

Consultant Psychiatrist, Dr C
A Rural Hospital

A Report by the
Health and Disability Commissioner

(Case 02HDC01804)



Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Mrs A	Consumer
Ms B	Complainant/Consumer's daughter
Dr C	Provider/Consultant Psychiatrist
Ms D	Provider/Nurse
Dr E	General Practitioner; later Clinical Director at the rural hospital
Ms F	Community Mental Health Nurse
Dr G	Psychiatrist
Ms H	Registered Nurse
Ms I	Nurse
Ms J	Community Mental Health Nurse
Dr K	Clinical Director of Mental Health Services at the DHB
A Rural Hospital	Provider
A DHB	A District Health Board

Complaint

On 12 February 2002 the Commissioner received a complaint from Ms B about the services provided to Mrs A by Dr C and a rural hospital between October 2000 and May 2001.

The complaint against Dr C was summarised as follows:

Dr C did not provide services of an appropriate standard to Mrs A. In particular, in October 2000:

- *Dr C inappropriately re-diagnosed Mrs A, on the basis of inadequate information and without adequately taking into account her almost 30-year history of paranoid schizophrenia*
 - *Dr C inappropriately prescribed Mrs A an antidepressant (Cipramil) and advised a regime to wean her off the antipsychotic (Risperdal) she had been taking, on the basis of inadequate information and without adequately taking into account her almost 30-year history of paranoid schizophrenia*
 - *Dr C did not adequately take into account concerns expressed by Mrs A's daughter and primary caregiver, Ms B, about Mrs A's mental health and the new medication regime she had been prescribed.*

In January 2001:

- *when Mrs A returned in crisis from overseas, Dr C did not arrange for her admission or alternatively arrange adequate support to allow her principal caregiver Ms B, to care for her at home.*

In February 2001:

- *Dr C inappropriately prescribed Mrs A the antipsychotic clozapine (Clozaril)*
- *Dr C did not ensure adequate monitoring of Mrs A's clozapine and did not take appropriate steps in a timely fashion when Mrs A became increasingly unwell.*

From October 2000 to May 2001, Dr C did not provide Mrs A with information that a reasonable consumer in Mrs A's circumstances would expect to receive. In particular:

- *when Dr C prescribed clozapine for Mrs A, he did not provide her with adequate information about clozapine, and in particular he did not inform her about the side effects and warnings associated with clozapine*
- *Dr C inappropriately recommended that Mrs A was well enough to travel overseas, when she was not. [Mrs A travelled overseas in December 2000 and became acutely ill. In January 2001 Ms B had to fly overseas to bring her mother home in crisis.]*

The complaint against the rural hospital was summarised as follows:

From October 2000 to May 2001, the rural hospital did not provide services of an appropriate standard to Mrs A. In particular:

- *when Mrs A returned in crisis from overseas in January 2001, the rural hospital did not arrange for her admission or alternatively provide Mrs A or her principal caregiver, Ms B, with adequate and appropriate psychiatric community support*
- *from February 2001 to May 2001, when Mrs A was prescribed the anti-psychotic clozapine (Clozaril), the rural hospital did not adequately monitor Mrs A's medication*
- *when Mrs A and her principal caregiver, Ms B, notified rural hospital staff that Mrs A was becoming increasingly unwell, the rural hospital staff did not take the appropriate steps to arrange further assessment and/or treatment in a timely manner.*

An investigation was commenced on 3 October 2002.

Information reviewed

The Commissioner received and reviewed information from the following sources:

- Ms B
- Dr C
- The Chief Executive Officer and Dr E of the rural hospital
- A District Health Board
- Two other District Health Boards
- Medical Council of New Zealand
- Ms D
- Ms F.

Independent expert advice was obtained from:

- Dr Felicity Plunkett, psychiatrist
 - Mr Tom Woods, mental health nurse.
-

Information gathered during investigation

Mrs A's history

Mrs A had a lengthy history of mental illness dating back to the 1970s. In November 1974 Mrs A became ill for the first time and, during an admission to a psychiatric unit, was diagnosed with paranoid schizophrenia. This remained her diagnosis until October 2000, although she was also treated for depression on several occasions.

Mrs A was treated in the community at a day clinic until February 1996 when she was discharged back to her general practitioner. Initially she was treated with fluphenazine decanoate, then in February 1981 her medication was changed to Melleril. She continued to take Melleril until May 1989 when she was commenced on thiothixene.

In February 1998 Mrs A's care was transferred to a Community Mental Health Centre (CMHC). At that time she was taking thiothixene 20mg daily.

In October 1998, Mrs A was prescribed risperidone as she had ongoing psychotic symptoms which were not responding to the thiothixene. She remained on risperidone until October 2001 when Dr C decided to change her medication to Cipramil.

On 18 February 1999 Mrs A took an overdose of risperidone and Imovane.

In December 1999 Mrs A's care was transferred from the CMHC back to the day clinic. A doctor at the CMHC described her diagnosis as "... chronic paranoid schizophrenia in remission with major depressive episode in remission". She was then taking risperidone, nortriptyline, Melleril and zopiclone. She remained under the care of the day clinic until April 2000 when she moved and her care was transferred back to the CMHC.

In August 2000 Mrs C moved to a rural township to live with her daughter, Ms B. Her care was transferred from the CMHC to the rural hospital. By the time Mrs A moved to the rural township, although at various times she had been treated for depression, her primary diagnosis of paranoid schizophrenia had stood for 25 years.

Mrs A's psychiatrist at the CMHC, Dr G, wrote to the rural hospital requesting that it accept a transfer of Mrs A's care on 28 August 2000. In his letter, Dr G stated:

“She has been treated for schizophrenia, paranoid type or schizoaffective disorder for over 30 years, with admissions in 1981, 1982 (and ? in early stages of illness, I am unsure). In February 1999 she was seen in the emergency department with a relatively minor overdose of Imovane and risperidone, reported as a suicide attempt precipitated by

domestic stressors concerning her relations with her daughters. This is the only reported episode of self harm.

She had remained stable and relatively free of psychotic symptoms for many years when her care was transferred to this centre from [the city] in February 1998. [Mrs A] had moved from one daughter's home to the home of another, and on transfer was taking thiothixene 20mg daily. Then in July 98 she began to hear derogatory voices with associated persecutory delusions, delusions of reference, and passivity delusions. There were some depressive symptoms and suicidal ideation. She had moved back to the daughter in [the city] and domestic stress was suspected as a contributing stressor. She settled and care was transferred back to the city, although she began to live with both daughters alternately until the overdose in Feb 99. Thiothixene had been replaced by risperidone in Oct 98 presumably because of refractory psychotic symptoms. Following the overdose major depressive episode was diagnosed and [Mrs A] started nortriptyline. Depressive symptoms remitted within a month and psychotic symptoms were much diminished within two months.

