Dr B

Dr C

Dr D

A medical centre

A Report by the

Health and Disability Commissioner

(Case 02HDC18949)

Parties involved

Mr A	Consumer
Dr B	General Practitioner / Provider
Dr C	General Practitioner / Provider
Dr D	General Practitioner / Provider

Complaint

On 18 December 2002 the Commissioner received a complaint from Mr A concerning medical care provided to him by Dr B and a medical centre. The complaint was summarised as follows:

- *Following a vasectomy operation on 4 January 2002, Dr B and the medical centre failed to advise Mr A of the results of sperm tests in a timely and appropriate manner.*

An investigation was commenced on 17 July 2003. On 10 October 2003 the investigation was extended to include Dr C and Dr D and the following issues:

- *Following a vasectomy operation on 4 January 2002, Dr C failed to advise Mr A of the results of sperm tests in a timely and appropriate manner.*
- *Following a vasectomy operation on 4 January 2002, Dr D failed to advise Mr A of the results of sperm tests in a timely and appropriate manner.*

Information reviewed

- Information provided by Mr A
- Response from Dr B
- Response from Dr C
- Response from Dr D
- Response from Mr A

Independent expert advice was obtained from Dr Ian St George, general practitioner.

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Information gathered during investigation

Vasectomy

On 4 January 2002 general practitioner Dr B, with his practice partner general practitioner Dr C in attendance, performed a vasectomy on Mr A at a medical centre in a city. Before the procedure Mr A was given an information sheet entitled 'Pre-Vasectomy Instructions for Men Undergoing Vasectomy'. The fact sheet contained the following statement:

> "Hundreds of millions of sperms are stored in the vas and the seminal vesicle, and are released over a period of weeks following vasectomy. It is therefore imperative that you continue with other forms of contraception until such time as two consecutive semen analyses have demonstrated no sperms, and you have received a letter, or have confirmed you are sterile."

At the time of the vasectomy Mr A and his wife signed a consent form which stated:

> "I understand that two consecutive negative sperm counts must be obtained before I abandon other method/s of contraception. I understand that there is a small risk of spontaneous reversal and/or other complications as explained to me."

Dr B recalled that he also advised Mr A of the need for two consecutive clear semen analyses before abandoning other forms of contraception.

Test results

On 5 February 2002 Mr A provided a semen sample for analysis. The laboratory request form for the semen analysis was in Dr C's name, which meant that he was to receive the test results, rather than Dr B whose patient Mr A was. This was the standard practice at the clinic at the time.

The results of the 5 February sample were in fact received and reviewed by Dr D, another general practitioner/partner in the practice at the time, as Dr C was on holiday. The results indicated 1 non-motile sperm/50hpf. This meant that although the semen count was low, it was not negative.

Dr D did not relay the first test results to Dr B, Dr C or Mr A, but instead placed them in Mr A's computerised patient file. Dr D understood that three sets of results were required and that the doctor who performed the operation would review the results. Dr D believed that if the first sample showed non-motile sperm to be present, but the next two samples were clear, the vasectomy had been successful. The presence of sperm in the first sample can sometimes be the result of sperm stored in the vas and seminal vesicle prior to the vasectomy.

Dr C advised me that at the time of Mr A's vasectomy it was standard practice at the clinic not to send a letter about the first specimen. He stated that "it was then explained to the

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patient that he would be contacted only after the second specimen". Dr B advised me that he had "no input" into this policy and that it was "impossible" to hold him in breach for the failure to notify the first test results.

Mr A said he was not told that it was standard practice for the medical centre not to send a letter informing clients of the first test results, which he never received. Mr A stated:

> "Both my spouse and I were never informed at any stage by [the medical centre] located in [the city] during:
> a) the initial pre operation interview
> b) during the actual operation
> c) or anytime there after
> d) or by any other means associated with [the medical centre]
>
> that it was standard practice for the clinic <u>not</u> to send a letter informing clients of the first specimen test results. Once again, we were assured that we would be sent notification from [the medical centre in the city] of the test results and it was never suggested at any stage that we would only be sent notification for just 2 from the 3 sample test results. Given the option, I would have <u>demanded</u> to have been notified of this initial test result. Alas, no option or even suggestion was ever made to us on proposed action for filing this initial test result."

