Obstetrician/Gynaecologist

Report on Opinion – Case 98HDC13810

Complaint

The Commissioner received a complaint about the services provided to the consumer by an obstetrician/gynaecologist. The complaint is that:

- *In mid-August 1997, the consumer visited an obstetrician/gynaecologist after being referred by her GP. She had suffered a severe post-coital bleed.*
- *The obstetrician/gynaecologist took an ultrasound scan of the consumer's uterus but did not examine her cervix or perform an internal vaginal examination.*
- *The consumer believed the obstetrician/gynaecologist was negligent in not examining her cervix on this initial referral, and feels that had the obstetrician/gynaecologist done so, the cervical cancer which she now suffers from would not have progressed to the stage it had by the time further medical action was taken.*

Investigation

The Commissioner received the complaint on 7 April 1998. An investigation was undertaken. Information was obtained from:

The consumer
The provider / Obstetrician/Gynaecologist
General Practitioner
Gynaecological Oncologist

The consumer's medical records were obtained and the Commissioner sought independent professional advice from an obstetrician/gynaecologist.

Information Gathered During Investigation

In mid-August 1997 the consumer visited a duty doctor. She was suffering from severe post-coital bleeding. The consumer had a cervical smear, which showed atypical cells of unknown origin (ASCUS). The duty doctor subsequently referred the consumer to her general practitioner (GP).

The following day the GP examined the consumer and noted that her cervix was inflamed and that her uterus was *"bulky"*. On this basis he referred the consumer to an obstetrician/gynaecologist (the provider).

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Information Gathered During Investigation *continued*

In the GP's letter of referral to the provider the next day, he stated:

> *"Her last cervical smear was in July 1996 and was normal…. On examination today the cervix looks slightly inflamed and it bled to the touch. I have repeated smear and swabs but I think the value may be diminished by blood contamination. On bi-manual palpation her uterus seemed anteverted, but quite bulky…I wonder if this merits further investigation and would welcome your expert opinion and advice."*

The provider had previously seen the consumer in March 1991, and in his letter of early March 1991 to another doctor he noted:

> *"I agree she has a small ectropian which is made more prominent with a bivalve speculum but when the speculum is closed this hides up into the canal. I suspect that perhaps intercourse and at mid-cycle when the cervix is a little bit more open this may be more easily traumatised. This has not happened every month and it is only isolated so I don't think any further treatment needs doing to it. She is quite happy with that. I don't wish to see her again but would be happy to do so if the problem persisted."*

The provider saw the consumer three days after the referral from the GP in mid-August 1997. He took an ultrasound scan of the consumer's uterus, ovaries and cervix. He did not do an internal vaginal examination.

In the consumer's letter of complaint of late March 1998, she stated:

> *"He* [the provider] *did NOT examine my cervix despite* [the GP's] *reference in his referral letter to an "inflamed cervix which bled to the touch". I felt this was unusual but, because he was the "expert" I didn't question this omission. However, when I returned to my husband who was waiting in the car I commented on the fact that* [the provider] *hadn't even given me an internal examination. Having travelled to* [another town] *and taken time off work I remember observing "Well, that was a bit of a waste of time", but I felt that* [the provider] *obviously considered that the bleeding was not of concern."*

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Information Gathered During Investigation *continued*

In the provider's letter of early May 1998 to the Commissioner he stated:

> *"The history that was presented to me was that* [the consumer] *had had a further episode of bleeding and that the letter from her GP,* […]*, said that "the cervix was slightly inflamed". She also had a smear which showed atypical cells of uncertain origin. I was falsely reassured by the smear as I have not even seen a case of invasive ca cervix with such a mild report from a cervical smear. The comments from the GP were that it was slightly inflamed and he obviously was not as concerned about it to make such a mild comment. Again I was reassured by this and felt it likely that what he was seeing was what I had previously seen, an ectropian… I therefore left the situation without really looking at her cervix but did say to her that she should come back if the symptoms continued…. As I say I believe that I was falsely reassured by her cervical smear and therefore went looking for other issues by the use of ultra sound."*

The provider explained to the Commissioner that, *"In doing the ultrasound, I was evaluating her endometrium. I evaluated the endometrium particularly looking for polyps or other causes of* [the consumer's] *bleeding."*

In the provider's letter of mid-August 1997 to the GP, he stated:

> *"Ultrasound today showed a slightly bulky uterus at 4.4cms, but not clinically significantly so. The endometrian was normal. She had normal ovaries. At this stage I wish to do nothing further unless this bleeding becomes a regular part of her life, in which case we should see her again or if her smear is abnormal we should see her again."*

