A Health Clinic

Counties Manukau District Health Board

A Report by the

Health and Disability Commissioner

(Case 08HDC06165)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Overview

On 24 April 2006, Mr C (aged 70) consulted his general practitioner, Dr B, with urinary symptoms that suggested an enlarged prostate. As part of his assessment, Dr B performed a PSA blood test.[1] The result of this test was elevated, which raised suspicion of prostate cancer, and Dr B decided that a repeat PSA should be performed in three months' time. Although the practice wrote to Mr C on 29 July 2006 to remind him to have this further PSA test, he did not attend for the test, and no further attempt was made to remind Mr C to have a repeat test.

On 21 May 2007, Mr C consulted Dr B about blood in his urine. A PSA test was taken and showed a higher level than the previous year, and Mr C was immediately referred to a urology specialist. Following prioritisation by a consultant urologist from Auckland District Health Board, the referral was received by Counties Manukau District Health Board urology service on 11 June 2007. However, the referral was misplaced, and not actioned until 25 July 2007.

Despite being prioritised as needing to be reviewed within four to six weeks (and Mr C being so advised), the waiting time was actually four to six months, due to resource constraints. Only after Dr B contacted the urology service in October 2007 was Mr C reviewed urgently. He was subsequently diagnosed with prostate cancer which had spread.

This report considers the care provided to Mr C by the Health Clinic (the Clinic) and Counties Manukau DHB, in particular, whether follow-ups and referrals were managed appropriately.

Parties involved

Dr A	Registrar in general practice
Dr B	Consumer's general practitioner
Mr C	Consumer
Dr D	Consultant urologist
The Clinic	Provider/Health Clinic
Counties Manukau DHB	Provider

[1] Prostate specific antigen (PSA) is a blood test for prostate cancer.

Complaint and investigation

On 21 April 2008 the Health and Disability Commissioner (HDC) received a complaint from Mr C about the services provided by a health clinic and Counties Manukau DHB. The following issues were identified for investigation:

The appropriateness of care provided to Mr C by the Clinic from 24 April 2006 until 5 October 2007; in particular, the adequacy of follow-up procedures following a raised PSA, and the systems for specialist referral.

The adequacy of the care provided to Mr C by Counties Manukau DHB from 25 May to 11 October 2007; in particular, the adequacy of systems to ensure that specialist urology review was arranged.

An investigation was commenced on 11 June 2008.

Information was reviewed from Mr C, Dr B, the Clinic, and Counties Manukau DHB. Independent expert advice was obtained from general practitioner Dr Keith Carey-Smith.

Information gathered during investigation

Primary care

24 April 2006
On 24 April 2006, Mr C consulted his general practitioner, Dr B, at the Clinic with symptoms described subsequently by Dr B as suggesting mild prostatic enlargement. Dr B performed a prostate examination, and noted "soft, smooth, [moderately] large, benign feeling prostate". Dr B requested laboratory tests looking for urinary tract infection, kidney disease, diabetes, and elevated prostate specific antigen (PSA). The latter of these tests, if raised, is an indicator of possible prostate cancer.

The PSA result (reported on 24 April 2006) was raised, at 10.8µg/L, which Dr B considered was "mildly elevated for his age of 70 years". The result form advised:

> "A PSA above 10µg/L is always an indicator for followup.
> In such patients malignancy is more likely than benign hyperplasia."

Dr B decided to repeat the test in three months' time. There is no evidence that Mr C was advised of his raised PSA, or its significance.[2] Mr C says that he had no idea in 2006 what PSA meant.

29 July 2006
On 29 July 2006, the following letter was sent by a practice nurse at the Clinic to Mr C:

> "Dear [Mr C]
>
> According to our records you are now due for a blood test.
> Please take the enclosed form to the laboratory as soon as possible to have this done."

A laboratory request form for a PSA blood test and a urine test was included with the letter. However, Mr C did not attend to have these tests performed, and he was not contacted again by the Clinic to remind him of the need for the tests or given an explanation of the reason for having them. Mr C does not recall receiving the letter of 29 July.

10 April 2007
Mr C consulted GP registrar Dr A at the Clinic on 10 April 2007 with chest pain. Following assessment, he was transferred to hospital and received treatment (including angioplasty) for a myocardial infarction. (There is no record that the PSA result was discussed.)

9–12 May 2007
On 9 May 2007, Mr C consulted Dr A at the Clinic as he had blood in his urine. The doctor noted that this was probably due to Mr C's anticoagulant therapy, and that a urinary catheter had been inserted while he was in hospital.

Dr B reviewed Mr C again on 12 May 2007, and provided a repeat prescription for Mr C's cardiac drugs. He also noted that there was "no further blood in urine".

21–25 May 2007
On 21 May 2007, Mr C again noticed blood in his urine, and consulted Dr B. Following a prostate examination ("moderately enlarged, smooth and soft outline, non-tender"), Dr B requested a further PSA test.

The PSA result was raised (67.4µg/L) and Dr B recalled Mr C on 25 May 2007 to discuss the result. Dr B explained to Mr C the concern about a possible diagnosis of prostate cancer, and discussed the range of treatments available. (This is confirmed by

[2] Mr C stated that he was told about this result in April 2008. However, Dr B's records indicate that the results were discussed on 25 May 2007.

his records.) On the same day, Dr B referred Mr C to the Urology Department at Middlemore Hospital.

Hospital care

Counties Manukau District Health Board (CMDHB) describes its Urology Service as follows:

> "[R]esidents are provided [urology services] through a 'Hub and Spokes' model by Auckland District Health Board … The proportion of services contracted for local delivery has remained constant over the last few years with most services continuing to be delivered at Auckland City Hospital … All specialist services are delivered by ADHB Senior Medical Officers.
>
> CMDHB provides serviced outpatient facilities at Manukau Super Clinic [MSC] including the nursing and administration staff associated with those urology clinics. In addition, 25 day patient theatre sessions are provided at MSC each year by visiting ADHB specialists. Day patient procedures undertaken include scrotal and minor tumour biopsy, cystoscopy, supra pubic catheter insertion, repair of hydrocele, circumcision, vasectomy, hernia repair and epidermal cyst."