In June this year she was troubled by worsening insomnia and derogatory voices; it emerged that she had stopped the nortriptyline 50mg by herself and ? halved her risperidone to 4mg. Medications were resumed at former doses but she continued to experience the auditory hallucinations, irritability with verbal aggression towards her daughter and disturbed sleep. Nortriptyline was eventually increased to 100mg nocte, and [Mrs A] spent a few days in our respite facility before deciding to move to be with her other daughter who had moved [to the rural township]. The daughter [in the city] with whom she had been staying had recently become a solo mother and I think life had become very stressful for both of them. On 17th August [Mrs A] seemed calm, euthymic, and the auditory hallucinations were much less troublesome.

Current medication: Risperidone 8mg nocte, nortriptyline 100mg nocte, zopiclone 7.5–15mg nocte. (has been used long term). Nortriptyline level on 10th August, on 75mg, had been low at 260nmol/l. It has not been measured on the higher dose.

I would be grateful if she could be seen quite soon.”

Dr G's letter was received by the rural hospital on 28 August 2000 and Ms F, a community mental health nurse (CMHN) employed by the rural hospital, had an introductory meeting with Mrs A on 6 September 2000. On 19 September 2000 Ms B advised that Mrs A was tearful and wanted to increase her antidepressants.

An appointment was made for Mrs A to be reviewed by Dr C on 19 October 2000. Dr C is a psychiatrist who was then employed by a District Health Board (the DHB) and visited the rural hospital's clinic once a week.

First consultation with Dr C — 19 October 2000

On 19 October 2000, Dr C met Mrs A for the first time. Ms B, who was also present, recalls that this was a 20-minute consultation. He advised me that he needs, “at least 40–50 minutes time to build rapport and gain a patient's confidence” at an initial consultation. However, Dr

C talked with Mrs A about how she was feeling and how things were going; he did not ask Ms B any questions about her mother. At this stage Ms B said that her mother was hearing voices but she felt this was to be expected given the stresses associated with her move from the city.

Dr C has consistently stated that he had seen several files and earlier notes detailing Mrs A's history before the 19 October 2000 consultation. Ms B, however, said that she was told by Ms D, a community health nurse, that the letter from Dr G at the CMHC dated 28 August 2000 had been faxed to Dr C only at the first consultation on 19 October 2000.

Other evidence relevant to the question of what records Dr C had available to him at the initial consultation includes:

- Ms B said that Ms F visited Mrs A at home on 6 September 2000 so that Mrs A could sign forms consenting to the release of her records from the CMHC;
- on 9 October 2000 Ms F recorded a plan to obtain Mrs A's files from the CMHC;
- there is no record of the rural hospital making a request to the CMHC for the files, nor is there anything on the CMHC's file recording a request for the file by the rural hospital or the provision of the file to the rural hospital;
- Mrs A's files at the CMHC did not include copies of material from the day clinic file;
- a note in Mrs A's day clinic file dated 10 May 2001 records a phone call from Ms H, another community mental health nurse at the rural hospital, seeking information on Mrs A;
- there is no record in the day clinic file of the rural hospital requesting Mrs A's records at an earlier date.

Dr C described this consultation in a letter dated 19 October 2000 to Dr E, Mrs A's general practitioner. In the letter Dr C advised Dr E that he had changed Mrs A's diagnosis to "major affective disorder (illusionary melancholia) result remit". He noted that in view of the change in diagnosis he would be changing the medication regime, phasing out the risperidone and nortriptyline Mrs A had been taking and introducing Cipramil gradually. It appears that Dr C did not review or sign this letter before it was forwarded to Dr E and a copy placed on Mrs A's file.

Dr C's letter of 19 October 2000 read as follows:

"To [Dr E]

Re: [Mrs A]

File No: [...]

The above named was seen by me on 19/10/00 with this history that she was subsequent to her husband's death and the passing away of both her parents was admitted to [a psychiatric unit] with a depression. Subsequent to this she also developed voices talking to her and saying non-specific derogatory things that she's f... bitch etc.

When her husband died the family went through [dire] straits and it is possible that she was annoyed with her former partner dying but also developed guilt feelings about it which could have formed the basis for her derogatory voices.

At present she suffers from episodes of depression for short periods but the derogatory voice is always there, worse when she is depressed but other times as well.

At present she is well orientated and although she was depressed yesterday she is not depressed at the moment and her affect is appropriate.

She has at present no suicidal ideation and no clear delusional system. Her insight around her situation is partial and her judgment is influenced by her insight and her illness.

Diagnosis: I — Major affective disorder (illusionary melancholia) result remit

II — Deferred

III — Deferred

IV — She exhibits frustration due to her fear that she may have to be hospitalised again since that hospitalisation at [the psychiatric unit] was for her a terrifying experience.

In the family home where she is staying at the moment the teenage children act with hostility towards her illness, saying adverse things to her.

Treatment: She has been taking risperidone up to 12mgs per day and nortriptyline up to 100mgs a day and there is no change in her asymptatology.

In view of the changing of her diagnosis I am phasing out the risperidone as well as the nortriptyline and introducing Cipramil gradually.

I will see her again and follow up.

The family is well aware of her suicidal ideation at times but I don't think it is imminent effect, maybe more a cry for help."

Dr C did not sign this letter but his name and the word 'psychiatrist' are printed at the foot of it and the letter appears to have been placed on Mrs A's file unsigned.

When interviewed during this investigation, Dr C said that at the consultation on 19 October 2000 he diagnosed Mrs A with:

"Major affective disorder with involution melancholia, in remission or in partial remission."

He said that this diagnosis should have been recorded in the 19 October 2000 letter. In Dr C's opinion the phrase "major affective disorder (illusionary melancholia) result remit" was

an error made by the typist when transcribing the letter from a tape made by Dr C. He said that he did not know what that phrase meant and the words were not in his vocabulary.

Dr C described “involution melancholia” as a mood disorder where patients have symptoms of depression and believe that bad things are going to happen to them. He said that nowadays this is described as a mood disorder with psychosis or melancholia but in the past it was called “involution melancholia”.