On 5 March 2002 Mr A submitted a second semen sample for analysis. The results of this sample were clear and on 10 March Dr C's practice nurse wrote to Mr A as follows:

> "We have recently received the tests of your latest laboratory test, it was clear and Dr [C] would like you to have one further semen test."

Mr A received this letter on 12 March.

On 5 April 2002 Mr A submitted a third semen sample for analysis. The results were received by Dr B (in Dr C's absence) on 11 April and revealed numerous motile and non-motile sperm, indicating that Mr A was fertile. Dr B deviated from his usual practice of posting the results to the patient within two or three days of receipt. Instead, he attempted to contact Mr A by telephone to tell him in person that the vasectomy had failed. He said that he tried unsuccessfully several times and then asked his practice nurse to telephone Mr A. She was also unable to get through and after several calls found that the telephone number had been disconnected. Dr B said that after his unsuccessful phone calls, the results escaped his notice for a time and that more time elapsed than he had intended before further steps were taken to contact Mr A.

Dr B advised me:

> "After the third test was received by our offices on 11 April 2002 (and was referred to me in Dr [C's] absence) several attempts were made to contact Mr [A] by phone directly. I decided to do this as it appeared that he had the misfortune of being of the

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> approximately 1:100 whose vas deferens had re-anastomosed. As it meant he would have to have his vasectomy redone, I wanted to break the news to him directly and personally. I thought this was a kinder and more professional way of dealing with his disappointment. It would also afford him the opportunity to ask any questions he might have about the failure of his vasectomy. I placed several toll calls to the number Mr [A] had supplied us in [a town] through our reception desk. The receptionists were unsuccessful as there was never any reply from his phone numbers. Some time later, I handed the result to my nurse. She also advised me that she tried repeatedly to get through and then eventually found that the number had become disconnected. We could only deduce from this that Mr [A] had shifted from his former address."

Mr A advised me that he tried to ring Dr B to follow up on his test results on 6 May 2002 and was told that Dr B would call him back. Dr B has no record of receiving this message, although the usual practice is for all telephone messages to be passed on to him by both written and electronic reminders from his nurse. Mr A said that when Dr B did not call him back he assumed that all was well, particularly as he was unaware that the first test was positive.

Mr A expressed scepticism at the explanation that staff at the medical centre had tried on a number of occasions to contact him by telephone in relation to his third test results. He was on holiday and at home during the whole of April and his wife was at home all the time with their young baby. He also noted that a letter during this period would have reached him, and that he did not consider it necessary to advise the medical centre when he moved to a new home in another town at the end of May, as the practice had had almost two months to inform him of the test results before he moved. His previous home phone was connected and working in April and May.

Dr B eventually sent Mr A a letter dated 2 October 2002, informing him that the third (April) test results showed numerous sperm and that he was still fertile, and asked him to supply another specimen to see if he had become sterile. The letter (addressed to Mr A's old home address) was redirected and reached him (at his new home address) on 10 October 2002.

Pregnancy

On 20 November 2002 Mr A's wife, Mrs A, discovered she was approximately 13 weeks' pregnant.

On 10 December 2002 Mr A submitted a fourth semen sample for analysis and on 11 December 2002 he was contacted by the laboratory and advised that it was positive, with "large number of spermatazoa".

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Obtaining test results

Mr A understood that he did not need to contact the medical centre to obtain his test results. He advised me:

> "Both my spouse and I were never informed at any stage by [the medical centre] located in [the city] during:
>
> a) the initial pre operation interview
> b) during the actual operation
> c) or anytime there after
> d) or by any other means associated with [the medical centre]
>
> that it was our responsibility to provide any level of follow up action to ensure that we received notification of the sample test results. On the contrary, we were assured that we would be sent notification from [the medical centre] in [the city] of these test results."