As urology services are provided by senior medical staff from Auckland DHB, referrals are sent to that DHB for prioritising.

The CMDHB Chief Medical Officer advised that Mr C's referral was received on 29 May 2007 and forwarded to ADHB, where consultant urologist Dr D graded Mr C's care as priority 2, and returned the referral to CMDHB on 9 June 2007. Dr D explained his rationale for this grading:

> "In [Mr C's] referral letter he is a 71-year-old gentleman with an elevated PSA at 67 who had recently had coronary artery stenting with Clopiderol. Under these circumstances he was graded as a Category 2 patient using the Regional Urology Guidelines and these were developed in conjunction with the Urologists across the region last reviewed in December 2004.
>
> We use these guidelines because it allows us to have equity of access for patients over greater Auckland. The plan with Category 2 patients is that they should be seen within a month of referral which was entirely appropriate for [Mr C]."

The CMDHB Chief Medical Officer advised that although the referral was received on 11 June 2007, the referral was not actioned by CMDHB until 25 July 2007. CMDHB has been unable to identify the cause of the six-week delay, apart from concluding that the referral was "misplaced" within the clerical/administration system.

Once the referral had reappeared, and following confirmation that Mr C was eligible to receive public funded services, he was placed on the waiting list (on 3 August

2007). The CMDHB Chief Medical Officer advised that priority 2 patients should be seen at a First Specialist Appointment (FSA) within six weeks of referral. However, he added that "due to resource constraints the waiting time is currently between four and five months". CMDHB stated that Mr C and Dr B were advised by letter that the anticipated wait was four to six weeks.[3]

In the meantime, Mr C had been reviewed at the Clinic on 13 August and 17 September 2007; however, there is no record of any discussion about the progress of the urology referral.

5 October 2007
On 5 October 2007, Mr C consulted Dr B with persistent pain. Dr B stated:

> "I was … dismayed to realise [Mr C] had been waiting for over four months to be seen in the Urology Clinic. I found his PSA had risen sharply to 456.8 and on review with my registrar, three days later we arranged by phone an urgent Urology review."

On 8 October, Dr B telephoned a CMDHB urology registrar. The urology registrar completed an internal referral that same day, and stated on the referral form:

> "This man should be seen in clinic urgently to commence … therapy. His GP called today, advised that he was referred in May but was categorised as level 2, hasn't been seen yet. No tissue biopsy. Not on any treatment."

Mr C attended an outpatient appointment on 11 October 2007 and was assessed by Dr D, who performed a biopsy of the prostate. Mr C reattended one week later and was told he had adenocarcinoma of the prostate. A subsequent bone scan showed that he had widespread metastatic disease in most of his bones.

On 12 April 2008, Dr D wrote to Dr A at the Clinic:

> "I am very sorry that it seems I have let [Mr C] and his wife down with regard to his metastatic prostate cancer. [Mr C] was referred originally in May. When I received a letter from [Dr B] outlining that [Mr C's] PSA had increased to 458, I arranged for him to be seen immediately in my outpatient's clinic and organised for him to have a biopsy from his prostate. This confirmed the diagnosis of prostate cancer. He was started immediately on hormonal therapy at that point and I organised for him to have a bone scan which confirmed the clinical suspicion of metastatic disease."

[3] CMDHB could not provide a copy of this letter. It stated that there is an error in the electronic archiving system that prevents a copy being produced, and this is currently being investigated. No copy was available in Mr C's GP record, and Mr C cannot recall receiving the letter. CMDHB described it as "a little bit unusual the GP does not have a copy of the letter on file and that Mr C does not recall receiving it", but accepts that in any event the waiting time information in the letter was incorrect.

The Clinic review

Dr B reviewed the care Mr C received from the Clinic, and advised as follows:

> "I fully accept the criticism that [Mr C] should have been advised promptly of the initial PSA test result [in April 2006] and its significance. I have always had the policy of explaining to patients their significantly abnormal test results, and in the case of a test such as the PSA which is complicated to interpret I would prefer to do this face to face rather than over the phone. I did not record in the notes any attempt to contact [Mr C] by phone, so although I expect I would have done so I cannot demonstrate that this took place. If unsuccessful in making phone contact, I should have asked my nurse to send him a letter asking him to come in for further discussion, but clearly I did not do this and I cannot explain why I failed to follow through on my normal practice on this occasion.
>
> I accept your finding that Right 6(1)(f) of the Code was breached. For this I am very willing to offer [Mr C] an apology.
>
> On the other hand, I would like to defend the management decision that a repeat PSA test after an interval of three months before considering referral was the most appropriate course of action for a man of [Mr C's] age and in the absence of significant symptoms or examination findings. I note that [HDC advisor] Dr Carey-Smith has expressed mild disapproval that the second PSA test was not recommended to occur sooner than three months.
>
> No clinical guidelines, including those referenced by Dr Carey-Smith mention an appropriate time interval for follow-up testing, although it is widely acknowledged that the rate of increase in PSA levels is as important as the actual level.
>
> Dr David Tulloch, a Urologist from Southland, was quoted in a recent issue of the 'NZ Doctor' as saying, '*Rather than comparing the PSA levels within a 'normal' range, a far more accurate way of testing now is to look at the rate of PSA rise over time. If the rate of change — regardless of the starting value — is rising at greater than 0.75ng/mL a year, then this would be of concern.*' To repeat the test after too short an interval runs the risk of being falsely reassured that the PSA level is static. I am a member of a [peer review group]. Last week I asked around the group for their opinions on an appropriate time interval for repeat testing in the case of a 70 year old man with a PSA of 10 and a normal feeling prostate clinically, and one member suggested two further tests at two monthly intervals would be his preference, while the others all elected to repeat the initial test after three months.
>
> Therefore, having reconsidered my practice in this regard at your request, I remain of the opinion that my practice is consistent with local standards.

