Health, the National Screening Unit, the Royal New Zealand College of General Practitioners, the Federation of Women's Health Councils Aotearoa/New Zealand and the Women's Health Action Trust.
- A copy of this report with details identifying the parties removed (but naming advisors Drs Maplesden, Page, Harilall, Tait and Ngan Kee) will be placed on the HDC website, www.hdc.org.nz, for educational purposes.

Appendix 1
Clinical advice – General Practitioner Dr David Maplesden

I am a registered general practitioner and a Fellow of the RNZCGP. I hold a Diploma in Obstetrics.

3. Clinical Summary

3.1 [Mrs A] transferred her medical GP care from her [own] GP to [the medical centre], following her emigration with her family to New Zealand. A record of her past medical history was sent from [her home country], including the record of normal cervical smear results on 24 January 2005 and 15 August 2000. There was no past history of dysfunctional uterine bleeding noted.

3.2 Following a period of secondary infertility she conceived and eventually underwent a Caesarean section (CS) for fetal distress following induction at term plus ten days. A large boy was delivered in good condition, but there was difficulty in securing haemostasis while repairing the uterus. Misoprostol 800mgm was used with extra sutures to stop bleeding. Following the operative delivery and usual care [Mrs A] was discharged home with her baby.

3.3 Extracts from her [medical centre] notes show that on 18 April 2007 (about ten weeks post-partum) [Mrs A] saw [Dr C] about three episodes of post-coital bleeding, with no bleeding in between the episodes. [Mrs A's] normal smear history was noted. [Dr C] consulted with […] (identity unclear) who suggested obtaining an ultrasound scan and a cervical smear. Mr A had conveyed his concern that a swab might have been lost in his wife at the time of the CS. An X-ray examination was also ordered and undertaken on 20 April 2007. This did not detect any swab markers in her abdomen.

3.4 On 7 May 2007 [Mrs A] saw [Dr D] with continuing post-coital bleeding, and a "vaginal discharge". She was treated with antibiotics, and the note made "not for cervix smear until after treatment". On 14 May 2007 an ultrasound scan "excluded the presence of retained products of conception, or a swab".

3.5 On 11 May 2007 the entry stated "vaginal swab clear but symptoms of bleeding and discharge continue so keep going was my advice awaiting scan. [Dr D] unable to do smear 'cos of discharge etc". Within the clinical notes there was a sheet labelled National Cervical Screening Programme. It listed a smear being taken on 7 May 2007. Given the notation in the notes above, and the lack of a cytology result in the notes, it is likely that the smear was not performed, after the relevant forms had been completed.

3.6 On 9 June 2007 [Dr C] at [the medical centre] wrote to [Dr F] at [the public hospital], referring [Mrs A] with the problem of post-coital bleeding and vaginal discharge. He related the concern of [Mr A] regarding a lost swab, and that imaging studies did not support the postulate of a swab being lost. Continuation of the abnormal bleeding after antibiotic treatment was stated with the description "bleeding

tended to be post-coital, not constant". There was no reference to the date of [Mrs A's] most recent cervical smear test in the referral letter but there was a comment "she has no hx of abnormal smears".

3.7 On 14 June 2007 [Mrs A] was seen at [the public hospital] by [Dr B], gynaecologist. [Dr B] noted her history of CS in February, the concern about a possible lost swab, and the vaginal bleeding, "especially post-coital". He noted that [Mrs A] was breastfeeding, with no regular period cycle. The clinical notes of the consultation are not complete, but his letter to [Dr C] again confirmed the bleeding after intercourse. On examination he noted some blood in the vagina, the cervix was noted as normal with a normal mobile uterus, and no appendage abnormality. No record of colposcopic examination of the cervix was noted, and there was no record of the performance of a cervix smear for cytology. [Dr B] ascribed the abnormal bleeding to the condition of anovulation, which is common while breastfeeding. He advised that the condition could be stabilised by taking the contraceptive pill, which for [Mrs A] would not be inappropriate as she was not a tobacco smoker. He concluded the letter by stating the reassurance he had given [Mrs A] seemed adequate for her, and he discharged her back to the care of [Dr C].

3.8 There is no record of any hormone treatment being commenced at this stage. There is also no record of [Mrs A] mentioning her vaginal bleeding symptoms again until 22 February 2008. [Mrs A] was seen at [the medical centre] on four occasions between June 2007 and February 2008 — three consultations were for skin complaints and one for a flu vaccination.

3.9 On 11 October 2007 the nurse notes ([Ms E]) (included in [Dr C] 2 March 2008 referral to Colposcopy Clinic) recorded that [Mrs A] asked for a booking for a cervical smear to be performed. This was denied, with the notation "not due till Jan" (January). It is unclear whether or not [Mrs A] mentioned her ongoing symptoms at this stage as there is no documentation as to the reason for her smear request.

3.10 On 22 February 2008 the GP notes recorded that [Mrs A] was still complaining of post-coital bleeding, and a cervical smear was performed. The result was abnormal, "showing atypical squamous cells, not excluding a high-grade lesion". She was referred to the colposcopy clinic at [the public hospital] by letter of [Dr D] on 2 March 2008. [Mrs A] was notified by letter of the smear result and need for colposcopy also on 2 March 2008. The letter to her stated that her "cervical smear showed some low grade changes" and that colposcopy was required.

3.11 On 15 March 2008 the GP notes stated [Mrs A] had "constant bleeding, not able to have intercourse, feels terrible as Gynae allegedly told her there was nothing wrong. Husband frustrated and feels as if hospital is not being straight with them". On 27 March 2008 [Mrs A] underwent a spiral Computerised Tomography (CT) scan of her abdomen and pelvis. No evidence of a swab or foreign body was seen.

3.12 On 28 March 2008 [Mrs A] was seen at [the public hospital] by [a] gynaecologist. [The gynaecologist] wrote to [Dr D], stating [Mrs A's] history since the pregnancy and CS. He performed a colposcopy examination, when some abnormal

changes were visible, and a directed biopsy was taken. Depending on the histological result of the biopsy, he planned further diagnostic procedures including a loop electrosurgical excision of her cervix transformation zone, and endocervical curettage to exclude an endocervical lesion.

3.13 On 10 April 2008 a histology report was received. It described findings of HPV infection, CIN 3, and lymphovascular invasion consistent with invasive squamous cell carcinoma of the cervix. On 10 April 2008 [Dr B] recorded in [Mrs A's] hospital notes the measures undertaken to convey the diagnosis to Mr and [Mrs A], who declined to see [Dr B]. They were referred to [Dr C] for information and discussion.

3.14 On 11 April 2008 [Mrs A] was seen at [the public hospital] by [a] gynaecologist. She wrote to [a] gynaecologist, at [the public hospital in a main centre], referring [Mrs A] for further investigation and treatment. On 15 April 2008 [the gynaecologist] saw [Mrs A] in [the main centre public hospital], and wrote to [the gynaecologist at the regional public hospital], undertaking care for investigation and treatment.

4. Comments

4.1 Definitions: Intermenstrual bleeding (IMB) refers to vaginal bleeding (other than post-coital) at any time during the menstrual cycle other than during normal menstruation. Postcoital bleeding (PCB) is non-menstrual bleeding that occurs immediately after sexual intercourse. Postcoital bleeding suggests the presence of cervical disease (eg. infection, benign or malignant lesions)[14] or trauma, while intermenstrual bleeding has a wide range of possible causes. IMB and PCB are not diagnoses; IMB and PCB are symptoms that warrant further assessment.

4.2 Most women with PCB or IMB will not have an underlying malignant cause for their bleeding. PCB is not uncommon — one study reported that 6% of menstruating women will experience PCB in any one year.[15] The same study calculated that the risk of a woman in the community who develops postcoital bleeding having cervical cancer ranges from 1 in 44,000 at age 20–24 years to 1 in 2,400 aged 45–54 years. Nevertheless the symptoms of PCB and IMB are both emphasised in referral guidelines for suspected gynaecological cancers (see section 2).