Changes at Medical Centre

Dr B advised me that the medical centre has made significant changes to its vasectomy services as a result of Mr A's complaint. In summary, the changes include:

- Additional conditions on the consent form which require that the patient contact his doctor if he has not received his test results and inform the doctor of any change in his contact details.
- Ensuring that laboratory request forms are processed in the name of the "lead" doctor caring for the patient and making that doctor responsible for all aspects of his patient's care.
- Introducing a policy to ensure that all patients are advised of test results by letter within two days of receipt by the medical centre.
- Amending the standard letter sent to request a further semen sample, so that it clearly states that the patient is not yet sterile.
- Introducing standard letters to notify patients of unusual results, to ensure there is a paper trail for later reference.
- Reminding staff to record any telephone conversations with patients.
- Employing a personal assistant at the medical centre to help with paperwork to ensure that future delays in processing results do not occur.

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Independent advice to Commissioner

Initial advice

The following expert advice was obtained from Dr Ian St George, an independent general practitioner:

> "1. I respond to your letter of 19 March 2004 seeking advice in relation to Mr [A's] complaints against Dr [B]. I am asked to advise the Commissioner whether Dr [B] provided services to Mr [A] that complied with appropriate standards.
>
> Mr [A] has fathered a child after a vasectomy and complains that Drs [B], [D], [C] and [the medical centre] failed to advise him of the results of sperm tests in a timely and appropriate manner.
>
> 2. I am asked to advise on whether
>
> - Mr [A] received enough information about the post-vasectomy semen sampling process at the time of his procedure;
> - the way the test results were handled was adequate, and if not whether the process itself was inadequate or the way it was implemented;
> - the specific information supplied to Mr [A] about each of the results was adequate – with respect to tests dated 5 February, 5 March and 5 April; who was responsible for informing Mr [A] about the results; whether attempts to contact him were appropriate and timely; whether he should have been provided further information about the results and their implications;
> - there are any aspects of the care provided to Mr [A] that warrant further exploration, and whether I have additional comments.
>
> 3. I have read
>
> - Your summary of the purpose, background, complaint and request for expert advice;
> - Correspondence from Mr [A] labelled 'A';
> - Correspondence from Dr [B] labelled 'B';
> - Correspondence from Dr [C] labelled 'C';
> - Correspondence from Dr [D] labelled 'D'.
>
> 4. I have assessed whether the doctors' actions were reasonable in the circumstances by the standards of the profession, as far as they have been stated or previously judged, at the time of the incidents. I state here I have no personal, financial or professional connection with any party that could bias my assessment.

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5. In my opinion

- Mr [A] received full information about post-vasectomy sperm counts; he signed a consent form with the words, 'I understand that two consecutive negative sperm counts must be obtained before I abandon other methods of contraception. I understand that there is a small risk of spontaneous reversal …'. In addition, Dr [B] has detailed an exhaustive interview with his vasectomy patients – which, if anything, contains too much information!
- The test results were handled entirely properly.
    - The first result was filed, and since no action would be taken, whatever the result, that was apt; Mr [A] did not contact the surgery for the result.
    - The second specimen still contained sperms, and Mr [A] was informed of that fact, and that a third specimen would be required.
    - The third specimen also contained sperms: several attempts were made to contact Mr [A] by phone, and six months later (when it was realised he must have changed address) a letter was sent to Mr [A's] old address in the hope it would be redirected; it was, and two months after that Mr [A] supplied a fourth specimen, though he still did not inform the practice of his new address.
- The specific information supplied to Mr [A] was clear and precise for all three dates; the responsibility for informing a patient about results has been the subject of wide debate in the profession, and there is a great deal of difference of opinion and practice. In this case it had been made abundantly clear to Mr [A] that he would not be sterile until he had produced two consecutive negative sperm counts, and further, that the vasectomy must not be regarded as effective until '… you have received a letter, or *have confirmed* you are sterile' (fact sheet – my italics); the message is unambiguous: 'it is up to you to confirm you are sterile before you assume you are'. I do not believe the doctors or the practice could have been expected to do more than they did, and it is quite clear from the fact sheet that Mr [A] was responsible for ensuring he continued other contraception until he had received a letter or otherwise confirmed his own sterility.
- I believe the doctors concerned should be congratulated on the thoroughness of their practices. Still better, they have learned from this experience and have put even more exemplary practices in place."