At an interview during this investigation, Dr C described his reasons for changing the diagnosis as follows:

“This woman ... has been treated for paranoid schizophrenia for 30 years. Now if she’s been treated for 30 years and she was still here, complaining, wanting to commit suicide and things like that, it means (a) that ... the diagnosis was probably not correct; secondly, that the medication was probably not correct.”

Dr C felt that Mrs A’s mood disorder was more important than her psychotic symptoms. In his opinion it was only during her episodes of mood disorder that her psychotic symptoms came to the fore. Her psychotic symptoms were associated with episodes of depression but at other times she was generally well and therefore fitted the prototypal depiction of major depression. In a letter dated 1 June 2004, Dr C stated:

“In [Mrs A’s] case, I held genuine concerns that her longstanding diagnosis did not readily fit with the nature of her symptoms. I did not categorically change her diagnosis, and I regret that it may have been interpreted in that manner. I have enclosed a diagram of what I perceive as [Mrs A’s] mood changes, from 1998 to February 2003 (the last medical records I have seen), to illustrate that she has mood changes, which I consider must be taken into account in her diagnosis and treatment. Recognition of these mood changes could well lead to the diagnosis of a mood disorder with psychosis (melancholia), which would influence and improve her treatment options.”

Dr C also noted:

“ ... [Mrs A] had always had the idea that she was going to [go] back to [the psychiatric unit] and that her kids were being abused and all these sorts of things. And she would be ... well maintained and then she would all of a sudden have these episodes when she felt that bad things were going to happen to her. In other words, during her periods of wellness, she really was well. But then she had these episodic periods when she fell into a depression and those are the things that I wanted to address because to give her antipsychotic medication wouldn’t prevent these relapses.”

Dr C decided that it was necessary to address Mrs A’s depression and “to get these depressive episodes out of the way”. He believed that Mrs A would need a mood stabilizer with antipsychotic properties to address the depressive episodes. He said:

“... a mood stabilizer with antipsychotic properties would probably be the only medication [Mrs A] would need for the future. Because that would keep her on an even keel and if the psychosis would pull up, that would stop that at the same time and we have medication like that.”

Dr C also speculated that Mrs A might have had a bipolar illness. He said:

“I speculated whether ... she [was] not, in fact, suffering from a bipolar illness. Because that’s maybe a little bit more real. But you know, bipolar illness, [they] ... not only ... have episodes of depression, but they also have episodes of hyperactivity. ... And it is sometimes possible that the patient can become psychotic there.”

Change in medication following re-diagnosis

Having decided that Mrs A’s diagnosis was major depression with psychotic symptoms, Dr C changed her medications. In the 19 October 2000 letter to Dr E, Dr C wrote:

“Treatment: She has been taking risperidone up to 12 mgs per day and nortriptyline up to 100mgs a day and there is no change in her asymptatology.

In view of the changing of her diagnosis, I am phasing out the risperidone as well as the Nortriptyline and introducing Cipramil gradually.”

Reduction of risperidone

Dr G’s letter stated that in August 2000 Mrs A was taking risperidone 8mg daily and nortriptyline 100mg daily. The rural hospital’s computer record for 19 September 2000 stated that Mrs A was taking 8mg risperidone and 100mg nortriptyline. Dr C, however, records in the 19 October 2000 letter that Mrs A was taking risperidone 12mg daily.

Dr C recorded the change in the medication chart as follows:

“19/10/00 Risperidone 5mg per day x 3 days then 4mg per day x 7 days then 3mg per day x 7 days then 2 mg per day x 3 days then 1 mg per day x 7 days.

Nortriptyline 50mg nocte x 7 days then 25 mg nocte.”

This plan would have reduced Mrs A’s risperidone to 1mg over 20 days. It appears, however, that the plan was not adhered to since according to the rural hospital’s record Mrs A had already reduced the risperidone to 1mg daily by 2 November 2000. Assuming that the change in medications was initiated on 19 October 2000, Mrs A’s risperidone had been reduced from 8mg to 1mg by 2 November 2000 — just 15 days later.

Reduction of nortriptyline

Mrs A’s nortriptyline was reduced from 100mg to 50mg and then to 25mg daily over the same 15-day period as the risperidone (19 October to 2 November 2000). The rural hospital’s computer record for 26 October 2000 noted the plan for the change in medications as follows:

“Nortriptyline and Risperidol gradually decreased over the next few weeks (as per medication chart). Commenced on Cipramil in weeks time (24/10). Use clonazepam 0.5mg PRN for agitation and a hypnotic.”

Introduction of citalopram

Dr C decided to treat Mrs A’s depression with citalopram. (The brand name for citalopram is Cipramil.) He recorded this decision in the 19 October 2000 letter but did not note it in Mrs A’s Current Medication Chart until 24 October 2000.

When interviewed, Dr C said that he prescribed citalopram to address Mrs A’s depression. He said:

“... the citalopram that I first used to get ... rid of the nortriptyline and to put an antidepressant in place [so that I could] ... see whether it [was] necessary to change to a mood stabilizer because a mood stabilizer [has] other inherent ... problems. So let’s first get [Mrs A’s] ... mood better and then when her mood is better, maybe we can just use lithium or maybe we want to use olanzapine or clozapine — which [are] antipsychotic[s] with mood stabilizing properties. ... Otherwise, if she doesn’t remain well on that, we’ll have to use another antipsychotic, but then at least [we’ve] got the risperidone out of the way and we can start on another antipsychotic.”

Dr C maintained that citalopram acts effectively to reduce psychotic symptoms associated with depression. He referred to a study by Pollock, B G, Mulsant, B H, Rosen, J, et al, “Comparison of citalopram, perphenazine, and placebo for the acute treatment of psychosis and behavioral disturbances in hospitalized, demented patients”, *Am J Psychiatry* (2002) 159(3): 460–465. The study compared the acute efficacy of citalopram and the neuroleptic perphenazine with a placebo in treating psychosis and behavioural disturbances in *nondepressed patients with dementia*. It concluded that citalopram was more efficacious than the placebo in the short-term hospital treatment of such symptoms in *nondepressed, demented patients*.

Dr C accepted, when challenged, that this study had no bearing on his treatment of Mrs A since she was depressed and was not, at that time, thought to be suffering from dementia.