4.3 What standards or guidelines are relevant to this complaint? Were those standards or guidelines followed?

4.31 I am not aware of any national guidelines that are specific to the investigation and management of female postcoital bleeding. There are national guidelines for the

[14] Goodman A. *Initial approach to the pre-menopausal woman with abnormal uterine bleeding* February 2008 http://www.uptodate.com (accessed 20 March 2009).
[15] Shapley M, Jordan J, Croft M. *A systematic review of postcoital bleeding and risk of cervical cancer* Br J Gen Pr. 2006 Jun;56(527):453–60.

management of heavy uterine bleeding[16] but they are of limited applicability in this case.

4.32 There are national elective services referral recommendations (for referral from primary care) for postcoital bleeding.[17] These state that the evaluation should consist of examination, cervical smear and high vaginal/endocervical swabs. If the problem is recurrent the recommendation is that the referral is urgent — to be seen at the next available clinic or within two weeks. It is emphasised that these are guidelines only and that if there is a conflict between the national referral recommendations and generally accepted clinical practice, then generally accepted clinical practice should prevail. In my experience these referral guidelines are not widely referred to in primary care. However the performance of a cervical smear as part of investigation of PCB in a patient prior to referral would, in my opinion, constitute accepted clinical practice.

4.33 The UK based National Institute for Health and Clinical Excellence (NICE) has developed guidelines for suspected gynaecological cancers[18] (2005). The guidelines suggest:

(i) a mandatory full pelvic examination, including cervical speculum examination for symptoms including IMB and PCB
(ii) where clinical features are suggestive of cervical cancer on examination, urgent referral of the patient
(iii) do not wait for a smear result or delay due to a previous negative smear result — refer immediately where there is clinical suspicion
(iv) consider urgent referral for women with persistent IMB but negative examination findings

I note that these are not New Zealand guidelines but suggest that they do not vary significantly from what would be deemed accepted clinical practice here.

4.34 There are national guidelines for screening for cervical cancer.[19] These guidelines were published in 1999 and updated in August 2008. If the patient is asymptomatic and has normal smear history (in terms of results and screening interval), the appropriate time for [Mrs A] to have been recalled for her routine smear would have been January 2008. However this recommendation does not apply if the patient is symptomatic (as [Mrs A] was), or if the patient has a macroscopically abnormal cervix but normal cervical cytology. It is important to realise that a cervical smear is a screening test rather than a diagnostic test. Cervical smears may be taken in the presence of vaginal discharge or bleeding but it is important to use liquid based cytology (LBC) in this instance to avoid obscuring the cervical cells. LBC is widely available in New Zealand and it has been routinely offered in my practice for at least

[16] NZ Guidelines Group *Guidelines for the Management of Heavy Menstrual Bleeding* 1998 www.nzgg.org.nz/guidelines/0032/HMB_fulltext.pdf (accessed 20 March 2009).
[17] See http://www.electiveservices.govt.nz/guidelines/postcoital-bleeding.html
[18] NHS *Referral guidelines for suspected cancer* June 2005 www.nice.org.uk/CG027 (accessed 20 March 2009).
[19] MOH *Guidelines for Cervical Screening in New Zealand* August 2008. http://www.nsu.govt.nz/Files/NCSP/NCSP_Guidelines_ALL_small(1).pdf (accessed 20 March 2009).

eight years. I am not aware of its availability in [the region]. The guidelines for screening for cervical cancer state that if a woman is symptomatic or there is a concern about the clinical appearance of the cervix, she should be referred for colposcopic assessment as per the RANZCOG guidelines (4.35).

4.35 There are Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) guidelines for referral for investigations of IMB and PCB[20] and I will quote directly from these: "*PCB is regarded as a cardinal symptom of cervical cancer. It is commonly accepted that a single episode of PCB in a woman who has a normal smear and cervical appearance does not warrant immediate referral, but recurrence of this symptom mandates referral for colposcopy … Any woman who has persistent or recurrent episodes of PCB must be referred for colposcopy.*" I note that these guidelines are due for review in July 2009 and had been revised three months after [Mrs A's] initial presentation with PCB. However the same guidelines in the pre-July 2007 form state, under "Investigations", that *if the patient has not had a Pap smear within the previous three months* (which [Mrs A] had not) *take a Pap smear using speculum carefully in order not to provoke further bleeding.*

4.36 Guidelines were not followed in this case. The failure to perform a cervical smear in a timely manner when faced with a patient with recurrent PCB who was being referred for assessment is at variance with both the national referral recommendations (4.32) and, in my opinion, with accepted practice in primary care. The recommendations contained in the cervical smear screening programme guidelines (4.34) may not have been followed in that there appeared to be no consideration that [Mrs A] remained symptomatic when the decision was made to decline her smear in October 2007 because the standard screening interval had not elapsed (see 4.34). However there are extenuating circumstances for both omissions (4.43 and 4.45) and as such I feel that neither represents a significant departure from accepted practice. The RANZCOG guidelines (4.35) may not have been followed by the specialist, [Dr B], but I acknowledge that such guidelines are for guidance rather than prescription and an individual's circumstances need to be taken into consideration.

4.4 Please comment generally on the standard of care provided to [Mrs A] by [Dr C] and [Dr D], and the practice, [the medical centre]. Please comment on the decisions made not to perform a cervical smear test in the period April to June 2007 and in October 2007. Please comment on the systems in place at [the medical centre] relevant to this case.

4.41 [Mrs A] had had three episodes of PCB when she presented to [Dr C] on 18 April 2007 just over ten weeks post-partum. In my experience this is not an unusual situation in the first three months post-partum (although the fact that [Mrs A] had had a Caesarean section means that there would have been less cervical trauma than with a

[20] RANZCOG (Royal Australian and New Zealand College of Obstetricians and Gynaecologists). 2004. *Guidelines for Referral for Investigations of Inter-menstrual and Postcoital Bleeding.* Statement No. C-Gyn 6. www.ranzcog.edu.au/publications/statements/C-gyn6.pdf. (accessed 20 March 2009).

vaginal delivery). There was also a question raised of a retained swab. The management plan of obtaining a cervical smear (and presumably concurrent bacterial swabs) and an ultrasound scan was reasonable under the circumstances. It is not clear why the decision was made to defer a smear and wait for the ultrasound scan result at this point and I can only assume that [Mrs A] may have been bleeding at the time of her consultation.

4.42 At consultation of 7 May 2007 [Mrs A] was still complaining of PCB and a "smelly vaginal discharge". An abdominal X-ray had shown no sign of a retained surgical swab (20 April 2007). It was reasonable for [Dr D] to assume that local infection was a likely cause for [Mrs A's] symptoms at this stage and appropriate swabs were taken and antibiotics prescribed. A decision was made to defer the smear at this stage which was also reasonable given that local infection can cause inflammatory changes in the cervix and lead to a suboptimal smear result — I take this to be the reason why preparations were made for a cervical smear including completion of relevant forms (3.5). However the use of LBC may have overcome this problem (see 4.34) although I accept that use of LBC in New Zealand, although common, is still not universal.

4.43 [Dr C] was aware of the negative result of [Mrs A's] vaginal swab on 11 May 2007 (3.5) and stated at the same time that [Dr D] was unable to take a smear because of ongoing discharge. There appears to be undue emphasis on the possibility of a retained swab as [Dr C] elects then to wait for the results of an ultrasound scan before acting further. While a retained swab might cause discharge and IMB it would not, in my opinion, have been a particularly likely cause for what [Mrs A] was clearly describing as PCB. Bacterial swabs had been clear and antibiotics had had no impact on the symptoms. I feel that [Dr C] failed to consider alternative diagnoses (most importantly a cervical lesion — either benign or malignant) as a cause for her symptoms having effectively excluded infection as the cause. However he did then refer [Mrs A] to specialist services (9 June 2007) two months after her initial presentation and with a variety of investigations having been undertaken. Even though a cervical smear had not been taken at this point (for technical reasons (4.42)) it had been recognised that this was an expected part of the investigation of PCB and it was reasonable, in my opinion, for [Dr C] to expect that all outstanding relevant investigations would be undertaken by the specialist ([Dr B]) or that [Dr C] would receive direction from the specialist regarding follow-up investigations. Overall I feel the management of [Mrs A] to this point was still consistent with accepted practice.