In mid-December 1997, the consumer returned to see her GP with a more severe post-coital bleed. In her letter of complaint of late March 1998, the consumer stated:

> *"I had not had occasion to visit* [the GP] *since, so told him then that* [the provider] *had not examined my cervix on my previous visit in August.* [The GP] *expressed obvious surprise, as* [the provider's] *follow-up letter had not mentioned this."*

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Information Gathered During Investigation *continued*

The consumer was referred back to the provider for an appointment nince days later at 10.30am. In the GP's referral letter to the provider, he stated:

> *"*[The consumer] *has had occasional episodes of spotting since you last saw her in August, but had a large bleed last night. I wonder if this merits further investigation, and am most grateful to you for seeing her."*

In late December 1997 the provider examined the consumer's cervix and took a smear and a biopsy. In the consumer's letter of complaint of late March 1998, she stated:

> *"When he examined my cervix and took a biopsy on that occasion I bled heavily. In fact I fainted in his surgery – possibly due in part to my realisation that cancer was a possibility and his comment that my cervix showed "sinister changes."*

In the provider's letter that day to the GP, he stated:

> *"The cervix looked quite different from what it did in August and looks considerably abnormal."*

As a result of the biopsy, an appointment was made by the provider for the consumer to have a cone biopsy at a nearby hospital in mid-January 1998. In his response to the Commissioner, the provider explained that it was standard practice at the time that, "[The] *Hospital clinicians would ring* [a] *(gynaecological oncologist) in* [another city] *with the biopsy results and he would then say we should go ahead and do a cone biopsy or get a better sample.* [The gynaecological oncologist] *would act further on the cone biopsy once he had received it. That was our understanding from the oncology staff at* [the other hospital] *at that time; two years ago."*

During the investigation the gynaecological oncologist informed the Commissioner that in 1998, "*it was normal practice for referrals of women from* [the hospital where the consumer went] *to be discussed at our regular Multidisciplinary Meetings. This was for women with invasive cancer. Therefore that did occur in this case as this woman did have an invasive cancer of the cervix. It was not normal practice for anyone who had a punch biopsy to undergo a laser cone biopsy unless there was evidence of possible invasion which was not adequately diagnosed by punch biopsy alone."*

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Information Gathered During Investigation *continued*

The cone biopsy was complicated by a severe post-operative haemorrhage which required a total abdominal hysterectomy. In the consumer's letter of complaint of late March 1998 she stated:

> *"During the operation I was transfused, my blood pressure dropped to zero, my heart stopped and consequently I spent three days in Intensive Care. Three weeks after discharge from hospital I haemorrhaged again and this was controlled at* [the first] *Hospital."*

In the operation note from the hospital, the findings state:

> *"Large cervix and obvious invasive Ca, routine laser cone, pack and catheter until this afternoon."*

A further operation note from the hospital was made with regard to the consumer's subsequent abdominal hysterectomy. The note stated:

> *"Pfannenstiel incision. Routine pedicles clamped, cut and tied. Pelvis reperitonealised after the vault was closed. Skin closed in layers with subcuticular Prolene."*

In early February 1998, the consumer was referred to the gynaecological oncologist at the hospital in the other city for further treatment. The consumer also consulted two other specialists at the hospital. She was advised that she would have to undertake radical radiotherapy for five weeks. This radiotherapy has meant that she has been unable to continue working.

In his letter of response to the Commissioner's provisional opinion, the provider commented as to delay in referral to the other hospital, "*I assume you are referring to a formal referral. I had had a telephone consultation with* [the gynaecological oncologist] *but this was not documented. This phone call normally leads to a review of the histology and further management depends on these discussions and timing of meetings*".

During the investigation, the gynaecological oncologist informed the Commissioner that he did not have a record of nor could he recall a telephone conversation with the provider in January 1998.

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Independent Advice to Commissioner

The Commissioner sought professional advice from an independent obstetrician/gynaecologist in relation to the consumer's complaint who commented as follows:

Examination of the Consumer in Mid-August 1997

- "*In view of the patient's age, the symptoms, the GP description of an abnormal cervix and the abnormal smear report (although it is not clear whether this was available on the day), urgent further investigation of the cervix and uterus were required. With such investigation pending, omission of a pelvic examination would be acceptable. Without the prospect of further, appropriate investigation (not simply a trans-abdominal scan), a pelvic examination and inspection of the cervix would be mandatory, although this would still fall short of sufficient management in this case. Relying solely on the examination findings of the GP is clearly unacceptable since it was uncertainty regarding these that was the principal issue of the referral."*
- *"It is quite possible to miss a cervical cancer on naked-eye inspection of the cervix (and indeed on colposcopy). Observable abnormality of the cervix might however raise awareness of the possibility of cervical disease and prompt further investigation."*