Dr C also maintained that citalopram added to risperidone can be an effective treatment for depression with psychotic symptoms. He referred to a study by Kallioniemi, H, and Syvalahti, E, “Citalopram, a specific inhibitor of serotonin re-uptake in treatment of psychotic and borderline patients”, *Nordic J of Psychiatry* (1993) 47 (Supplement 28): 79–84 which concluded that citalopram, when added to previous neuroleptics improved the clinical condition of psychotic patients and markedly reduced anxiety, aggression and impulsiveness. Dr C said that this study supported his argument that citalopram, along with the reduced dose of 1mg risperidone, would address Mrs A’s psychotic symptoms.

Introduction and tapering of citalopram

Dr C recorded the introduction of citalopram in Mrs A’s medication chart on 24 October 2000 as follows:

“24/10/00 Cipramil 20 mg, 10mg mane x 7days then 20 mg mane.”

Dr C prescribed an initial dose of 10mg daily. The dose was then increased to 20mg daily on 2 November 2000 and by 7 December 2000 the dose was 40mg daily. Over a six-week period, therefore, Dr C increased the dose from 10mg to 40mg daily.

Consultation with Dr C on 26 October 2000

Dr C saw Mrs A again on 26 October 2000. Ms B, who was present, said that at this consultation Dr C asked Mrs A questions about her everyday life and about her feelings. She recalled Dr C asking Mrs A whether she felt sad and whether she cried when she felt sad. He asked her whether she felt sad because she was hearing voices or just because she felt sad. Mrs A said she felt sad because she was sad not because of the voices.

Ms B said that Dr C did not ask her for any information about Mrs A’s history or mental state. Ms B said that Mrs A routinely claimed that she was well when asked by a doctor because she feared going to hospital again. Mrs A would conceal her feelings from doctors but would tell her daughters how she really felt.

Dr C did not make any note of this consultation. Ms F’s note recorded a plan to reduce Mrs A’s risperidone and nortriptyline and introduce Cipramil:

“26/10/00 ([Ms F]): MAJOR DEPRESSION WITH PSYCHOTIC FEATURE

Seen by Psychiatrist

Hx: Attended clinic with [Dr C], daughter [Ms B] also present. Assessment completed and on file.

OUTCOME — ?diagnosis of schizophrenia not appropriate. Provisional Diagnosis Major Depression with Psychotic Features.

PLAN

Nortriptyline and Risperidol gradually decreased over the next few weeks (as per medication chart).

Commenced on [Cipramil] in weeks time (24/10).

Use Clonazepam 0.5mg PRN for agitation and a hypnotic.

CMHN to visit tomorrow with a pill tray to simplify the changing meds.

Process.

OE: Visited after appt. With psychiatrist at home.

Arranged pill trays as arranged.

[Mrs A] slightly anxious but managing with the changes.

Spoke at length with [Ms B] who asked for a family meeting to discuss management of [Mrs A].

PLAN

CMHN to visit next Wednesday

Family meeting next Friday afternoon.”

Management of medication change

Dr C did not document any management plan covering the change in Mrs A's medication. He saw her again on 2 November 2000, and made no notes of the consultation. Ms F recorded the consultation as follows:

"02/11/2000: ([Ms F]): MAJOR DEPRESSION WITH PSYCHOTIC FEATURE

Discussion with psychiatrist about reducing medications.

Hx: [Mrs A] has gradually decreased Risperidol, [nortriptyline] and Imovane, using clonazepam PRN.

But has only needed it once in the past two weeks. Cipramil is now at 20mg daily.

[Dr C] wants the regime to remain as follows until reviewed by him 16/11/00.

Current meds — Risperidol 1mg nocte

Cipramil 20mg mane

Nortriptyline 25mg nocte

Clonazepam 0.5mg PRN

PLAN

CMHN visit next week for pill trays."

Mrs A was visited by Ms F on several occasions after the consultation on 26 October 2000. On 7 November Ms F recorded that Mrs A was:

"... feeling well with no increase in the 'voices', mood has improved, energy levels have increased. This was confirmed by family who noticed a significant improvement in the past week."

On 14 November Mrs A told Ms F that she was feeling much better. Ms F's note of her visit that day stated:

"[Mrs A] appears bright in mood with no obvious agitation. She reports feeling much better and is looking forward to stopping the old medication. [Mrs A] is going [overseas in] early Dec. To stay with daughter so a review with psychiatrist is needed.

PLAN

Appt with [Dr C] Thursday."

Consultation on 16 November

Dr C saw Mrs A on 16 November 2000. Dr C did not make any notes of this consultation and his only record of it is a letter of 16 November 2000 to Dr E, in which he makes no mention of any family concerns. The letter reads:

"To [Dr E]

Re: [Mrs A]

File no. [...]

The above named was seen by me on 16/11/00. As written to you previously we have reduced her medication and she is at the moment taking Cipramil 20mg per day, nortriptyline 25mg per day and Risperidol 1mg per day.

I suggest that we increase the Cipramil to 40mg per day and with the idea of phasing out the risperidone in about a month's time and by reducing it to 1mg every second day and then once every three days and then discontinuing it.

We will however have to see how her hallucinations and general condition go.

I have requested that she see a Doctor if she is not feeling well in lieu of the fact that she might develop hypernatraemia which rarely occurs in old people who are taking serotonin uptake inhibitor.

Yours sincerely

[Dr C]

Psychiatrist"

Advice on overseas trip

When Dr C reviewed Mrs A on 16 November, Ms B (who was present) asked Dr C whether it was advisable for her mother to go overseas given the recent change in medication and phasing out of risperidone. Dr C said that he had no reservations about Mrs A going overseas. According to Ms B, Dr C thought the trip was a wonderful idea.

Ms B says that at this consultation she advised Dr C that she was not happy with his rediagnosis. She said:

"[Dr C] and I had a big clash her last visit before going ... as I didn't agree with his way of change with her medication on this day. I was in tears and recall telling him Quote: 'You don't know what you're doing. I have to live with your wrong doing you don't!' And walked out. I was invited back in and told he wanted to speak to me. He simply said 'We can do it my way or you can find another psychiatrist!' By then I had my back up and said 'You're the [doctor] do what you like'. He told Mum she could stay on the 1mg of [risperidone] or if she felt better and OK she could come off it altogether but she must start taking it as soon as she felt unwell. We left."

Dr C's recollection of the consultation on 16 November is somewhat different to Ms B's. He disputes that Ms B vigorously questioned the wisdom of her mother going overseas. He accepts, however, that Ms B sought his advice and that he did not advise against the trip.