4.44 [Mrs A] was seen promptly by the specialist, [Dr B], one week after referral. [Dr B] performed a speculum and bimanual examination on [Mrs A] (3.7) and noted the cervix to be macroscopically normal. There is no record of a cervical smear being taken or colposcopy being performed and a diagnosis of bleeding secondary to anovulation was made. A suggestion was made that the condition could be stabilised by use of the combined oral contraceptive pill. I have not been briefed to comment on the specialist management of [Mrs A] but have made some brief comments in section 4.51. However I feel that the assessment and advice given by the specialist has influenced further management of [Mrs A] by [Dr C] in that it could be assumed that [Mrs A] was likely to continue to have an "anovulatory pattern" of bleeding while she

breastfed and that no particular additional management was therefore warranted. Such advice may also have been reassuring to [Mrs A] to account for the apparent absence of complaints from her regarding persisting bleeding through the remainder of 2007 and into 2008 (see 4.45).

4.45 [Mrs A's] symptom of PCB apparently failed to settle although there are no recorded complaints of the symptoms between June 2007 and February 2008 (3.8). She requested a booking for a smear on 11 October 2007 and this was declined by the smeartaker as it was "not due till (January 2008)". On the face of it this action to decline a smear in a patient who is symptomatic is a departure from accepted practice and would garner the disapproval of a majority of providers. However it is not clear that the smeartaker would have been aware of [Mrs A's] ongoing symptoms as there had been no record of them in her clinical notes for the preceding five months and there is no record as to whether symptoms were discussed at the time of the telephone call. Furthermore smeartakers are generally aware that the national guidelines discourage screening smears being undertaken at sooner than the recommended interval and [Mrs A] had had a previous negative smear history and had been presumably fully assessed and reassured by a specialist five months previously. The letter from the specialist gave no indication that any follow-up rather than routine was required and [Mrs A's] symptoms had presumably persisted but there is no record of them having changed at this stage. While, in retrospect, the decision not to perform a smear at this stage resulted in further delay of [Mrs A's] eventual diagnosis, in my opinion and for the reasons outlined, it does not represent a departure from accepted practice. However to accept the decision as normal clinical practice would be inappropriately advocating that the opinion of a specialist should override clinical judgement in the event of a patient's symptoms persisting or changing after the specialist assessment. [Mrs A's] abnormal symptom of PCB presumably persisted between June and November and good clinical judgement might have suggested that there was an ongoing cervical cause for this in spite of the specialist's reassurance.

4.46 On 22 February 2008 (ten months after her initial presentation), [Mrs A] still had symptoms of PCB and a cervical smear was performed in response to a recall letter [Mrs A] was sent for routine screening. The result was abnormal (3.10). [Dr D] referred [Mrs A] to the colposcopy clinic at [the public hospital] following receipt of the result and she was seen on 28 March 2008 when colposcopy was performed and was abnormal (3.12). [Mrs A] was then referred to [a main public hospital] for further management. The management of [Mrs A's] abnormal smear result by [Dr D] was consistent with recommended guidelines.

4.47 I cannot find any significant deficiencies in the systems in place at [the medical centre] as they relate to the cervical smear screening programme. However I recommend that [the medical centre] incorporate the use of LBC into their programme (if this has not already been done) — this would reduce the need to delay non-routine smears when bleeding or discharge is present. There should also be a protocol for management of patients who request a cervical smear at sooner than the recommended screening interval including ascertaining reasons for the request, documenting the reason for the smeartaker declining the request and ensuring an appropriate response for patients who are currently symptomatic.

4.5 Further comments

4.51 The assessment of [Mrs A] by her specialist, [Dr B], in June 2007 does, in my opinion, require expert review. Such a review is outside my level of expertise. However I note that the diagnosis of bleeding secondary to anovulation was made without undertaking either a cervical smear or colposcopy and relying on a macroscopic view of the cervix to exclude any cervical abnormality. So the question remains as to whether there was adequate exclusion of the cervix as the source of bleeding when PCB (rather than IMB) was the predominant symptom. These actions need to be examined in the context of risk — the risk of a patient with PCB having a malignancy as the cause of their bleeding is low. Another recent English study[21] found that the frequency of finding invasive lower genital tract neoplasia on colposcopy in women with postcoital bleeding is low — none of 142 women seen over twelve months with PCB had invasive cancer although 19% had cervical intraepithelial neoplasia (CIN) with 74% of the CIN group having had a negative smear within the previous 36 months. The study concluded that postcoital bleeding should remain an indication for referral to the colposcopy clinic for a detailed evaluation of the lower genital tract, mainly because of the significant prevalence of CIN. It can only be surmised that had [Dr B] performed a colposcopy on [Mrs A] in June 2007 her condition might have been discovered at a less invasive stage. However internationally there are wide variations in the management of PCB. A just-released study looked at the variations amongst consultant gynaecologists all over the UK in managing women with PCB[22] found that 281 (49.8%) of 614 respondents see women in gynaecology clinic, 94 (16.7%) in colposcopy clinic, while 163 (28.9%) see them in either clinics depending on the workload. Only 275 (48.8%) respondents repeat the cervical smear for those with negative smear history who are still within the national screening interval. However there are RANZCOG guidelines for the investigation of PCB in this country, but, as mentioned in 4.36, such guidelines are for guidance rather than prescription and individual's circumstances need to be taken into consideration.

5. Clinical opinion

5.1 On the basis of the information available to me, and with reference to the comments in section 4, in my opinion the management of [Mrs A] by [Dr C], [Dr D] and [the medical centre] was consistent with expected standards. Recommendations regarding possible process improvements are outlined in section 4.47.

[21] Abu J, Davies Q, Ireland D. *Should women with postcoital bleeding be referred for colposcopy?* J Obstet Gynaecol. 2006 Jan;26(1):45–7.
[22] Alfhaily F et al. *Postcoital bleeding: A study of the current practice amongst consultants in the United Kingdom.* Europ J Obs Gyn (in press) Avail online from 24 Feb 09 http://www.ejog.org/article/S0301-2115(09)00087-6/abstract.

Appendix 2
Independent advice – Gynaecologist Dr Ian Page

I undertook my medical training in the United Kingdom, qualifying MB. BS. (London) in 1979. My training in Obstetrics & Gynaecology was also undertaken in the UK, and I was awarded my Certificate of Completion of Specialist Training in 1988. I practised as a Consultant Obstetrician & Gynaecologist in the UK from 1988 until 2000, when I moved to New Zealand following my appointment at Whangarei Hospital. I am registered with the Medical Council of New Zealand as a Specialist in the Scope of Obstetrics & Gynaecology.

I have been asked to advise the Commissioner whether, in my opinion, [Dr B] and [the] DHB provided an appropriate standard of care to [Mrs A], and in particular to:

1. comment generally on the care provided to [Mrs A] by [Dr B]
2. comment generally on the care provided to [Mrs A] by [the] DHB
3. state what standards and guidelines are relevant to the case, and advise as to whether or not they were met/followed
4. comment on the appropriateness of [Dr B's] management plan
5. comment on the appropriateness of [Dr B's] decision not to perform a smear test in the context of the RANZCOG Guidelines Investigation of intermenstrual and postcoital bleeding
6. comment on the appropriateness of the responses to the incident by [Dr B] and [the] DHB.