> … I was surprised to read your opinion that [the] Clinic failed to provide services that complied with professional standards. In September 2006 our [Clinic] completed Cornerstone Accreditation by meeting all the standards contained in the 2002 edition of Aiming for Excellence. We had a system in place for tracking cervical smears and histology and certain important tests, but not for routine tracking of blood test requests. This was acceptable to our Cornerstone assessors. At that time we were ahead of the majority of NZ general practices in achieving Cornerstone accreditation, and few practices would then have been tracking all blood test requests. The systems we had in place at the time did not fail. They were simply not comprehensive enough to identify when patients who have been asked to have a follow-up blood test fail to do so. As previously advised, we have a few months ago in response to [Mr C's] case, adopted the higher standard contained in the 2008 version of Aiming for Excellence and we now track every blood test that we request.
>
> In doing so we are once again ahead of most of our colleagues in general practice and ahead of such systems in secondary outpatient care.
>
> I appreciate the contribution [HDC] is making toward driving professional standards in New Zealand, and am aware that general practice here has more advanced computerised systems than those of most other countries. It would appear to be unfair to judge a service as not complying 'with legal, professional, ethical, and other relevant standards' when that service is already of a high standard by criteria in place at that time, but not meeting the more exacting standards of the latest version as quoted by Dr Carey-Smith.
>
> Only the most exemplary of practices would have had a system in 2006 to ensure that a requested blood test was in fact carried out. […]."

Remedial actions taken

Dr B advised that changes have been made to the systems at the Clinic as a result of this case:

> "We have looked into ways of more systemically tracking the outcomes of laboratory test requests and referral since this complaint was made, and have obtained the 2008 version of the Aiming for Excellence Cornerstone standards. In this 2008 version, the section on managing patient test results and reports has been expanded with four new items in addition to those contained in the 2002 version under which we achieved accreditation in 2006.
>
> As a practice we are seeking to meet all these standards, and have adopted a system within MedTech32 whereby every laboratory test request is automatically entered into the staff task manager for the doctor making the request, appearing initially in black but becoming red in two weeks' time. As the test reports come back from the laboratory there is now an extra step whereby they are ticked as completed and deleted from the staff task manager. This is working well so far,

> although the challenge will come a little later when faced with the task of chasing up the outstanding requests. We anticipate this will be a matter of the doctor making a judgement on how important or urgent the request was, and then either asking the practice nurse to phone or write to the patients or to flag the outstanding request in the patient task manager, which would draw the attention of the doctor to the outstanding request the next time the patient attends.
>
> Similarly, we have set up a computerised system whereby referral letters generate a staff task memo which we have initially and rather arbitrarily set to activate in two months' time. At the time of making the referral this recall date can be manually changed from the default position of two months, as some referrals are urgent but most can expect to be waiting for some months for an appointment.
>
> Although this will add to the non-patient contact workload, which is relentlessly growing for general practitioners, we are pleased to be keeping up with current best practice standards and will review how effective these changes are proving to be after two months."

Dr B summarised the remedial actions taken by the Clinic as follows:

> "As mentioned earlier, at [the Clinic] we now have an automatic tracking system for every blood test requested, every X-ray or scan requested, and every referral letter generated. When the report is received or when we receive acknowledgement that a referral letter has been received, the appropriate task is deleted from the requesting doctor's or nurse's staff task list. This enables us to become aware of outstanding requests, after two weeks in the case of a blood test and after two months in the case of a non-acute referral, and the provider can then decide on the most appropriate further action. This does mean further work in the evenings after patients have gone, but the system is working well and is welcomed by all concerned.
>
> Another step we have taken is to revise our previous policy on advising patients of test results, and a copy of this is displayed in the waiting room, while a further copy is now automatically printed as page 2 of every laboratory test request form and given to the patient.
>
> …
>
> In summary, I accept that I was remiss in not explaining to [Mr C] the significance of his initial PSA test, but that in all other respects I am of the firm belief that [the] Clinic has provided a consistently high standard of medical care with professionally appropriate standards. We have made further improvements to our practice in the light of this case, and continue to take great pride in fulfilling our mission statement of providing high quality compassionate medical care to one of Auckland's most deprived and needy suburbs."

Counties Manukau DHB review

As a result of this case, CMDHB undertook a review of its Urology Service. The key issues identified by the interim report of the review are set out below.

Grading criteria
CMDHB noted that there is a variation in the grading criteria used within the Auckland region to prioritise access to First Specialist Assessments (FSAs). CMDHB advised:

> "The regional urology grading tool that is used by the three Auckland DHBs has significantly more descriptors for the types of conditions and clinical symptoms that determine the grading categories than the national grading tool. The regional tool is preferred by clinicians because of the greater level of detail that is included. This enables grading practices to be monitored to ensure consistency. … The regional tool results in approximately 80% of referrals requiring a first specialist appointment within 3 months.[4] This results in significant pressures on service delivery.
>
> Following discussions with clinicians there appears to be a willingness to review the Regional Guidelines with the aim of aligning time frames for categories with the timeframes used in the National tool. This may assist the DHB to better meet the clinical needs of the patients on the waiting list by ensuring there is a differentiation between those that definitely need to be seen within 12 weeks and those for whom a 6 month time frame is clinically appropriate. It is hoped this will allow better management of the limited urology resources available and ensure priority is appropriately given to those needing more urgent review based on their presenting symptoms. The Regional Guideline timeframes will be an agenda item at the next regional meeting … "

CMDHB stated that an audit would be undertaken on priority 2 urology referrals, to determine the consistency of grading.

Sending referrals to Auckland DHB for grading
CMDHB advised that the practice of referrals being sent to ADHB for grading has been reviewed and the volume of referrals audited.

> "The tight timeframes for travel between clinics at CMDHB and ADHB mean it is not possible for ADHB clinicians to also grade referrals while they are present at CMDHB for outpatient clinics and at this stage referrals will continue to be graded at ADHB."

[4] CMDHB subsequently clarified that not all FSAs occur within this time-frame (see discussion of "Waiting list management" below), although it does not have the data to show this.