When interviewed during my investigation, Dr C said:

"I'd like to say that both [Ms B] and [Mrs A] felt happy about her Mum going [overseas]. I mean I didn't organise this trip and they ... looked forward to this trip. So even looking

back I would hesitate today, I would sort of feel they would have been really disappointed if I said, no, she may not go.”

Dr C said that he emphasised strongly that Mrs A must continue with her medication while overseas and directed Ms B to speak with her sister about this. He increased Mrs A’s dosage of citalopram to 40mg daily to address the voices she continued to hear with a view to phasing out the risperidone completely after a month or so, depending on how her hallucinations and general condition responded.

On 22 November Ms F noted that Mrs A was hearing voices. By 27 November the voices were becoming more persistent and it was decided that Mrs A should take clonazepam again. When Ms F visited on 29 November Mrs A seemed cheerful and well although she was still hearing voices.

Trip overseas

On 7 December Mrs A flew overseas. She took with her a letter dated 5 December 2000 from the rural hospital written by Ms H, registered nurse, stating:

“[Mrs A] has suffered from Depression with psychotic features for the last 20 years.

For this she takes:

Cipramil	40mg daily
Nortriptyline	25mg daily
Risperidal	1mg daily
Clonazepam	.5mg prn.

For further queries her general practitioner is [Dr E].”

Deterioration whilst overseas

Mrs A stopped taking her medication while overseas. Ms B recalled:

“[Mrs A] was having break throughs of voices [on 16 November 2000] and she went [overseas]. She was only there for 3 days and all merry hell broke loose. She thought I was dead in NZ and we had to maintain phone calls nearly every day if not 3x to 4x day. It was at the stage of crisis ...”

On 15 January 2001 Ms B telephoned the rural hospital and advised Ms H that her mother had become extremely unwell while overseas. Ms H’s note of the telephone conversation records:

“Ph/call received from [Ms B], [Mrs A’s] daughter. Reporting mother is very unwell at present. Is away [overseas] having holiday with daughter. Mother did not take Med risperidone with her and has not been taking medication as directed, has become non compliant with meds. Mental Health Status has rapidly declined. The signs of mother becoming unwell, [Ms B] says, is:

1. Talking all day + night

2. Hearing + swearing at voices
3. Hallucinations 'seeing aunty at neighbours'
4. Becoming paranoid 'People out to get me'
5. While out visiting supermarket swearing + talking very loudly at + to people in store
6. Continuous talking and answering voices.

[Ms B] says her mother is in denial of being unwell. Has seen the psychiatrist 3 weeks prior to going on Holiday.”

Ms B borrowed money to travel overseas and brought her mother home on 18 January 2001. Ms B said that before she left to go overseas, the rural hospital advised her that Mrs A would be “sectioned” under the Mental Health (Compulsory Assessment and Treatment) Act 1992 and admitted to hospital on her return.

Causes of Mrs A's deterioration while overseas

Dr C attributed Mrs A's deterioration while overseas to her failure to continue taking her medication as prescribed. He said:

“If they continued with the medication ... she would probably, at the worst, I think have [had] a bit of a relapse and they would ring me then or the GP there would ring and say well up the risperidone or give her whatever they might have there. ...
... the point is even ... if I increased the Citalopram or whatever she ... left the medication here. ... I feel that taking the medication was not really my responsibility. She wasn't so psychotic that she didn't know what she was doing. She could travel [overseas] by herself. It was her daughter's responsibility as well ... to [ask] ‘Mum, are you taking your medication?’ ”

In response to the provisional opinion, Dr C stated that Mrs A's deterioration was attributable to her failure to continue taking not just the risperidone but also the citalopram, nortriptyline and clonazepam prescribed for her.

In a letter to my office dated 1 June 2004, Dr C said:

- “1. It is fundamental that at the time she chose to travel, [Mrs A] was not sufficiently unwell to be prevented from travelling. That is, even had I considered it unwise I was not in a position to prevent her from going. In that situation, I consider I could only do my best to ensure [Mrs A] (and her daughters) were aware of the need for [Mrs A] to maintain her medication, and who to contact should they experience any difficulties — which I did.
2. It is an obvious point that if [Mrs A] had not stopped her medication she would not have had such a total relapse. I gave clear instructions about the need for compliance.
3. I consider that if she or her daughter had acted on my instruction to contact her GP or another psychiatrist [while overseas], a total relapse could have been prevented.

4. If her daughter, [Ms B], with whom she was staying had advised me as soon as she found that her mother had left all her medications behind we could have taken steps to remedy the situation. However I was not advised.
5. [Mrs A's] daughter living [overseas] likewise made no contact (that I was aware of) in regard to [Mrs A's] medication. I had advised [Ms B] that she should ensure her sister's cooperation as to the taking of medication before [Mrs A] travelled [overseas]."

Ms B disputes Dr C's allegation that Mrs A did not take her medication with her overseas. Ms B said that her mother took with her the medication Dr C had prescribed. When Ms B flew to bring her mother home, she gave her mother the dose of risperidone and Cipramil Dr C had prescribed from the medications her mother had with her while overseas.

Consultation on 18 January 2001

On their return from overseas, Ms B and her mother were seen by Dr C at the the rural hospital's clinic on 18 January. Dr C said that he wanted Mrs A to go to a city hospital. However, there were no beds there and Ms B was opposed to her mother being admitted. Dr C said at interview:

"... My impression then was that she had [had] a relapse ... [Ms B] insisted on going back to the medication that she was on previously. ... at that stage I wanted her to ... go to the hospital. I wanted her to be admitted in the hospital so that we could just get control over this situation. I applied for a bed in hospital and there wasn't a bed available. ... Circumstances in [the city hospital] [were] bad. They had a ward there of round about 30 patients and that ward was usually so full they ... put patients up for respite in motels and things in the town. So it was difficult to get a bed for her and the fact that Mrs A didn't want to go to hospital and the fact that [Ms B] and her sister made a pact that they wouldn't ... force their mother again to hospital, made going to the hospital difficult ... One had to do something, and the ... thing that I ... could do was to reintroduce the risperidone because she was using it previously. I ... thought ... let's go back to step one then we can again see what we're going to do from there on."

After discussions with Ms B, Dr C advised her that Mrs A should be cared for at home, where she felt most secure, with the assistance of a respite caregiver. Ms B said:

"The doctor was running late as usual. Eventually we were asked in to see him. He spoke to Mum and said to us he felt that Mum [felt] secure in our home environment so she [would go] home with me. I was assured that it was called Crisis Home Respite and she would have up to 70 hrs max per week."