Further advice

In response to comments made by Mr A, I obtained the following additional advice from Dr St George:

"You have asked me to review my opinion of 24 March 2004 in light of Mr [A's] response.

The second specimen was indeed clear, and I accept I was in error in suggesting otherwise. That observation does not change my opinion. Mr [A] signed a

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> statement saying 'I understand that two consecutive sperm counts must be obtained …'
>
> I reiterate my statement that the specific information supplied to Mr [A] was clear and concise; when I wrote that it was clear and concise 'for all three dates', I meant that the statement he signed ('I understand that two consecutive sperm counts must be obtained …') applied, whatever the date of the specimen.
>
> Mr [A's] other points of dispute involve credibility issues, matters involving the Commissioner's opinion, or the practices of other doctors, which are not relevant to my opinion, and on which I am not willing to argue."

Responses to Provisional Opinion

Dr B
In response to my provisional opinion, Dr B advised me that he "accepts that the third result should have been notified in a more timely fashion to Mr [A]", and provided a written apology for his breach of the Code.

The medical centre
In response to my provisional opinion, Dr C submitted the following statement on behalf of the medical centre:

> "I am pleased with your report and find it to be a just assessment. It has been a beneficial process for us to have gone through as it has enabled us to look at our systems and improve on them."

The medical centre provided a written apology for the medical centre's breaches of the Code.

Code of Health and Disability Services Consumers' Rights

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

RIGHT 6

Right to be Fully Informed

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1) Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including –

(a) An explanation of his or her condition; and

...

(f) The results of tests; ...

Opinion: Breach – Dr B, The medical centre

First test results

Right 6(1)(f) of the Code of Health and Disability Services Consumers' Rights (the Code) affirms a patient's right to receive the information that a reasonable patient, in that patient's circumstances, would expect to receive, including the results of tests. At the time of his vasectomy in January 2002, Mr A was told that two consecutive clear sperm tests were required to confirm that the procedure had been successful and that he and his wife could abandon other forms of contraception. He submitted his first sample for testing on 5 February 2002. The results of the first test were positive. Mr A was not informed of the results, which were received and filed by Dr D.

Dr D followed the system the medical centre had in place at the time – which was not to advise Mr A of his first test results, even though they were positive. Dr B, who had performed the vasectomy, advised me that he had "no input" into the policy for handling sperm results at the medical centre – even though he was a partner at the practice. The rationale for the policy was that two clear sperm samples are required following a vasectomy, before a man can be considered sterile. Accordingly, on its own, even if clear, the first sperm sample post vasectomy is not determinative. My expert advisor considered that as no action would be taken, whatever the result, Dr D's actions were "apt".

I do not agree. Patients are entitled to be notified of test results (even if there is no cause for concern, or further tests are to follow) unless clear arrangements have been made with the patient to the contrary. The medical centre has provided no record of such an arrangement being explained to Mr A. Dr C stated that "it was then [ie, after the first test results] explained to the patient that he would be contacted only after the second specimen", but there is no record of Dr D (or a practice nurse) contacting Mr A, who denies that he was so informed. In the circumstances, notwithstanding the clinic policy at the time not to notify post-vasectomy results, I consider that the medical centre breached Right 6(1)(f) of the Code by not advising Mr A of his first test results.

Dr D was simply acting as an agent to handle the test results for Dr C (who in turn was doing so on behalf of the doctor who had performed the procedure, Dr B) and followed the standard practice at the medical centre for first post-vasectomy results. In my view, Dr D cannot reasonably be held liable for the failure to notify the results, particularly when Mr A was not his patient. I consider that Dr B had a responsibility to be familiar with the clinic

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policy and to inform his patients accordingly. I reject his lawyer's submission that it would be "impossible" to hold him in breach for the failure to notify the first test results. However, in my opinion the breach finding in respect of the first test results most appropriately lies with the medical centre.