CMDHB subsequently stated that 80% of referrals require an FSA within three months, but although the DHB accepts that not all of these referrals are seen in this time-frame, it does not currently have the means to record this data. CMDHB states that it is currently working to resolve this.

Referral logging
CMDHB advised that in 2007, urology referrals were not logged on receipt. The practice has now changed. Once received at CMDHB all referrals are logged and documented as having been transferred to ADHB for grading. They are then logged again on return to CMDHB. The referral management stamp used for referrals has also been enhanced to include eligibility information to further streamline the booking process and to help prevent further delays checking eligibility prior to a clinic booking being allocated. The monthly audits being undertaken by the Team Leader and Quality Coordinator for the Referral and Appointment Centre will include monitoring the use of the stamp. Provisional results from the July audit indicated that there were no delays in the expected referral turnaround time between ADHB and CMDHB, although the full analysis is not yet complete.

Waiting list management
CMDHB advised that the waiting time for patients assigned a priority 2 FSA had grown from 4 to 6 weeks, to 4 to 5 months. CMDHB stated that eight extra FSA clinics were planned for July 2008, with a further 12 clinics being negotiated. In addition, outpatient clinics have increased from 34 clinics per month to 38, with an expected further increase in the number of clinics to 44 per month by the end of June 2008.

CMDHB subsequently advised that additional clinics have been scheduled in the evenings during September and planning is under way for a second Saturday "mega clinic" to see 70 patients during the same month. These clinics are addressing the outstanding referrals to bring appointments into line with clinical grading criteria by 31 October. As referrals fall due in their grading category these will be reviewed by clinicians and given a higher priority if required. CMDHB is proposing to develop additional clinics to keep the waiting list time frames within acceptable limits in the future without the use of these "extra-ordinary measures" which are not possible to sustain on an ongoing basis.

Communication of waiting times
CMDHB advised that a process has been introduced to ensure that the patient and the GP are informed if there are any changes from the waiting time they are initially advised. The new sign-off process has been further enhanced to ensure there is clear responsibility for communication around waiting times. The FSA waiting times are now being reviewed monthly and the waiting list acknowledgement letters are updated to reflect any changes to the expected waiting time.

Reasons for incorrect information about waiting times

CMDHB advised that information given to patients in 2007 about expected wait times was incorrect because it did not have robust processes in place to regularly update the standard patient and GP referral acknowledgement letters. This has now been dealt with by reviewing and updating the waiting times on a monthly basis (see communication of waiting times above). Previously, the letters included content based on expected timeframes rather than "real time" waiting periods, which are subject to change depending on the number of referrals and pressures on resources in various areas. There was definitely no intention to mislead patients or GPs. CMDHB accepts the importance of ensuring they have accurate and up-to-date information about expected delays, and believes that the changes described above should help address this issue.

CMDHB review conclusion
CMDHB concluded its review report by stating:

> "[Mr C] experienced a considerable delay between his GP's referral to our Urology Service and his first specialist appointment with the consultant urologist despite being graded at Priority 2.
>
> We are unable to explain the delay from 11 June to 25 July, but are reviewing our administrative procedures and current patients under the urology service to prevent such a delay occurring in future.
>
> CMDHB acknowledges that the delay to the first specialist appointment for the urology [priority] 2 patients is both regrettable and unacceptable. We take full responsibility for this delay and have apologised to [Mr C] and are following up issues identified during the investigation to prevent a reoccurrence.
>
> The delay for a first specialist appointment is something CMDHB is actively working on resolving. The Urology Service is currently working on strategies to reduce patient delays and improve their service to CMDHB residents.
>
> We have discovered several additional internal system processes … where processes are currently in the process of being improved and/or already implemented. CMDHB [has] developed an action plan and [is] working on getting these improvements/actions implemented as quickly as possible.
>
> While some clerical/administrative issues have been identified, key issues are service capability and waiting list management ie the wait time was 4–5 months."

Ministry of Health advice

Dr Ray Naden, Clinical Director of the Elective Services Programme at the Ministry of Health, reviewed this case and provided the following advice:

> "I have confined my comments to the issues relating to the waiting time for First Specialist Assessment (FSA).

The Ministry of Health Elective Services policy requires district health boards (DHBs), in responding to a referral for an elective Specialist Assessment, to:

- advise patients and their primary care provider whether the patient can be seen by a specialist within six months
- ensure that patients so advised are seen within six months.

It is expected that patients will be assigned an appropriate time to be seen within the six months, according to their clinical priority. The actual time from referral to specialist assessment should reflect this priority. Patients should be informed of the time they can expect to wait. These expectations are covered in the Code of Health and Disability Services Consumers' Rights, and the Medical Council of New Zealand's 'Statement on safe practice in an environment of resource limitation', October 2005.

…

It is not ideal that patients assessed as priority 2 (P2) should have to wait 4–6 months. However, when patients cannot be seen as soon as clinically appropriate, it is all the more important that they are prioritised well, so that the most urgent are seen first. Assuming the assignment to P2 was appropriate (this is not clear from the information I have), within the group of patients assigned to P2, there will be a wide variation from quite urgent to not very urgent. I suspect Mr [C] would be regarded as 'quite urgent', in terms of the concern about 'cancer' even if treatment options were limited. The problem is the lack of differentiation of priority within this category P2, both in assigning the priority and acting on it. Appropriate prioritisation requires adequate differentiation between higher and lower priority patients. This is not achieved when a large number of patients are given a single undifferentiated priority (such as 'P2'). This issue was addressed by the Commissioner in an earlier case (Southland Urology 04HDC13909).

I strongly support the principle that available services should be provided to patients in accordance with their individual clinical priority. This requires appropriate assignment of priority relative to others and ensuring that the assigned priority is acted on. There are sometimes circumstances which make this latter difficult; however these circumstances need to be identified and addressed as far as possible. The needs of patients are not well served when relative priority is obscured by broad categorisations. It is fair to say that this is common in health systems in New Zealand and in other countries. Nevertheless it is cases such as that of [Mr C] which show clearly the consequences for individual patients which can result."