Dr C made no notes of the consultation. However, Ms D recorded the consultation as follows:

"18/01/2001: ([Ms D]):

Urgent Psychiatrist review

Hx: Has been [overseas], not co-operating with taking prescribed medication. Daughter concerned about exacerbation of auditory hallucinations of a persecutory nature.

OE: During clinic [Mrs A] spoke little of her concerns. Admits to hearing four different 'voices', mainly close relatives. Distinctly reports that members of family are being harmed. Did not present during interview as distressed, however [Ms B] states that [Mrs A] becomes easily frustrated if family don't respond to demands.

Daily review by CPN;

Increase support to family with CSW [Community Support Worker];

Utilise clonazepam 0.5mg x3prn increasing to 6mg daily

Commence risperidone 1mg."

Respite care

The possibility that Mrs A might be provided with respite care at home appears to have been raised for the first time on 18 January 2001. A note in Mrs A's rural hospital records states:

"Talked about support needs. ... Family needs support, maybe respite care although client refuses this. Alternative could be to put respite worker in house with client while daughter goes somewhere else."

Ms B said that Dr C indicated that Mrs A would be provided with up to 70 hours of respite care a week at home but there is no record of 70 hours having been promised in Mrs A's rural hospital records. The Respite Care Service Treatment Plan completed by Ms D on 23 January 2001 notes "respite worker in home over next four days". The rural hospital says that it was not contracted to provide respite care and therefore could not and did not promise to provide 70 hours respite care.

Although Mrs A was seen by Dr C on 18 January, a respite care application was not completed until 23 January. The application (completed by Ms D) requested a respite worker to provide care to Mrs A over the following four days. The focus of the respite care was to:

"assist in monitoring and treating exacerbation of schizophrenia in home as requested by family. ... Reduce potential for harm to [Mrs A]. Assist daughter in caring for [Mrs A]. Reduce stress for family. Ensure given support. Ensure safety is maintained."

Mrs A signed a written consent to respite care on 23 January.

The rural hospital did not have a contract to provide respite care services. The DHB was contracted to provide these services but did not have the capacity to provide Mrs A with respite care. Although it was not contracted to provide respite care services, the rural hospital tried to assist [the family] and assigned Ms I to provide the respite care. Ms I had been a member of the rural hospital's Home Help team since 1995 and was an enrolled nurse (although her registration had lapsed at the time she provided respite care to Mrs A). Ms I had completed a course for respite caregivers and attended in-service training as a member of the Home Help team. She had also completed specific training in respite care through the DHB's mental health services training programme. The programme was focused on training non clinical staff to learn the skills to undertake respite care in the home.

Ms I provided respite care for Mrs A at home between 23 and 26 January.

Although Dr C had assured Ms B at the consultation on 18 January that Mrs A would have a respite caregiver for up to 70 hours a week, she was provided with a caregiver for four days, 23–26 January. Ms B said:

“We had a nurse ??? come in and she used to sit down do crosswords and have lunch and then go home. I had to go to [the city] 25th Jan to pick my daughter up. [Dr C] was doing home visit and they were going to come in the morning so I could leave early. They didn’t turn up until late that afternoon. ... That night the Helper was staying over night so she could make sure Mum took the medication. I wrote it all out and all [Ms I] had to do was tell Mum at 6pm to take it. My 8 yr old son rang me [...] at 8.45pm and asked if Grandma should have her tablets or not??? [Ms I] went home Friday morning. When [she] returned on Saturday she had two children under 4 with her. Mum was having a bad day with crying and [paranoia] and approx 1 hour after [Ms I’s arrival] Mum decided she was going to walk out on the road to kill herself. [Ms I] stayed inside with her kids and I walked outside to Mum and told her she’s going inside to make a cuppa and not going to kill herself. [Ms I] appeared after it was all over and asked if all was well now! [Ms D] arrived not long later and asked [Ms I] to take Mum for a ride. I then complained ... about [Ms I’s] apparent lack of service. [Ms D] advised that [Ms I] was unqualified and not really suitable as a crisis help, tell her to go home when she gets back. I didn’t receive any more helpers.”

The rural hospital advised that Ms I was accompanied by children only when she kindly visited Mrs A on a day off.

The Respite Service Treatment Care Plan of 18 January recorded that there were to be daily visits by a CMHN to monitor Mrs A’s mental state. However, no visits by a CMHN are recorded until 7 February, although the notes record telephone contacts by Ms D on 30 January and 7 February. Ms B indicated that Ms D did visit between one and three times a week, and a rural hospital community support worker also visited from time to time.

According to the rural hospital’s records, Mrs A’s mental state improved considerably once she recommenced her medication and, by 30 January, Ms B described her as “almost back to normal”. The improvement was short-lived, however, as on 7 February Ms B reported that her mother had been less well over the preceding four days and was irritable, distrustful and suspicious. Mrs A thought people were talking about her and responded by yelling and swearing.

Decision to trial clozapine

Dr C saw Mrs A on 15 February. At this consultation he decided to change her medication by phasing out the risperidone and commencing clozapine. (The brand name for clozapine is Clozaril.)

Clozapine is an “atypical” antipsychotic medication mainly used in treatment-resistant chronic schizophrenia or schizoaffective disorders. It is also used where severe side effects preclude the use of other “traditional” antipsychotic medications (eg, Parkinson’s disease-like symptoms or dyskinesias — involuntary muscle movements). Clozapine is given orally,

across a wide dosage range, and must be preceded by careful physical screening, as it can cause serious side-effects in a small proportion of patients. During clozapine use, regular monitoring and blood tests are required.

Dr C made no notes of the 15 February consultation but Ms D recorded that Mrs A was to start on clozapine in the week beginning 19 February. Ms D's note stated:

“15/02/01: ([Ms D]): SCHIZOPHRENIC DISORDERS
Clinical Review.
Hx: Deterioration in mental state.
OE: Discussion about change in medication with visiting psychiatrist Dr C.
To commence on Clozaril. Current medication — [risperidone] 6mg and Clonazepam 0.5mg x 6 daily.
Start on Clozaril 25mg and reduce risperidone to 4mg for three days.
Increase Clozaril to 50mg and reduce risperidone to 2mg for one week.
Dosage of Clozaril to be increased to 100-200mgs depending on response.
Clonazepam to be continued to be utilised, then reduced by 1mg every two weeks.
Daily observation for neuroleptic symptomology during this period. Observe for signs of muscle rigidity, increased temperature and excessive sweating.
→Commence Clozaril week beginning 19th February.
→Homevisit [Mrs A] to discuss change.
→Obtain Clozaril from Pharmacy.”