The background (provided by the investigator and based on the material supplied) is as follows:

I have abbreviated the history to the events of [Mrs A's] pregnancy and the period afterwards until she saw [Dr B] in [the public] Hospital, as the ones relevant to the complaint and my opinion about her care my understanding, from the documents supplied, is that the complaint has now changed from being one about [Mrs A's] care during her pregnancy to one about the perceived failure to diagnose her cervical cancer at the earliest opportunity.

[Mrs A] booked for maternity care with her [LMC] on 27 July 2006. At 15 weeks gestation she was seen at [the public] hospital emergency department with vaginal bleeding. This was diagnosed as a threatened miscarriage, and she was discharged and subsequently given anti-D.

She was re-admitted on 28 October 2006, again with vaginal bleeding. This was diagnosed as being due to the location of her placenta (praevia), which had been demonstrated by ultrasound scan. The bleeding settled and she was discharged the next day.

She was subsequently admitted for induction of labour on 2 February 2007. During the process the fetal heart rate became abnormal, so she was delivered by caesarean section. This was made more complicated by bleeding from her placenta praevia, but

this was ultimately managed successfully. [Mrs A] then made an uneventful recovery, and went home a few days later.

Her post-natal period appears to have been uneventful initially, but at the end of February her vaginal loss was noted to be yellow/green and offensive. Antibiotics were prescribed for this, and the discharge was noted as non-offensive on 1 March. She was discharged to her General Practitioner's care by her midwife on 5 March 2007.

She attended her GP with her son on 18 April 2007. At the end of the consultation about her son she mentioned she had had three episodes of post-coital bleeding, with no bleeding in between. This was discussed by her [GP] with one of his colleagues, a management plan made and put into effect. Conversation later that day with [Mr A] led to increased emphasis on the possibility of a retained swab being included in the differential diagnosis.

An abdominal X-ray was performed on 20 April and excluded a retained swab. On 7 May [Mrs A] presented with a vaginal discharge. She was examined, swabs taken and antibiotics prescribed. She was advised to return for a smear when the discharge had settled. She was seen again on 9 May with her son, and mentioned her ongoing vaginal discharge and bleeding. Her GP eventually managed to arrange for her ultrasound scan to be performed on 14 May. This did not show any evidence of retained products or swabs, but did suggest blood clot within the cervical canal.

[Mrs A's] bleeding persisted and so she was referred to [the public] hospital on 9 June 2007. The letter was graded as routine. Following intervention from the General Practitioner the appointment was expedited, and [Mrs A] was seen by [Dr B] (Consultant Gynaecologist) on 14 June 2007.

[Dr B's] notes record that [Mrs A] complained of intermittent PV bleeding, especially post-coital, since her caesarean section in February and that there was concern about a possible retained swab. He noted she was breast-feeding, not on any hormonal contraception and had no regular cycle at the time. A full general history was also completed. [Dr B] then examined [Mrs A] abdominally and vaginally, and did not detect any abnormalities. He concluded the bleeding was probably anovulatory in origin, related to breast-feeding. He reassured her there were no retained swabs, and that the "pill" could be used to stabilise her cycle if she wished. [Dr B's] letter to the GP reiterated this. She was then discharged back to the care of her GP.

OPINION

1. "Comment generally on the care provided to [Mrs A] by [Dr B]"

I think that [Dr B] provided an appropriate level of care to [Mrs A]. I believe the referral letter was graded appropriately by [Dr B], as it did not imply an urgent problem and he intended for her to be seen by the surgeon who had performed her caesarean section. However when asked by the GP to expedite the appointment he did so, responding to the situation discussed with him.

When [Mrs A] was seen in the clinic a full history was obtained, and a full examination performed. This is what I would expect in this situation.

A reasonable diagnosis was then reached, taking into account all of the information available at the time. [Dr B] has stated that he did consider the possibility of cervical pathology (p00016 and p00030), and explained why he did not pursue it.

As noted by Dr Ngan Kee (p00041) medicine is not an exact science. We start with a history to make a list of possible diagnoses, then examine the patient to reach one or two. Investigations are then performed, if they are felt to be necessary, to reach a single diagnosis. I believe that it was quite appropriate for [Dr B] to reach the diagnosis he did, and other consultant gynaecologists would have done the same.

2. "Comment generally on the care provided to [Mrs A] by [the] DHB."
I am only giving an opinion with regard to the care given between the initial consultation with the GP (18 April) and [Mrs A] being seen by [Dr B] (14 June), as events outside that period are separate from the main thrust of the complaint.

The X-ray was performed within 2 days, and the ultrasound scan within 4 weeks (albeit after pressure from the GP). Given the clinical situation these times are perfectly reasonable, and reflect the public health system in many parts of New Zealand. Although not a specialist in ultrasound interpretation, I think the conclusion that the appearances were of blood clot within the cervical canal would be reasonable.

The availability of gynaecology services to [Mrs A] appears to have been adequate, as where a more urgent assessment was requested it was provided.

3. "State what standards and guidelines are relevant to the case, and advise as to whether or not they were met/followed."

I do not know of any guidelines or standards that refer specifically to abnormal vaginal bleeding in women who are breast-feeding. The guideline (appendix 1) referred to in (5) below was produced to guide the management of these symptoms in women without the confounding effect of the hormonal changes that follow pregnancy and persist during breast-feeding (see point 2 of Dr Ngan Kee's letter of 2 March 2009).

4. "Comment on the appropriateness of [Dr B's] management plan."
As I stated above I believe [Dr B's] management plan was appropriate. The only caveat I would make is that he does not appear to have given a likely [timeline] for resolution of the symptoms. He offered a possible solution for [Mrs A], namely the "pill", but left it for her to decide whether to use it. The alternative of actively prescribing the "pill" and giving it a limited time to resolve the symptoms, might have allowed earlier recognition of the development of [Mrs A's] cervical cancer. That, however, is an assumption and not a fact.

5. "Comment on the appropriateness of [Dr B's] decision not to perform a smear test in the context of the RANZCOG Guidelines Investigation of intermenstrual and postcoital bleeding."

Technically the guideline enclosed (appendix 1) was not in place in June 2007, and so the previous version referred to by Dr Ngan Kee should be studied. It is also relevant that [Dr B] had not been made aware (p00016) of the RANZCOG guidelines during his orientation to [the] hospital or during his Medical Council supervision it would, therefore, be unfair to criticise him in this regard.

The guideline also notes that "clinical management must be responsive to the needs of the individual patient and the particular circumstances of each case." I believe this means that where a reasonable alternative diagnosis is reached then the guideline need not be followed. I believe this was the situation here.

6. "Comment on the appropriateness of the responses to the incident by [Dr B] and [the] DHB."

I believe [Dr B] has acted openly and constructively in his responses to the complaint and Dr Donoghue's[23] report, a view supported by [the] DHB (p00180).

However I have grave concerns over the approach that appears to have been adopted by [the] DHB to the initial letter of complaint (19 March 2008) from [Mr & Mrs A]. To immediately undertake what they describe as internal peer review (see p00144/00145), possibly without even bringing the complaint to the attention of [Dr B], was likely to cause problems. There is discrepancy between [Dr B's] views on this (p001) and that of the DHB (p00162). [Dr B] has stated he should have been given the opportunity to respond to the complaint when it was received by the DHB, yet the DHB states that [Dr B] was aware of the DHB's intention to initiate a review and was fully supportive of Dr Donoghue undertaking it. I cannot understand why the DHB felt the need for such a review, as at the time of receiving the letter [Mrs A] had not been diagnosed as having cervical cancer.