Independent advice to Commissioner

Initial expert advice from general practitioner Dr Keith Carey-Smith

"In order to provide an opinion to the Commissioner on case number 07/01315, I have read and agree to follow the Commissioner's Guidelines.

My opinion is based on my training in general medicine, and general practice, and my experience and ongoing education as a rural general practitioner in Taranaki for over 30 years. In addition I am a RNZCGP Cornerstone Assessor. My qualifications are FRNZCGP, Dip Obstetrics (NZ) and DA(UK). I have no conflict of interest in relation to this case.

Purpose	*To provide independent expert advice about the care of [Mr C] by [Dr B] and his practice over the period 24 April 2006 to 25 May 2007.*

[At this point in his report, Dr Carey-Smith sets out the background to the case, the documents sent to him, and the questions asked of him — which he repeats in his report. This detail has been omitted for the purposes of brevity.]

General comments:

The background provided appears to be accurate. In addition I would make the following general and specific comments:

1. The standard of **medical records** is high, allowing me to reach a clear opinion about the standard of care.

2. **Consultation 24 April 2006**. There is no comment in the records from [Dr B] about what instructions were given to [Mr C] regarding notification of results and follow-up. Patients had access to the practice policy, and it is presumed that [Mr C] was aware of it, having previously undergone a number of tests. The records also indicate that the result was seen and noted, and a recall set for a repeat in 3 months. However there is no indication that [Mr C] was notified of the result at that time, and [Mr C] and his daughter state that he was only told of this result in April 2008. (This differs from the statement and records of [Dr B], which indicated that the abnormal tests were discussed on 25 May 2007 when he was referred.)

   The test was mildly abnormal, necessitating further action, and notification was therefore to be expected according to the practice Policy (notify patient if 'significantly abnormal or needs actioning in some way'). The records then indicate that a repeat test form at 3 months was generated, but not how this form (or the reason for doing it) was communicated to [Mr C]. A copy of the covering letter sent by the nurse is not available, but presumably was a form

letter with no clinical content.[5] [Mr C] does not state whether or not he received this letter. If he did, he did not have the repeat test done.

3. **Consultation 10 April 2007**. This was conducted by a GP registrar and again excellent records allow an opinion that the consultation was carried out appropriately. The concern was chest pain which turned out to be due to a heart attack, so that attention to other issues such as the previous PSA result and missed follow-up was not appropriate. If observed (as might have happened if a recall alert was set up), this might have been notified in the admission letter or followed up after discharge. I was impressed by the measures taken by the practice to follow up [Mr C] after his heart attack.

4. **Consultation 9 May 2007**. Another doctor saw [Mr C] because of haematuria. Since he had recently undergone catheterisation in hospital the doctor apparently considered this to be a likely cause. A urine test was done but full results of this were not provided to me (the notes say just 'no casts'). If haematuria has been confirmed on the urine test, normal practice would be to follow up with further tests. This was arranged appropriately when [Mr C] was seen on 12 May. The test was positive so [Mr C] was recalled and seen on 21 May.

5. **Consultation 21 May 2007**. Appropriate interrogation and investigations were carried out for the haematuria by [Dr B], including prostate examination, blood tests and repeat PSA. When this result was found to be markedly elevated, [Mr C] was rapidly recalled (25 May) and according to the records given a full explanation of the possibility of cancer, and referred for specialist attention (the referral letter is not available to me). A repeat urine test was done on 9 June. During visits to the practice in August and September it is admitted that no check was made as to whether he had seen the urologist. The records indicate a 'modified referral' to urology on 4 August (no copy of this available to me).

Subsequent events

There were further delays before the prostate cancer was addressed by the specialist/hospital but this later period is not the subject of this advice.

Documentation

Records from [the] Clinic are of high quality, and provide clearly the time sequence of events. The records indicate that phone conversations are normally recorded, which suggests that no information had been provided by phone to [Mr C] about the abnormal tests and significance until 25 May 2007. Copies of

[5] Commissioner's note: A copy of the standard cover letter sent was provided to HDC.

investigation results and referral letters would allow confirmation of the referral quality and process.

OPINION

1. The standard of care provided to [Mr C] by the [Clinic] in relation to his urological problems. (See below).

2. Advise on the adequacy of the GP assessment, and the subsequent management decisions, on 24 April 2006. In particular, was the decision to repeat the PSA in three months' time appropriate?

The records along with [Dr B's] comments indicate that the complaint was managed on 24 April more than adequately. History, examination and investigations were appropriate, and [Mr C] attended for the blood test. The result was checked and appropriate action taken in repeating this in 3 months, although in my view ideally the repeat test should have been done earlier (ref 1, 2). However it is likely that [Mr C] was not notified when the result came back, and was not aware of the need for, or the reason to repeat the test. The practice's own policy was not fully complied with in this respect.

3. Comment on the adequacy of the systems in place at the [Clinic] to follow up [Mr C's] 24 April 2006 PSA result of 10.8.

Several possible systems are available for this type of follow-up:

1. Notifying the patient of the abnormal result at the time of receipt of the test (either by phone or letter, or recalling the patient for a consultation). If indicated, the patient can be provided with a lab order form for a repeat to be done at a later date.
2. Setting a recall at the appropriate date, for the patient to be contacted (by phone or letter) and the repeat test requested (or the patient reminded if test already ordered and not done).
3. Scheduling a repeat appointment at the appropriate date to review and order further tests (or noting to deal with the issue at the next routine appointment).

In my opinion, any one of these follow-up methods is satisfactory for a result with low risk of serious outcome (eg mildly elevated lipids, mild anaemia). However if there is significant concern at least two of the above should be put in place. For an abnormal result, the patient should ideally be notified at the time, rather than three months later. College standards include agreeing with the patient the method of notifying results, and having a process to deal with patients who don't attend a follow-up appointment to discuss the results (ref 4). In the case of a mildly elevated PSA and absence of signs of prostate cancer, I would judge the situation to be of only mild concern, but still significant. Therefore ideally the patient

should have been notified when the test was received about the result and follow-up arrangements.