Second test results

Mr A submitted a second sample for analysis on 5 March 2002. The results indicated that no sperm had been detected.

Dr C reviewed Mr A's second sample promptly and arranged for his practice nurse to notify Mr A of the results. On 10 March the practice nurse sent a letter to Mr A that advised that the test was clear, but that one further semen test was required. The letter did not spell out that the reason a further test was required was that Mr A did not yet have two clear samples, and therefore should assume that he was still fertile.

In my opinion, the letter should have included the results of the first test and explained the need for a further sample. Patients are entitled to be given information about their condition (Right 6(1)(a)). However, Dr C did notify Mr A of his second test result and the need for a further test, in a timely fashion. In the circumstances, where Dr C was aware that prior to the vasectomy Mr A had been told that two consecutive clear sperm counts must be obtained and notified before he could be assumed to be sterile, I consider that Dr C and the medical centre did not breach Right 6(1) of the Code.

Third test results

Mr A submitted a third sample for analysis on 5 April 2002. The results of this test were received by Dr B on 11 April and revealed the presence of numerous motile and non-motile sperm, indicating that Mr A was fertile. I accept that Dr B wanted to tell Mr A in person that he believed the vasectomy had failed and that he, his nurse and the receptionist attempted to telephone Mr A on several occasions shortly after the results were received, but were unable to reach him. Mr A moved house on 31 May, seven weeks after the results were received by Dr B, by which time Mr A's telephone was disconnected. He did not give the medical centre his forwarding address or other contact details. When he moved he had not been advised by telephone or letter of his test results and it was not until 2 October 2002, almost six months after the results were received, that Dr B wrote to Mr A, at his old address, advising that the results were positive and indicated that Mr A was "still fertile". The results were forwarded to Mr A's new address by 10 October.

I accept that Mr A was clearly told, at the time of his vasectomy, that he needed to use contraception until he knew he had two consecutive clear sperm results and received written or oral confirmation that he was sterile. Mr A's failure to provide a forwarding address when he moved house made it more difficult for Dr B to contact him. However, I do not consider that these factors relieved Dr B and the medical centre of the obligation to inform Mr A of his third test results in a timely manner. If a letter had been sent, Mr A would have had the results before he moved at the end of May.

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While, as my expert advisor pointed out, there was an onus on Mr A to continue to use contraception until he knew he was sterile, in my view there was also an onus on Dr B and the medical centre to notify Mr A of his test results in a timely manner. By failing to inform Mr A of his third (and most concerning) test results, Dr B and the medical centre breached Right 6(1)(f) of the Code.

Other Comments

The medical centre

The medical centre did not have an efficient system for handling post-vasectomy test results at the time Mr A was a patient. Several gaps in the system lined up to result in Mr A not being told, until after his wife was pregnant, that he was still fertile. The three test results were reviewed and dealt with by three different doctors. Laboratory forms were completed by a doctor who did not have primary responsibility for the patient. Mr A did not receive the first test results, he was not told when given the second test results that he was still fertile, and he did not receive the third test results for several months. I do not accept Dr St George's advice that "the test results were handled entirely properly" and that "the doctors concerned should be congratulated on the thoroughness of their practices".

In response to Mr A's complaint, the medical centre has undertaken a review of its vasectomy services. The medical centre has identified areas for improvement and made changes to procedures, to ensure prompt notification of test results in future. The processes now in place should ensure that all vasectomy patients are notified promptly and clearly in writing of the results and implications of all sperm tests. I note, however, that the use of archaic language ("I also understand that if I do not receive timeous written information") on the revised consent form – which many patients will not understand – should be avoided.

Patient responsibility

While I have formed the opinion that Dr B and the medical centre breached the Code by failing to notify Mr A of his test results in a timely manner, I endorse my expert advisor's comments that Mr A was provided with very clear information prior to his vasectomy, and there was an onus on him to continue using contraception until he knew he was sterile. In upholding Mr A's complaint, I do not accept that Dr B or the medical centre can be held responsible for the unplanned pregnancy.

Follow-up actions

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

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- A copy of this report, with details identifying the parties removed, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

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