That the reviewer (Dr Donoghue) was not given clear instructions (including a timeline) with regard to his review is surprising, as I would expect senior managers to understand the need for clarity in any such case (p00151). [The] DHB knew that [Mr & Mrs A] were actively seeking a response to their letter, yet even three months later (p00222) they were nowhere near getting the report from their internal review. I note that Dr Donoghue broadened the field of enquiry during the investigation (p00227) but gives no reason or justification for this.

I also note that Dr Donoghue has responded as a private practitioner, and not as a DHB employee, which again reflects the lack of clarity of the [the] DHB when seeking the review. The DHB also acknowledges the report was not of the nature it expected (p00145).

The sequel to the poorly directed internal review has been a proliferation of legal briefings and correspondence. All of these predictable consequences have led to further delay in resolving the complaint (see p00177), and probably made it more

[23] Dr Al Donoghue, O&G, was asked to write a report for the DHB. The purpose of the report was to analyse the delay in diagnosis of invasive carcinoma of uterine cervix suffered by Mrs A.

likely that the complainants would believe the system was conspiring against them. This makes satisfactory resolution of their complaint even more difficult.

CONCLUSIONS
I believe the care given by [Dr B] to [Mrs A] was appropriate. It is true that there was a missed opportunity for the possible earlier diagnosis of her cervical cancer. Had a smear been taken or colposcopy performed at her visit to him in June 2007, they *might* have indicated the presence of the cancer. Nonetheless I think that many of his peers would have adopted the same approach that he did, and not performed a smear or colposcopy at that visit.

I think the investigation of the initial complaint by [Mr & Mrs A] has been prolonged by the process followed by [the] DHB. I believe much of this could have been avoided had they given clearer instructions to Dr Donoghue at the outset.

Dr Ian Page MB BS, FRCOG, FRANZCOG

Further advice
Thank you for your further enquiry, as detailed in your letter of 2 June 2009 (24826.pdf), with regard to the 2004 RANZCOG Guidelines (C-Gyn 6 Referral of 1MB & PCB Final Jul O4.pdf).

You have specifically asked about the care provided by [Dr B] in light of the Investigation section of the guidelines. My memory of [Dr B's] statement (returned to you with my original opinion) is that he had not been made aware of the existence of the RANZCOG guidelines. This ties in with my own experience of coming to New Zealand, where the existence of College guidelines was not mentioned during my induction to local practice. It is therefore not surprising that he did not follow it.

Had he been aware of the guideline he may still have felt it was not clearly applicable to [Mrs A's] situation. The guideline was primarily written for General Practitioners, and I believe the section about hormonal therapy could be viewed as applicable in the post-partum period. Irregular bleeding, due to hormonal changes, is a common problem at that time.

In that case the second bullet point of section 7 (no need for further investigation at that time) applies. However the fourth bullet point (when to return if symptoms persist) should have been followed, as I noted as a caveat in my initial opinion I can only guess as to the reason for this omission. I suspect it was a reflection of the strains within the gynaecology service at the time due to staff shortages and [Dr B] may be able to offer an explanation.

I hope that clarifies my initial opinion, and thank you for finding the original guideline for me to view.

Appendix 3
Independent advice – Gynaecologist Dr Mahesh Harilall

Summary of Clinical case — (as I have interpreted from the notes I have received): Patient [Mrs A], aged 39 presented to her general practitioner in April 2007 with abnormal vaginal bleeding, of which post-coital bleeding was a component of that presenting symptom.

[Mrs A] had a caesarean birth 10 weeks prior to this presentation — for as I am informed a diagnosis of placenta praevia. I do not have access to those antenatal and delivery notes, nor any of the clinical records from that pregnancy — to establish whether there were any concerns about the uterine cervix antenatally, nor at delivery by a caesarean. There is comment however from [the gynaecologist] in a subsequent clinical entry (Page 108) at time of a subsequent colposcopy evaluation clinic — that there was excessive bleeding at the caesarean birth, and additional vascular measures were taken at the caesarean to control haemorrhage. He also notes that there was concern with further haemorrhage at two weeks post partum. (This may suggest that cervical pathology may have been already active by that antenatal period.)

There is documentation of [Mrs A] having had a normal cervical screening smear test two years prior in [her home country].

The general practitioner performed a swab test because of the patient's persistent symptom of an abnormal vaginal discharge, and prescribed a course of antibiotics. The swab test was reported negative for infection. Clinical examination and an ultrasound scan was arranged to exclude the presence of a "lost swab" from the surgery. Her symptoms did not resolve over the next two months, and a referral was arranged for [Mrs A] to be seen at [the local DHB] to see a Gynaecologist.

[Mrs A] saw [Dr B] on 14 June 2007. [Dr B] took an appropriate clinical history, and performed a clinical assessment. In particular, note was made of the normal prior cervical screen history. He visualised the cervix, commented that the cervix appeared macroscopically normal, did a bimanual pelvic examination, and commented that the cervix, uterus and adnexum appeared normal. He reviewed the radiological tests that had been performed — Ultrasound scan, and the blood / swab tests that were attached to the referral.

[Dr B] from the information given in his letter, and his subsequent comments — gave a recommendation of a care plan based on his clinical impression — that he believed the clinical diagnosis was that of "Anovulation". This means that he believed that he could at that stage not establish any pathological organic cause for the abnormal bleeding pattern and by exclusion thereof gave a "Hormonal Imbalance" cause thereof to explain his diagnosis and care plan recommendation.

[Dr B] recommended that [Mrs A] could consider ceasing breastfeeding, and commence the oral contraceptive pill. He states in his letter that he had given this advice and reassurance to [Mrs A] based on his assessment, and states (page 18) that he (as he normally does) ended his consultation with a statement to the effect that "the

patient should represent to her General practitioner if her symptoms were still on-going after ceasing breastfeeding or if she had any ongoing concerns".

[Mrs A] stated that she would not stop breastfeeding, nor use the oral contraceptive pill.

It does not appear that [Mrs A] re-presented to her General Practitioner for a clinical review until Feb 2008 — 8 months later, when she presented for a cervical smear test.

That cervical smear test was reported abnormal, whence a referral was made for a Colposcopy, and then a diagnosis of cervical cancer was confirmed.

Tragically [Mrs A] with advanced cervical cancer [died] with complications from advanced cervical cancer.

Advice and Comments addressed to the Health and Disability Commissioner:
This is a tragic and very sad outcome for [Mrs A] and her family — her husband [Mr A] and their two young children.

Re: Questions asked for Purposes of Expert Advice

Please comment generally on the care provided to [Mrs A] by [Dr B]
Please comment generally on the care provided to [Mrs A] by [the] DHB

System issues identified:
[Dr B] was a new Doctor to this DHB, having trained and worked overseas prior to taking up this position in New Zealand. At the time of this consultation with [Mrs A], he had been in employment at this hospital for 3 months. The Department was short staffed, and he was working long hours.

[Dr B] appears to have been working at this DHB under remote supervision of his clinical obstetrics and gynaecology practice; whilst at that stage still not yet a full fellow of the College, nor with full vocational registration with Medical Council. This should not have been allowed to happen — and is an issue that the NZ branch of RANZCOG has made very clear to its Fellows, and to the NZ Medical Council.

Re: Whether a cervical smear test should have been done, and when should this have been considered?
I would suggest that a cervical smear test should have been considered and probably done by the referring general practitioner (GP) — particularly given that the GP service had provided primary care to this patient. A Liquid-based Cytology specimen collection should have been considered in the presence of the symptoms she had described. I am led to understand that this type of cytology testing was not routinely available to this practice, but has since this investigation been introduced where clinically deemed appropriate.

[Dr B] took an appropriate history, and performed an appropriate clinical examination noting the relevant positive and negative clinical features. He made a conscious decision not to perform a cervical smear at this one consultation with this patient.

Given the referral, the history obtained and the clinical assessment — I believe that his decision to not perform a cervical smear test was not unreasonable.