The Consumer's Smear Results

- *"The abnormal smear report should have prompted at least a repeat smear, particularly since the validity of the original smear due to "blood contamination" was rightly questioned by the referring GP* […]. *Because of the ongoing possibility of unsatisfactory smears, a more thorough assessment of the colposcopy would have been more appropriate, particularly since other clinical factors pointed strongly to the possibility of cervical disease.* [The provider's] *personal experience of not having "seen a case of invasive ca cervix with such a mild report from a cervical smear" cannot dismiss the fact that the false negative rate of cervical smears is widely recognised and quoted (often on lab reports) thus:*

  "…cytology is not a diagnostic test, rather a screening test. In other words, a mildly abnormal (smear) may only suggest the least severe form of disease a given patient may have. Indeed, about 6% to 8% of patients with an ASCUS smear have in fact high-grade squamous intraepithelial lesions (HSIL) on histology, and 30% of women with invasive cervical cancer have had two ASCUS smears!" (Professor Alex Ferenezy, Montreal, Canada.)"

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Independent Advice to Commissioner *continued*

Other Comments

Other relevant points raised included:

- [Early] *March 1991* - [the provider] – *ectropion cited as cause. No Mx or FU:*

Advisor's Comment:

"From the information provided, the bleeding was plausibly attributed to the cervical ectropion but there appeared to be no plan for long-term management or advice regarding the abnormal smear."

- [Mid-] *August 1997* – [the provider] – *no pelvic examination. No Mx or FU "unless this bleeding becomes a regular part of her life… or if her smear is abnormal, we should see her again."*

Advisor's Comment:

"At the age of 45 significant pathology is more common. Rather than an isolated, minor episode of bleeding, several bleeding episodes, at least one of which was heavy, had already occurred, suggesting the likelihood of significant disease… Such pathology is often not obvious and further evaluation of the endometrium and cervix is always required. An abnormal smear of any grade would prompt some form of further evaluation of the cervix… Pelvic examination might thus be a useful preliminary assessment to help dictate the mode of further investigation but could justifiably be omitted if such investigation were both appropriate and undertaken urgently…"

Ultrasound: Not a recognised method of assessment for cervical cancer. In large tumours there might be some detectable distortion of cervical shape, but the specificity would be low. There is little published data…"

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Independent Advice to Commissioner *continued*

- [Late] *December 1997* – [the provider] - *cervix looked quite different from what it did in August, and looks considerably abnormal. Smear taken: 7x7x5mm, biopsy taken:*

Advisor's Comment:

"The change in appearance of the cervix is presumably based on the earlier GP description since it appears that the cervix was not previously visualised. A sizeable biopsy was taken. Usual practice would be to undertake this as part of a colposcopy procedure, since colposcopy helps to make the diagnosis and accurately locate the appropriate site for biopsy. The obvious abnormality of the cervix and the size of the biopsy probably compensate for the omission of the colposcopic examination."

- [Mid-] *January 1998* – [the provider] – *"Large cervix and obvious invasive carcinoma. Laser cone biopsy complicated by severe post-operative haemorrhage requiring a total abdominal hysterectomy."*

Advisor's Comment:

"Cone biopsy is aimed at establishing a clear diagnosis when the colposcopy and/or biopsy has proved inconclusive. However the diagnosis has already been clearly established and the cone biopsy is unnecessary and ultimately counter-productive since dangerous haemorrhage resulted in a simple (rather than radical) hysterectomy. This is insufficient to eradicate the disease surgically and absence of the uterus complicates the application of radiotherapy and possibly undermines its value."

- [Early] *February 1998* – [the provider] – *referred to* [hospital in another city] *for further treatment.*

Advisor's Comment:

"Referral is made one month after the diagnosis is established."

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Code of Health and Disability Services Consumers' Rights

RIGHT 4
Right to Services of an Appropriate Standard

1) Every consumer has the right to have services provided with reasonable care and skill.
2) Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.
3) Every consumer has the right to have services provided in a manner consistent with his or her needs.
4) Every consumer has the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer.

Obstetrician/Gynaecologist

Report on Opinion – Case 98HDC13810, continued

Opinion: Breach Obstetrician/ Gynaecologist

In my opinion the provider breached Rights 4(1), 4(2), 4(3) and 4(4) of the Code of Health and Disability Services Consumers' Rights.