Ms B said that Dr C did not provide any information about clozapine. He simply reassured her that when he worked overseas they used clozapine often and that it would work. He gave her the impression that clozapine was some kind of miracle drug.

Dr C said that he did not provide information about clozapine to Ms B because she did not want to speak to him at that stage and had left the room. Instead, Dr C said he asked the community mental health nurse (Ms D) to tell Ms B about clozapine. He said:

“... [Ms B] didn't want to talk to me so I didn't provide any information to her, but I told the nurse to go through quite a strict protocol about the introduction of Clozaril. First of all ... the blood tests and things that have to be done ... [have] to be discussed with the family because [Ms B] is the one that has to bring the patient in. So it's unfair of [Ms B] to say that we didn't tell her anything about the Clozaril. I might not have told her anything about the Clozaril but the nurse certainly did.”

Ms D's note of 19 February recorded a discussion with Mrs A and her daughter about the transition to clozapine. Ms D said that she also gave Mrs A and her daughter a booklet about clozapine. Ms B disputes this and says that she herself obtained a booklet about clozapine from Novartis, the manufacturer of the drug, before her mother was started on clozapine. Ms B would therefore have been aware of some of the risks and side effects associated with clozapine.

On 19 February Ms D noted:

“Will commence on [clozapine] on Friday as per regime previously documented. Follow-up over weekend to monitor mental state. Blood tests to be done on Monday’s.”

Ms D’s notes of 5 March record that Ms B obtained information about clozapine from the manufacturer. The notes also state Mrs A was “given written outline of plan to reduce risperidone and introduce Clopixol [sic]. Will have daily monitoring mental state and blood pressure over the next two weeks.” The outline is likely to have been the following handwritten note.

“[Mrs A]
1st 3 days → Clozaril 25 mg at night
 → Risperidone 4 mg

then → Clozaril 50 mg
 Risperidone 2 mg

→
Clonazepam continue using to sedate;”

Ms D said that there was plenty of opportunity for discussion about clozapine as the testing and monitoring regime involved twice daily blood pressure and temperature readings during the first fortnight of the trial, and weekly blood testing.

Ms B, however, felt that her mother was being made responsible for her own medication and blood tests and that she was being shut out, even though her mother was reliant on her for managing her medication and ensuring she had regular blood tests.

Physical assessment before commencement of clozapine

There is no record that Dr C either performed, or arranged for Mrs A’s GP to perform, a physical examination. Nor is there any record suggesting that Dr C arranged for Mrs A to have an ECG before she was started on clozapine.

Monitoring of clozapine

Mrs A began taking clozapine on 5 March 2001 (commencement was delayed because she had a cold). The table below sets out the monitoring undertaken by community mental health nurses from the rural hospital, as well as details of blood tests.

Date	Action	Details of blood testing
15 February 2001	Decision to commence clozapine.	
5 March 2001	Clozapine commenced.	
6 March 2001		Blood sample received by a pathology laboratory.
7 March 2001	Home visit by Ms D. Blood pressure and temperature taken twice.	Blood test results reported by a pathology laboratory.

8 March 2001	Home visit by Ms H. Blood pressure and temperature taken twice.	
9 March 2001	Blood pressure and temperature taken twice.	
10 March 2001	Blood pressure and temperature taken twice.	
11 March 2001	Blood pressure and temperature taken twice.	
12 March 2001	Home visit by Ms D. Blood pressure and temperature taken twice.	
13 March 2001	Blood pressure and temperature taken twice.	Blood sample received by a pathology laboratory.
14 March 2001	Home visit by Ms D. Blood pressure and temperature taken twice.	Blood test results reported by a pathology laboratory.
15 March 2001	Blood pressure and temperature taken once.	
16 March 2001	No blood pressure or temperature results recorded.	
17 March 2001	Blood pressure and temperature taken once.	
18 March 2001	Blood pressure and temperature taken once.	
19 March 2001	Home visit by Ms D. Blood pressure and temperature taken once.	Blood sample taken to test clozapine levels.
20 March 2001	Blood pressure and temperature taken once.	
21 March 2001	No blood pressure or temperature results recorded.	Clozapine level reported as 300 nmol/L. Pathology laboratory reports results of testing on blood sample received 20 March 2001.
22 March 2001	Consultation with Dr C. Blood pressure and temperature taken	Dr C sees Mrs A for first time after commencement of

	once.	clozapine.
23 March 2001	Blood pressure and temperature taken once.	
24 March 2001	Home visit by Ms D. Blood pressure and temperature taken once.	
25 March 2001	Home visit by Ms D. Blood pressure and temperature taken once.	
26 March 2001	Home visit by Ms D. Blood pressure and temperature taken once.	
27 March 2001	Blood pressure and temperature taken once.	
28 March 2001	Home visit by Ms H. Blood pressure and temperature taken once.	
3 April 2001		Blood sample taken for clozapine levels. Reported on 5 April as 1590 nmol/L.
10 April 2001		Blood sample taken for clozapine levels. Reported on 12 April as 1430 nmol/L.
14 April 2001	Clozaril reduced to 200mg nocte.	
24 April 2001		Blood sample taken for clozapine levels. Reported on 27 April as 660nmol/L.

Ms B said that on a number of days she checked her mother's blood pressure and temperature. There are no records of Mrs A's pulse having been checked at any time and the rural hospital accepted that the pulse was not recorded as it should have been.

Titration of clozapine

In a letter dated 23 March 2001, Dr C stated:

“[Mrs A] was seen by me on 22/3/01.

She has been treated [for] a number of years for an acute psychotic condition, with abusive voices aimed against herself and her family. She tended to respond to these voices and it caused a lot of family disharmony.

She has been prescribed many other medications, without any response and in view of that I have started her on Clozaril, starting off with a low dose and increasing it gradually, while phasing [out] the [risperidone] that she was on, having stopped the Cipramil previous to that.

At present we are increasing the dose to 100mgs a day, again increasing it to 200mgs a day in five days time and again to 300mgs a day in another five days time.

In the meantime [the] key worker will evaluate her, keeping a close eye; blood monitoring is going ahead according to schedule. It is reported to be normal today and the necessary arrangement has also been made for further necessary blood evaluations.

She and her daughter have been warned about the possibility of hypotension and to take the necessary steps.”