In the comment about whether [Dr B] was aware, or not, of the RANZCOG guidelines on management of intermenstrual and post-coital bleeding — at the time of his employ at [the] DHB. A specialist or general practitioner working in Women's health should be aware of the content of these guidelines.

I have drawn directly from the 2004 College Guidelines the following paragraph: "4. Management and referral

> The following patients should be referred:
>
> Women with persistent IMB and/or PCB without unusual features:
> These women should be referred for specialist opinion. In general, hysteroscopy/D&C by a specialist should be the primary imaging procedure in women with persistent IMB, while colposcopy should be the primary procedure with persistent PCB or if a suspicious lesion is present on the cervix. Both investigations may be required. In some instances high resolution transvaginal ultrasound scanning may provide additional information, but this skilled and expensive technology should not usually be the primary or the sole investigation. Saline infusion sonohysterography may also be useful."

Like any Guideline, this one provides a guide to recommended best practice, and does not replace the full history and clinical assessment. The guideline does state that a "colposcopy should be the primary procedure with persistent PCB or if a suspicious lesion is seen on the cervix."

Faced with a similar clinical presentation and examination findings by [Dr B], I would not be over-critical of a colleague's decision not to perform a Colposcopy examination in this first clinical setting. If the symptoms were persistent, then a cervical smear with a colposcopy would have been indicated.

A cervical smear test on its own is not very sensitive to a diagnosis of cervical cancer. It is an adjunct to a full clinical assessment to assist the diagnosis. A cervical smear test will miss up to 20% of major underlying cervical pathology — including cervical cancer. A cervical smear test also has a high false negative rate, in the presence of blood, mucous or inflammation — in the sample collection technique, hence the value of liquid based cytology. Liquid Based Cytology is now accepted as superior to conventional cytology — particularly in reduction of false negative reports.

[Dr B] saw [Mrs A] for one consultation. He states in his subsequent letter to the [family] — that he advised the patient in person to re-present if her symptoms continued after this consultation. He says his care-plan was advised directly to his patient.

[Mrs A] had decided not to stop breast-feeding, and not to start the oral contraceptive pill.

Four months later (Page 116) on 11 October 2007, [Mrs A] contacted the General Practice rooms to arrange a smear test. The nurse/receptionist who received this phone call states that she had neither asked [Mrs A], nor had [Mrs A] volunteered any change in symptoms like abnormal bleeding pattern or a previous history of an abnormal smear. [Mrs A] was told she was "not due 'til January 2008." [Mrs A] was apparently satisfied with the plan to wait until Jan 2008, for her next smear test.

[Mrs A] saw her GP again on 22/02/2008, to have a cervical smear test (Page 116).

I am uncertain what the relationship is between the referring general practitioner and the local DHB was, and whether there were any perceived barriers to access of secondary public health services from either the GP or the patient. If there were ongoing clinical concerns from the patient, there should have been realised an opportunity for reassessment by the primary caregiver, and referral for another specialist opinion. It does not appear that [Mrs A] re-presented to the GP for a repeat consultation following discharge by the specialist [in] June 2007, until her next cervical smear test consultation in Feb 2008.

I believe [Dr B] acted in good faith in [Mrs A's] care. The decision that he made to not do a cervical smear will heavily weigh on his conscience. I trust that he really did advise [Mrs A] to re-present to her primary care-giver should there have been ongoing or worsening symptoms.

When a patient as in the case of [Mrs A] feels let down by the system, I understand the need for full accountability.

I do not believe that [Dr B] should shoulder the weight of this accountability.

I believe there were several system-related factors that contributed to the overall care provided to [Mrs A] as being sub-standard. I believe the fact that [Dr B] was working under remote supervision, in an overall poorly staffed Gynaecology Unit, and was new to the DHB.

I do not believe that [Dr B's] decision not to perform a cervical smear test was the main factor that resulted in the eventual tragic outcome for [Mrs A].

I believe that [Dr B] has [through] his professional actions since this experience — to attain Full Vocational registration, Accreditation as an Associate Membership status of RANZCOG, and taking up leadership roles at the [the] DHB — confirm[ed] his intention to promote best practice in Women's Health in NZ.

Appendix 4: Expert advice – Gynaecologist Dr Digby Ngan Kee

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24/8/2008

Dear

Re:

Thank you for your request for a medical report regarding the care of Mrs . I have based my report on the records you have provided to me from DHB. Having duly considered this information I have come to the following conclusions:

CASE HISTORY

Mrs was referred to the Gynaecology service at Health approximately 4 months post-partum with a history of intermittent vaginal bleeding and a smelly vaginal discharge. She had been delivered by caesarian section. The General Practitioner had requested a plain abdominal X-ray to exclude a pack retained from the caesarian section. The X-ray had revealed no radio-opaque markers. An ultrasound scan of the pelvis had also been requested. This revealed a normal uterus and ovaries with a thin endometrium measuring 2.1mm in thickness. On transvaginal scanning there was some increased echogenicity in the region of the cervix suggestive of the passage of clot.

Mrs was seen at Hospital by Dr , Gynaecologist on 4/6/2007. Dr took a thorough history and carried out an abdominal and vaginal examination. He noted the abdominal wound to be well healed. On vaginal examination a small amount of blood was noted. The cervix was noted to be normal and the uterus normal and mobile. There were no adnexal masses.

9

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Dr concluded that the clinical picture was consistent with annovulation, which he noted was common whilst breastfeeding. He reassured Mrs and suggested to the GP in his letter that no active treatment was necessary. He also commented that the oral contraceptive pill could be used, if necessary, to stabilize the situation.

CONCLUSIONS

1. Mrs General Practitioner had requested a plain abdominal X-ray to exclude the possibility of a retained surgical pack. Retained surgical packs are a well recognized complication of surgery and as a result all packs contain a readily detectable radio-opaque tracer. The fact that no radio-opaque tracer was found on plain X-ray makes it extremely unlikely that this complication had occurred.

2. When Dr saw Mrs at Hospital he carried out a thorough assessment including a detailed history and examination. His consultation was also documented quite adequately in the notes. I consider that in his assessment, Dr met the standard that would be expected from a consultant Obstetrician and Gynaecologist.

3. Dr h concluded that Mrs bleeding and discharge were due to annovulation and needed no active treatment. I concur with this assessment. Mrs was seen by Dr when she was approximately 16 weeks post-partum. It is highly unlikely that endometritis or retained products of conception would be the cause of her problems at such a late stage. In addition an ultrasound scan had revealed a thin endometrium measuring 2.7mm in thickness. This is extremely thin when it is considered that in post-menopausal women the endometrial thickness is generally less than 4mm in thickness. Such a thin endometrium would be in keeping with the diagnosis of annovulation.

4. Annovulation following pregnancy and delivery is a relatively common occurrence and usually due to the effects of breastfeeding or early use of contraceptive agents such as depot provera or the oral contraceptive pill. The problems caused by annovulation are usually irregular bleeding and/or dysparieunia due to low estrogen levels resulting in atrophic