Right 4(1)

The provider's examination of the consumer in mid-August 1997 was inadequate. At the time of her examination, the consumer was in her mid-40's. Her symptoms, as described by her GP, included an inflamed cervix and bulky uterus and the provider knew of her history of bleeding. In my opinion, given these symptoms, the consumer required urgent further investigation of her cervix and uterus. The provider neglected to undertake this further investigation and failed to inspect and examine the consumer's cervix. Moreover, the fact that he relied solely on the examination findings of the GP is unacceptable given that it was the GP's uncertainty regarding these findings that was the principal cause of his referral.

Right 4(2)

Although I accept that it is quite possible to miss a cervical cancer on a naked eye inspection of the cervix (and indeed on colposcopy), in my opinion, if the provider had inspected the consumer's cervix, he may have been alerted to the *possibility* of cervical disease and investigated further.

At the very least the consumer's abnormal smear results should have prompted the provider to at least undertake a repeat smear. This is particularly so because the validity of the original smear had been questioned by the GP because of "blood contamination". In my opinion, because of the ongoing possibility of unsatisfactory smears, a more thorough assessment by way of colposcopy would have been appropriate, particularly since other clinical factors pointed strongly to the possibility of cervical disease. The provider should not have dismissed the fact that the false negative rate of cervical smears is widely recognised and often quoted.

In my opinion, the provider's failures were serious and did not meet his obligation to provide services to the consumer *"with reasonable care and skill."*

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Obstetrician/Gynaecologist

Report on Opinion – Case 98HDC13810, continued

Opinion: Breach Obstetrician/ Gynaecologist *continued*

Rights 4(2), 4(3) and 4(4)

In my opinion, in addition to breaching the consumer's right to services with reasonable care and skill, which was also a breach of professional standards, the provider's care breached Rights 4(2), 4(3) and 4(4) of the Code as follows:

Long Term Management Plan
When the consumer presented to the provider with an abnormal smear in early March 1991 and again in August 1997, the provider should have provided a plan for the consumer's long term management. Because the consumer's smear was mildly abnormal and because of the well recognised error rate of smears, a new smear test should have been repeated within six months of visits. If the consumer continued to present abnormal smears, this would have warranted a colposcopy. In my opinion the provider should have provided a long term management plan.

Ultrasound
During the consumer's visit to the provider in mid-August 1997, he did an ultrasound of the consumer's uterus, ovaries and cervix. Ultrasound is not a recognised method of assessment for cervical cancer. Whilst there might be some detectable distortion of cervical shape in large tumours the specificity is very low. Additionally, there is little published data on ultrasound treatment in relation to cervical cancer. In my opinion the provider should not have relied on ultrasound as the only method of examination of the consumer.

Laser Cone Biopsy
A laser cone biopsy is aimed at establishing a clear diagnosis when a colposcopy and/or biopsy have proved inconclusive. However, the consumer's diagnosis had already been clearly established and the cone biopsy was unnecessary and ultimately counter-productive given the dangerous haemorrhage which resulted in a simple (rather than radical) hysterectomy. A cone biopsy is insufficient to eradicate the disease surgically, and the absence of the uterus complicates the application of radiotherapy and may possibly undermine its value. In my opinion, the consumer's laser cone biopsy, performed by the provider in mid-January 1998, was unnecessary.

Referral to Oncology Unit
The provider did not immediately refer the consumer to the hospital in the other city. In my opinion, the provider's failure to make this referral until one month after the biopsy was unacceptable.

Obstetrician/Gynaecologist

Report on Opinion – Case 98HDC13810, continued

Actions

I recommend the provider takes the following actions:

- Provides a written apology to the consumer for breaching Rights 4(1), 4(2), 4(3) and 4(4) of the Code of Health and Disability Services Consumers' Rights. This apology should be sent to the Commissioner, who will forward it to the consumer.

- Undertakes a medically approved refresher course in cervical cancer procedures and treatment following discussions with the Medical Council of New Zealand and the Royal New Zealand College of Obstetricians and Gynaecologists. Specific education should be undertaken in relation to the following areas:

    - available options when treating and assessing a patient with cervical cancer;

    - long term management of a patient with cervical cancer;

    - the benefits of internal examinations;

    - the benefits of a colposcopic examination;

    - the advantages and disadvantages of laser cone biopsy treatment;

    - awareness of all his duties under the Code.

Other Actions

A copy of this opinion will be sent to the Medical Council of New Zealand who have been asked to undertake an immediate review of the provider's competence. A copy will also be sent to the Royal New Zealand College of Obstetricians and Gynaecologists who will be asked to suspend the provider's membership pending completion of the above.

I will refer this matter to the Director of Proceedings who will decide what action to take under Section 45 of the Health and Disability Commissioner Act 1994.