Most men (approx ¾) with mildly elevated PSA (under 10) do not have cancer and there are other reasons for an elevated result (ref 1). However the likelihood of cancer increases above PSA 10. In [Mr C's] case, with the history of reluctance to accept medical advice mentioned by [Dr B], method 2 was appropriately chosen. However immediate notification (method 1) was also appropriate.

The failure to notify the abnormal test, and lack of information provided to [Mr C] to allow fully informed consent, is likely to have contributed to the failure to have the repeat test done. In addition, discussion about the pros and cons of further tests allowing full informed consent is particularly important for PSA tests (eg if an older patient is unwilling to undergo invasive procedures, further tests may be unhelpful). These deficits are viewed with moderate disapproval.

4. Advise on the adequacy of the GP assessment, and the subsequent management decisions, on 10 April 2007, when [Mr C] attended with chest pain. In particular, should the GP have noted the earlier PSA result, and the missed follow-up at 3 months?

The action taken by the registrar on this occasion was appropriate, and the failure to address the missing follow-up result is not considered to constitute a deficit in care. However, since patients are seen in this practice by a number of different doctors, an alert system indicating important missed recalls would have allowed this deficit to be addressed after the heart attack.

5. Advise on the adequacy of the GP assessment, and the subsequent management decisions, on 9 May 2007, when [Mr C] attended with haematuria.

The doctor involved conducted this consultation and investigated appropriately. Appropriate follow-up arrangements were made.

6. Advise on the adequacy of the GP assessment, and the subsequent management decisions, on 21 May 2007, when [Mr C] attended with haematuria.

[Dr B] assessed the patient fully and to an adequate standard, and ordered appropriate investigations. Follow-up of the abnormal result was prompt and thorough.

7. What standards are relevant to this case? Were these standards complied with?

It should be noted that the place of PSA screening is not yet fully clarified, the test has a significant number of false positives (and negatives), and some authorities recommend avoiding the test over age 70 because the disease is often slow

developing, and intervention reduces quality of life. Testing over the age of 70 is unlikely to save lives unless the man is otherwise in excellent health (ref 2).

Standards relating to informed consent are outlined in 'Aiming for Excellence' (ref 3) and are based on Rights 6 & 7 of the Code of Health and Disability Services Consumers' Rights. This includes having information available for patients to assist them decide on a test or procedure, and recording this informed consent. Indicator C 6.5.4 states 'Clinical team members document discussing contentious screening tests with eligible patients in relation to harm versus benefit'. Testing/screening for PSA is recognised as a procedure requiring informed consent. Pamphlets are available for patients to help explain the pros and cons of PSA screening. Information to allow informed consent has not been provided in this case. However since the test was done for diagnostic rather than true screening reasons, these standards are only partially relevant to this case.

In this case the test was done as part of diagnostic work-up of urinary symptoms, and is therefore not true screening. Most general practitioners include a PSA test when investigating elderly men with urological or other non-specific symptoms (as in this case). Cut-off levels for initiating further investigations and referral are inexact, and depend on age, frailty, co-morbidity, and other factors, as well as the rate of change of the PSA result over time. In general for a 70 year old man results over 6.5 would be repeated after a period of time to recheck. Results over 10 should lead to earlier review, and referral if this level is confirmed or the level has increased (ref 2). In my view, depending on the wishes of the patient (not known in this case), the test should have been repeated earlier than 3 months. This deficit is viewed with mild disapproval.

Standards relating to recall systems and management of test results are included in the 'Aiming for Excellence' practice accreditation standards document (ref 3). Indicator D10.3 covers managing test results, and includes a policy for tracking and managing test results, informing patients about the procedure for notification of results, a procedure for identifying significant missing results, and recording communications with patients informing them of results. An additional RNZCGP document also covers this topic (ref 4), including a system for tracking results, and for alerting the doctor if significant results have not been received. The HDC considers GPs are responsible to ensure the patient is made aware of 'significant' results. In this case I would class the initial abnormal PSA as 'significant'. [Dr B] did not institute a tracking system other than the 3 month recall to repeat the test. No follow-up system to ensure the repeat test had been done was in place. However since this event the practice has instituted measures to ensure improved tracking and follow-up. [Dr B's] letter (27/6/08) indicates that the practice has discussed and instituted changes. However a decision has been made not to call patients in to notify and discuss mildly abnormal results. The reasons for this decision are understandable, but alternative methods of notifying patients about abnormal results (eg phone call, letter) could be instituted.

8. Are there any aspects of the care provided by the [Clinic] that you consider warrant additional comment.

Protocols were in place for managing abnormal tests, but these were not fully adhered to. The further measures now instituted by the practice should lead to avoidance of this problem in the future.

There is debate within general practice about how much effort should be put into ensuring patients carry out tests (and take medications) that have been ordered. The gold standard would be three contacts (by phone or letter) before assuming the patient had declined. This usually happens with cervical smear and other important screening procedures. An essential requirement for practices for Cornerstone accreditation is an efficient recall system, and system for managing test results (ref 3). This practice has fulfilled the Aiming for Excellence standards and appears to have good systems. However the systems need to be better utilised for follow up of any tests which are considered to be particularly important. The changes described and now in place should go a long way to achieving this aim.

CONCLUSION

Overall the care of [Mr C] by [Dr B] and the [Clinic] was of satisfactory standard throughout, and the records and recall systems were appropriate. However in this case lack of information given to [Mr C] about his abnormal test and the options for further management did not allow full informed consent, and is viewed with moderate disapproval. The practice systems were not utilised adequately in setting a recall to ensure the blood tests had been carried out and viewed, although systems are being improved, and this deficit has now been addressed. I would view this deficiency with mild disapproval.

Although only mildly elevated, the initial PSA was above 10, and ideally notification to the patient at the time, and earlier follow-up should have been carried out. This is also viewed with mild disapproval.

It is accepted that patients have some responsibility for attending for relevant tests and referrals. However to ensure this happens patients need adequate information about the reason for the repeat test, and in this case, this information was not provided.