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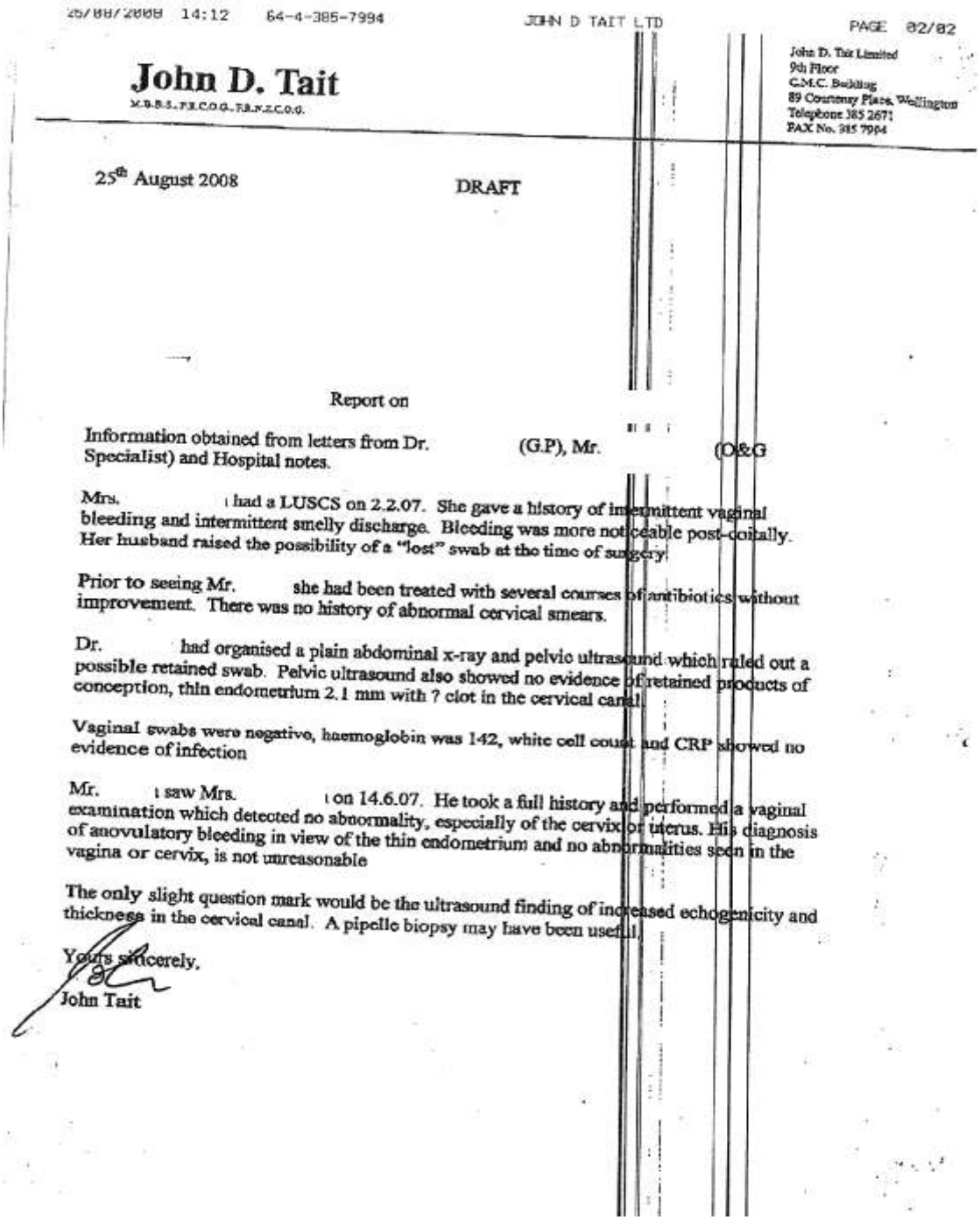
vaginitis. This is a difficult condition to manage. Usually it is self-limiting and resolves when ovulation returns. Estrogen therapy, as suggested by Dr can help to limit the condition, but is not guaranteed to cure the problem.

In conclusion it is my opinion that Dr carried out an assessment that is consistent with current professional standards. The conclusions he reached were logical, and in my opinion correct given the clinical situation and available investigation results. I would also concur with his recommendation that no active treatment was required, given that this condition often resolves with time. The recommendation that the oral contraceptive pill might be useful is sound. Overall I can find no fault in the standard of care given to Mrs by Dr

Yours sincerely

Dr Digby Ngan Kee *FRANZCOG,MRCOG*
Obstetrician and Gynaecologist

Appendix 5: Expert advice – Gynaecologist Dr John Tait



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25th August 2008 DRAFT

Report on

Information obtained from letters from Dr. (G.P), Mr. (O&G Specialist) and Hospital notes.

Mrs. had a LUSCS on 2.2.07. She gave a history of intermittent vaginal bleeding and intermittent smelly discharge. Bleeding was more noticeable post-coitally. Her husband raised the possibility of a "lost" swab at the time of surgery.

Prior to seeing Mr. she had been treated with several courses of antibiotics without improvement. There was no history of abnormal cervical smears.

Dr. had organised a plain abdominal x-ray and pelvic ultrasound which ruled out a possible retained swab. Pelvic ultrasound also showed no evidence of retained products of conception, thin endometrium 2.1 mm with ? clot in the cervical canal.

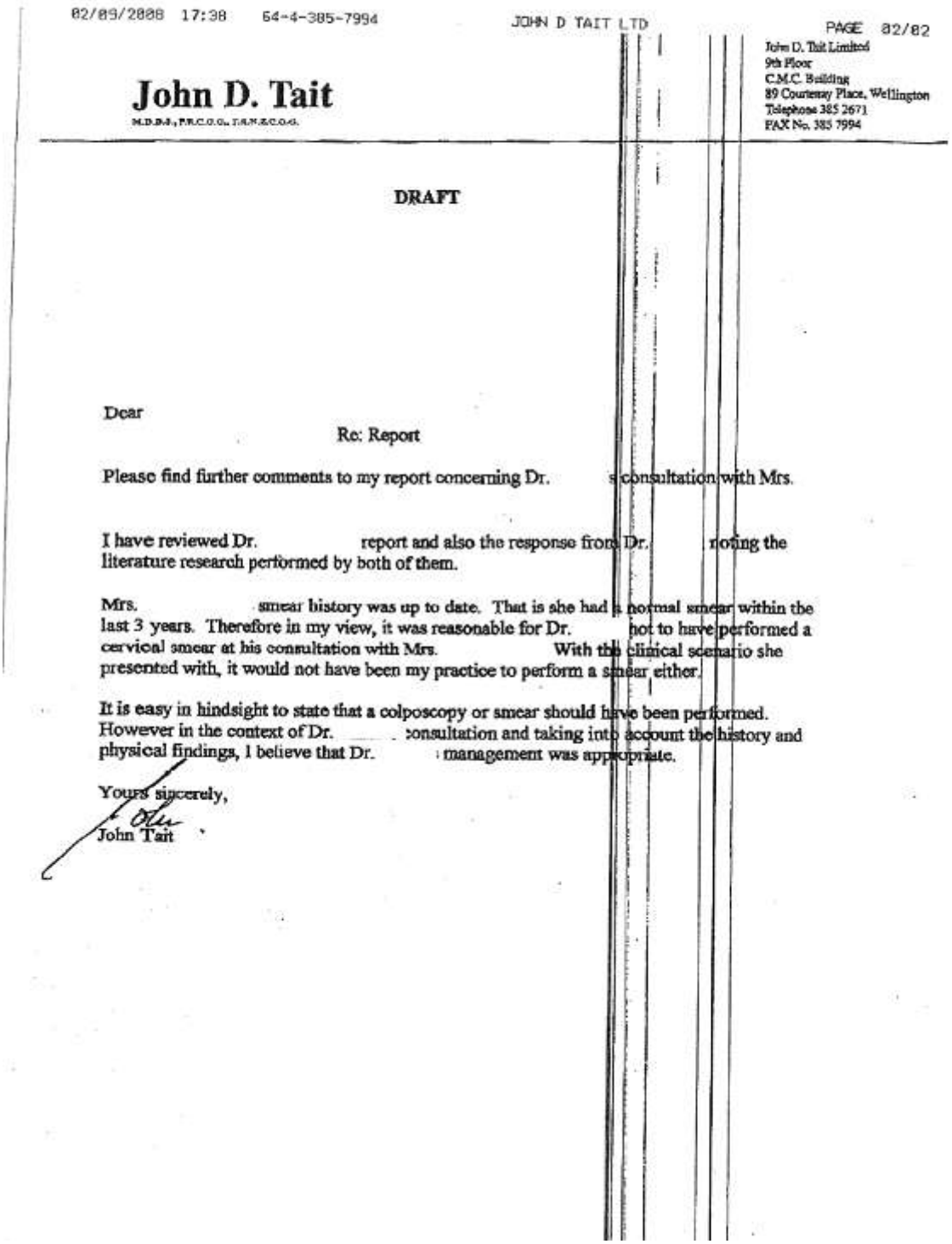
Vaginal swabs were negative, haemoglobin was 142, white cell count and CRP showed no evidence of infection

Mr. saw Mrs. on 14.6.07. He took a full history and performed a vaginal examination which detected no abnormality, especially of the cervix or uterus. His diagnosis of anovulatory bleeding in view of the thin endometrium and no abnormalities seen in the vagina or cervix, is not unreasonable

The only slight question mark would be the ultrasound finding of increased echogenicity and thickness in the cervical canal. A pipelle biopsy may have been useful.