References:

1. Prostate cancer screening in NZ National Health Committee April 2004.
2. PSA for the General Practitioner. Sticker & Phelps, Urological Society of Australasia, 2005.
3. 'Aiming for Excellence' (An assessment tool for General Practice). RNZCGP (Revised 2006, 2008).
4. Managing patient test results — minimising error. RNZCGP 2005.

Further expert advice from general practitioner Dr Keith Carey-Smith

"In my opinion, a practice policy to track ALL ordered tests (as now introduced at [the] Clinic), is **not** essential, and (as pointed out by [Dr B]) results in significant workload. I would not expect all practices to do this, and the College Aiming for Excellence does not require such a policy. Tracking of 'significant' tests is however clearly established as a standard for general practice.

Thus the question in this case boils down to whether the elevated PSA (done for diagnostic and not screening purposes), was sufficiently elevated to justify tracking the follow-up test. Although this is clearly a contentious area, with no clear guidance from current guidelines, my opinion remains that the follow-up test in this case was 'significant', and therefore justified follow-up and tracking according to the existing College guidelines and the practice's own policy. My opinion takes into account not just the abnormal PSA level, but also the patient's age and satisfactory clinical status. In addition I would normally take into account the patient's own opinion (after discussion), which did not happen in this case. Therefore I differ from [Dr B] in this respect, but accept that opinions differ even amongst experts in the field! It would be interesting to do a survey on the topic."

Code of Health and Disability Services Consumers' Rights

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

RIGHT 4

Right to Services of an Appropriate Standard

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

(2) Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.

…

(5) Every consumer has the right to co-operation among providers to ensure quality and continuity of services.

RIGHT 6

Right to be Fully Informed

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

…

(c) advice of the estimated time within which the services will be provided; and

…

(f) the results of tests; …

Names have been removed (other than Counties Manukau DHB/Auckland DHB) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

Other relevant standards

In his advice, Dr Carey-Smith quoted from the 3rd edition of the Royal New Zealand College of General Practitioners' publication *Aiming for Excellence: RNZCGP Standard for New Zealand General Practice* (2008). The second edition, published in 2002, is more relevant to this case, although the standards are comparable to those quoted by Dr Carey-Smith.

Indicator C.6.5

The practice targets patients in identified national or regional health priority areas.

…

- There is a process for active follow up of patients identified as having conditions in a national or regional health outcome priority area.

Indicator D.8.2

There is a system to manage patient test results and medical reports.

…

- There are procedures to track and manage patient test results, medical reports, investigations and follow up missing results.

Opinion: Breach — The Clinic

April 2006 PSA test
Mr C's PSA test on 24 April 2006 showed a raised level of 10.8µg, which my expert, Dr Keith Carey-Smith, considered "mildly abnormal, necessitating further action". However, there is no evidence that Mr C was told what a PSA result means or of the significance of his raised level. Dr B believes that he would have tried to contact Mr C by telephone and invite him in for a face-to-face consultation (since PSA results are complicated to explain), but he did not document this.

At the time any test is proposed, patients have a right to be told by their doctor *why* the test is recommended, and *when and how* they will be informed of the results. If a doctor or medical centre has a standard practice of not notifying normal test results, patients must be informed and their consent obtained to non-notification in such circumstances. It must be made clear to patients that they are entitled to be notified of *all* test results, and that even if they agree to be notified only of abnormal results, they are welcome to call the medical centre and check if their results have been received

and what they are. Finally, in the absence of any other arrangement being made, when results are received by a medical centre, the patient must be informed. This is especially important if the results raise a clinical concern and need follow-up.

Keeping patients well informed in this way is fundamental to good medical practice. Patients need this information if they are to be partners in their own care. This approach recognises their autonomy — that it is ultimately the patient's choice whether to follow medical advice and have a test. Knowing when and how results will be notified is reassuring for patients, and also provides an important safeguard. A patient who knows that a test is being undertaken because of a clinical concern, and that the results should have been received by a certain date, can play a valuable backstop role by checking with the medical centre if that date has passed and they have heard nothing further. In a complex health system where results sometimes go astray, patients are right to assume that "no news" does not necessarily mean "good news".

On the evidence available, Dr B did not explain to Mr C why he was having a PSA test, nor when and how he would be notified of the results. Mr C was not told that his result was a "mildly elevated" PSA of 10.8µg/L, nor what this meant. The only information Mr C was sent by the Clinic (although he has no recollection of receiving it) was a letter saying "you are now due for a blood test", enclosing a laboratory request form for another PSA blood test and urine test.

Doctors are often quick to talk about patient responsibility and patient compliance. Of course patients have a key responsibility for taking steps to look after their own health. But a 70-year-old patient who does not know why he needed to have a blood test, nor what the results were, can hardly be held responsible for not having a follow-up test on the basis only of a standard form letter.

I conclude that the Clinic breached Right 6(1) of the Code in failing to properly inform Mr C about the need for the PSA tests and the results of the April test. To his credit, Dr B accepts full responsibility for the failure to properly inform Mr C.

Follow-up of April 2006 PSA test

As noted above, Mr C was sent (by letter dated 29 July) a request form to have the PSA test repeated, but he did not have the second test performed. The Clinic took no action to follow up the matter when no further PSA test result was reported. Mr C was lost to follow-up until a year later, in May 2007.

Dr B submitted that "[o]nly the most exemplary of practices would have had a system in 2006 to ensure that a requested blood test was in fact carried out". He added that the Clinic had an accredited system for tracking cervical screening and "certain important tests", but not "routine tracking of blood test requests".

It may be debated whether Mr C's PSA was just a "routine blood test request". My advisor, Dr Carey-Smith, described it as a "significant result", stating that Mr C's PSA

was "sufficiently elevated to justify tracking the follow-up test" that had been recommended.

It might be argued that if the second test was important enough to recommend, it warranted tracking by the Clinic.[6] In fact the Clinic did have a system to track "cervical smears and histology and certain important tests", but not all blood test requests (including a follow-up blood test).