Yours sincerely,

John Tait



02/09/2008 17:38 64-4-385-7994 JOHN D TAIT LTD PAGE 02/02

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DRAFT

Dear

Re: Report

Please find further comments to my report concerning Dr. s consultation with Mrs.

I have reviewed Dr. report and also the response from Dr. noting the literature research performed by both of them.

Mrs. smear history was up to date. That is she had a normal smear within the last 3 years. Therefore in my view, it was reasonable for Dr. not to have performed a cervical smear at his consultation with Mrs. With the clinical scenario she presented with, it would not have been my practice to perform a smear either.

It is easy in hindsight to state that a colposcopy or smear should have been performed. However in the context of Dr. consultation and taking into account the history and physical findings, I believe that Dr. management was appropriate.

Yours sincerely,

John Tait

Appendix 6: RANZCOG Guidelines

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists

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Excellence in Women's Health

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College Statement

Title	**Guidelines for referral for investigations of intermenstrual and postcoital bleeding**
Statement No.	**C-Gyn 6**
Date of this document	**July 2004**
First endorsed by Council	**1995**
Next review due	**July 2006**

Background

These guidelines were first developed in 1995 by the Royal Australian College of Obstetricians and Gynaecologists, the Royal Australian College of General Practitioners, the Australian Society for Colposcopy and Cervical Pathology and the Commonwealth Department of Human Services and Health.

The purpose of the guidelines is to assist general practitioners to decide when it is necessary to refer women with intermenstrual or postcoital bleeding (IMB, PCB) for further tests or to a specialist gynaecologist, and to assist gynaecologists in formulating management plans.

Genital tract malignancy is an uncommon cause of bleeding at any age and is rare in younger women. Nevertheless it is a possible cause. Since intermenstrual and postcoital bleeding are common, especially in women using hormonal contraception or on hormonal therapies, it is obviously impractical, unreasonably worrying and inappropriate to refer every case for immediate investigation. These guidelines recommend appropriate management of women presenting complaining of IMC or PCB and referral indications.

1. Careful History

Take a careful history noting:

- patient's age
- nature, frequency and clinical associations of the bleeding
- hormonal therapy and contraceptive history
- past history of bleeding
- previous abnormal Pap smears
- cigarette smoking
- sexual history and relevant symptoms in a partner

2. Examination

Conduct abdominal examination, speculum examination (with a good light) and bimanual pelvic examination.

Check:
- complete normality of ectocervix
- contact bleeding and cervical tenderness
- friability of tissue, ulceration or cervical polyp
- other possible sites of bleeding
- signs of vaginal discharge, foreign body or IUCD tail

Practitioners must always bear in mind the need to re-examine a patient if particular symptoms recur at a future stage.

3. Investigations

If the patient has not had a Pap smear within the previous three months, take a Pap smear using speculum carefully in order not to provoke further bleeding. These diagnostic (rather than screening) Pap smears (Medicare item no. 73055) should be sent to laboratories using appropriate quality control procedures. Cervical swabs should be taken for chlamydia trachomatis if appropriate.

Cervical ectopy is a common finding in premenopausal women, especially in combined oral contraceptive users and pregnant women, and contact bleeding from the cervix is relatively common when taking a smear, particularly from the endocervix using a cytobrush. A thin prep sample should also be sent if bleeding is likely to obscure the cells on the slide.

The occurrence of contact bleeding or abnormal bleeding in the case history should be noted on the request form. Contact bleeding or ectopy should not prompt referral unless other features are present or IMB or PCB has been persistent. In women with PCB or IMB a negative smear does not rule out the possibility of pathology. IMB and PCB are, by nature, intermittent, and duration, volume and frequency need to be taken into account in determining whether symptoms are "persistent". It is not possible to give a simple and all encompassing definition of "persistent", but, for example, several minor episodes over a three month period or 2 episodes of heavy bleeding should generally prompt referral.

4. Management and referral

The following patients should be referred:

- *Women with persistent IMB and/or PCB without any unusual features:*
  These women should be referred for specialist opinion. In general, hysteroscopy/D&C by a specialist should be the primary imaging procedure in women with persistent IMB, while colposcopy should be the primary procedure with persistent PCB or if a suspicious lesion is present on the cervix. Both investigations may be required. In some instances high resolution transvaginal ultrasound scanning may provide additional information, but this skilled and expensive technology should not usually be the primary or the sole investigation. Saline infusion sonohysterography may also be useful.

- *Women with a friable cervix:*
  Where this is causing persistent symptoms, women should be referred for assessment and possible treatment. After careful exclusion of significant pathology by colposcopy, a variety of ablative methods may be used. Generally the problem will resolve without treatment.

- *Women with IMB/PCB and an abnormal Pap smear:*
  These women should be referred for colposcopy if:
  a) the smear report suggests the presence of CIN-1 or greater or the presence of any glandular abnormality.
  b) on repeated diagnostic Pap smear testing 2-3 times over a twelve month period, the smear contains cells suggestive of an underlying low-grade squamous lesion less than CIN-1 (eg minor atypia, HPV atypia)

Practitioners in remote areas should consider telephone consultation with a specialist if the circumstances are unclear.

5. **Women on Hormonal Therapy**

Women with IMB who are on the progestogen-only minipill or in the first 6 months of Depo-Provera treatment (often called breakthrough bleeding) should generally not be referred in the first instance unless bleeding is excessively frequent or prolonged, and provided Pap smears are normal and up-to-date. Low oestrogen-dose combined pills and IUCDs are also frequent causes of IMB.

6. **Documentation**

Brief documentation as outlined above must be maintained on:
- type of abnormal bleeding
- hormonal therapy
- past history of bleeding and previous investigations
- date and report of last Pap smear
- examination findings
- action taken for investigation and treatment
- follow-up recommended

7. **Information for Women**

Consideration should be given to the following points when informing women who present with symptoms of IMB or PCB:
- the most likely cause or causes
- either that serious causes like cancer are so rare, or other causes so likely, that further investigation is not indicated OR that the cause needs to be investigated
- instructions about investigations, if indicated
- when to return for routine review if symptoms persist
- that a Pap smear is a screening test, and is only 80-90% sensitive and may therefore not detect underlying pathology in 10-20% of affected women

Companion Documents (or References)
none available

Links to other related College Statements

Patient Resources
none provided

Disclaimer

This college statement is intended to provide general advice to Practitioners. The statement should never be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of each patient.

The statement has been prepared having regard to general circumstances. It is the responsibility of each Practitioner to have regard to the particular circumstances of each case, and the application of this statement in each case. In particular, clinical management must always be responsive to the needs of the individual patient and the particular circumstances of each case.

This College statement has been prepared having regard to the information available at the time of its preparation, and each Practitioner must have regard to relevant information, research or material which may have been published or become available subsequently.

Whilst the College endeavours to ensure that College statements are accurate and current at the time of their preparation, it takes no responsibility for matters arising from changed circumstances or information or material that may have become available after the date of the statements.