Dr B submitted that the Clinic's tracking system in 2006 was at least up to the standard required by professional standards — as confirmed by the Clinic's obtaining Cornerstone Accreditation in September 2006. Even in 2008, the relevant Royal New Zealand College of General Practitioners indicator for "a system to manage patient test results" requires only that the practice has "a procedure to identify missing results of patients with significant cytology, histology test and urgent referrals".[7]

Dr Carey-Smith accepts that in relation to systems to manage patient test results, "opinions differ even amongst experts in the field". Given the varying opinions, even in 2008, I do not consider it justified to find that the Clinic breached Right 4 of the Code in 2006 in failing to have in place a system that tracked all blood test results, or even somewhat significant blood test results.

I note that the Clinic now has a system that will track every blood test requested, with automatic follow-up after two weeks has elapsed with no results reported. That is an exemplary standard of care. I commend the Clinic on the changes it has made and in its commitment to high standards of patient care.

Opinion: Breach — Counties Manukau District Health Board

Introduction

District health boards owe patients a duty of care in handling outpatient referrals, under Right 4(1) of the Code.[8] This duty applies to referrals from GPs within the district and from other DHBs. A specific aspect of the duty of care is the duty to co-

[6] In case 99HDC11494 (7 May 2001), I stated: "In my view any test ordered where the doctor has reason to suspect a cancer diagnosis requires a proactive follow-up by the referring doctor." Further, in case 02HDC13523 (4 February 2004), I highlighted the need for efficient systems for handling test results and referrals, particularly in cases where the diagnosis may be serious.

[7] *Aiming for Excellence: RNZCGP Standard for New Zealand General Practice* (2008), indicator D.10.3–4.

[8] For fuller discussion of a district health board's duty of care in handling outpatient referrals, see cases 07HDC19869 and 07HDC20199 (3 October 2008).

operate with other providers to ensure continuity of care, under Right 4(5) of the Code.

Loss of referral

Following Dr B's referral of Mr C to the Urology Service and the prioritisation by Dr D, the referral was "lost" for six weeks between 11 June and 25 July 2007. CMDHB has been unable to ascertain how or why the referral was lost.[9]

A district health board must have robust systems for managing referrals, so that referred patients do not fall through cracks in the system.[10] Mr C was let down by CMDHB staff and the system responsible for ensuring that the referral was actioned.

CMDHB did not have an appropriate referral receipt system in place for urology services in 2007. In handling the referral, CMDHB failed to co-operate with Mr C's GP to ensure continuity of care. Accordingly, Counties Manukau DHB breached Rights 4(1) and 4(5) of the Code.

Information about waiting times

Right 6(1) of the Code gives patients the right to receive full information about their condition and treatment options, including advice about the estimated time within which services will be provided. This duty applies to GP referrals of patients for first specialist assessments.[11]

Although the actual waiting time for a first specialist assessment (FSA) at the time of Mr C's referral was four to six months, both he and his GP were advised by letter from CMDHB that the wait was four to six weeks. The actual waiting time was well known to CMDHB, and that is the information that should have been given to Mr C and Dr B. Had he known of the expected delay, Dr B could have taken further action to expedite the process, and could have monitored Mr C's condition more closely. For his part, Mr C may have been in a position to consider alternative options, such as private medical care, had he known of the long delay, and been told of the option of being treated as a private patient.

Mr C was provided with misleading information from CMDHB about the expected wait for an FSA appointment. Accordingly, Counties Manukau District Health Board breached Right 6(1)(c) of the Code.

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[9] I note that CMDHB is undertaking a full review of the Urology Service, and has already improved systems to prevent a similar event occurring.

[10] For a recent HDC case on a DHB's duty to manage outpatient appointments appropriately, see: http://www.hdc.org.nz/files/hdc/opinions/06hdc15893ophthalmologist.pdf (28 May 2008).

[11] See http://www.hdc.org.nz/files/hdc/opinions/04hdc13909urologist,dhb.pdf (7 April 2006).

I note that CMDHB has apologised to Mr C for the delays. I also note that CMDHB is continuing to review its Urology Service in association with Auckland DHB, and that significant efforts are being made to reduce the waiting times for FSAs.

It is clear that further work is still required in this area. I note in particular advice from CMDHB that, while 80% of referrals are categorised as requiring a patient to be seen within three months, the DHB does not have the data to show how many of these patients are actually seen within this time-frame, although the DHB accepts that it is not all.

Other comment

Waiting times for outpatient appointments
There are three issues in this case that relate to the care provided to Mr C by Counties Manukau District Health Board: the inadvertent loss of the referral in the internal systems; the inaccurate information relating to waiting times provided to Mr C and Dr B; and the wait of four to six months due to a lengthened waiting list. Of these, the most important to Mr C is undoubtedly the latter.

Fairness supports the use of prioritisation tools, such as the referral tool being used by the three Auckland district health boards to prioritise patients for FSA. As noted by Dr Naden (on behalf of the Ministry of Health), it is important that large numbers of patients are not given a single undifferentiated priority (such as 'P2'). I agree with Dr Naden's observation that "the needs of patients are not well served when relative priority is obscured by broad categorisations", something that occurs in New Zealand and in other countries. It is also important that, following appropriate prioritisation, patients are actually seen within specified time-frames.

Recommendations

- I recommend that the Clinic apologise to Mr C for its breaches of the Code.
- I recommend that CMDHB advise HDC by **31 January 2009** of the progress of the review of the Urology Service, and provide a copy of the final review report to HDC.

Follow-up actions

- A copy of this report, with details identifying the parties removed (other than Counties Manukau District Health Board and Auckland District Health Board, my

advisor, Dr Carey-Smith, and Ministry of Health Clinical Director Dr Naden), will be sent to the Minister of Health, the Quality Improvement Committee, the Health Information Strategy Action Committee, the Director-General of Health, the Royal New Zealand College of General Practitioners, and the Royal Australasian College of Surgeons, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Names have been removed (other than Counties Manukau DHB/Auckland DHB) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.