The letter does not state the starting dose or the period over which the starting dose was to be increased to 100mgs a day.

In Mrs A’s medication chart, Dr C recorded the regime for the introduction of clozapine as follows:

“Clozaril regime as documented in her notes. Increase Clozaril to 100mg nocte, then 200mg nocte, then 300mg nocte then 400mg nocte with 5 day intervals between dose increases.”

Nurse D’s clinical note for 15 February 2001 records the introduction of clozapine as follows:

“Start on Clozaril 25mg and reduce [risperidone] to 4mg for three days. Increase Clozaril to 50 mg and reduce [risperidone] to 2mg for one week. Dosage of Clozaril will be increased to 100-200mgs depending on response.”

The manufacturer’s recommended regime for the introduction of clozapine is:

	Morning Dose (mg)	Evening Dose (mg)
Week 1		
Day 1	nil	12.5
Day 2	nil	25
Day 3	25	25
Day 4	25	25
Day 5	25	50
Day 6	50	75
Day 7	50	100

Week 2		
Day 1	50	100
Day 2	100	100
Day 3	100	100
Day 4	50	200
Day 5	50	200
Day 6	100	200
Day 7	100	200

A comparison of the actual introduction of clozapine (in bold) compared with the manufacturer's recommendations appears below:

		Morning Dose (mg)		Evening Dose (mg)	
Week 1					
Day 1	5 March	nil	25	12.5	
Day 2	6 March	nil	25	25	
Day 3	7 March	25	25	25	
Day 4	8 March	25	50	25	
Day 5	9 March	25	50	50	
Day 6	10 March	50	50	75	
Day 7	11 March	50		100	
Week 2					
Day 1	12 March	50	50	100	
Day 2	13 March	100	50	100	
Day 3	14 March	100	50	100	
Day 4	15 March	50	50	200	
Day 5	16 March	50	100	200	
Day 6	17 March	100	100	200	
Day 7	18 March	100		200	

Ms D's role in introduction of clozapine

Ms D said that prior to her employment as a CMHN by the rural hospital in September 2000, she had worked as a CMHN in another part of the country. There clozapine was only commenced on an in-patient basis, never in the community. Ms D had always worked in the community and as a result had never been responsible for commencing a patient on clozapine (either as an in-patient or in the community) before she cared for Mrs A.

The rural hospital commented:

“[Ms D] had had considerable experience with the application of clozapine and was fully aware of the protocols.”

Ms D said that Dr C discussed with her the introduction of clozapine, the monitoring regime and the side effects to be looked for. I think it likely that Ms D's entry in the rural hospital's records on 15 February 2001 is a record of this discussion. Ms D also recalled that because of her experience, she questioned Dr C about the advisability of commencing clozapine in the community.

When asked what he knew about Ms D's experience in introducing clozapine in the community, Dr C said:

“... all [nurses] go through the wards ...where many patients are on ... Clozaril. ... I don't know specifically whether [Ms D] had been [responsible for commencing patients on clozapine in the community]. She would have been during her training ... this is like [asking whether] a different nurse ... [has had] experience with putting on a bandage ... one assumes she has.”

The rural hospital's clozapine policies/protocols

In a letter dated 4 September 2003, Dr E, at this time the Clinical Director at the rural hospital, advised me that there is a national protocol for monitoring patients receiving clozapine, which the rural hospital complied with. He referred also to the warning contained in the datasheet issued by Novartis that clozapine can cause agranulocytosis, which must be monitored for with regular blood tests in the first 18 weeks of use. The rural hospital does not appear to have developed its own policy on the introduction and monitoring of clozapine.

Dr E said:

“The Health and Disability Commissioner should be aware that there is a national protocol for the monitoring of patients receiving clozapine. There is a significant risk of agranulocytosis and, for this reason, the medication is not dispensed unless a blood test has been done to check for this.

Below is a copy of the warning with which [the rural hospital complies]:

‘Clozaril can cause agranulocytosis. Its use should be limited to patients with schizophrenia

- who are non-responsive to or intolerant of classical neuroleptic drug treatment
- who have initially normal leukocyte findings (white blood cell count (3.5×10^9 , normal differential blood count), and
- in whom regular white blood cell (WBC) counts and, absolute neutrophil counts (ANC) (weekly during the first 18 weeks, at least monthly thereafter throughout treatment, and for 1 month after complete discontinuation of Clozaril) can be performed.

Prescribing physicians should comply fully with the required safety measures. At each consultation, a patient receiving Clozaril should be reminded to contact the treating physician immediately if any kind of infection begins to develop. Particular attention should be paid to flu-like complaints such as fever or sore throat and to other evidence of infection, which can be indicative of neutropenia.

The following conditions apply to the sale, supply and use of Clozaril in New Zealand under the consent notice from Medsafe. Novartis draws prescribers, nurses and patient's attention to the following criteria:

Clozapine must only be prescribed by:

- Medical practitioners who are vocationally registered under the Medical Practitioners Act 1995 in the branches of physiological medicine or psychiatry; and
- Medical practitioners employed as registrars in psychological medicine or psychiatry who are under the supervision of persons of the kind referred to in the paragraph above.

Persons prescribing clozapine must comply with the requirements of the New Zealand Guidelines for the use of Atypical Anti-Psychotic Drugs (3rd Edition, January 2002) and the requirements of local Hospital and Health Service Protocols for use of clozapine.'

I should point out that clozapine treatment was instituted by [Dr C] on 7/03/2001. [Mrs A's] blood was tested on 17/04/2001 and again on 24/04/2001. She was admitted to [the city hospital] psychiatric inpatient unit on 16/06/2001 and during that admission, clozapine therapy was discontinued. As [Mrs A] was only on clozapine for nine or ten weeks, this hardly seems a big issue. As I have stated above, a pharmacist will not dispense clozapine unless there has been a recent, normal full blood count."

The rural hospital also advised that their mental health team is supported by an integrated multi-disciplinary clinical team and is fully supported by the Medical Director, Dr E. All clinical staff have access to the latest information and have regular in-service training and staff development.

Mrs A's response to clozapine

On 5 March 2001 Mrs A began taking clozapine. By 14 March 2001, Ms D recorded that Mrs A was experiencing some difficulties with auditory hallucinations and sleeplessness. On 19 March 2001 Ms D noted:

"Over the weekend had some difficulties with auditory hallucinations. At night consequently didn't sleep. [Ms B] reports that was stressful to manage and considered that hospitalisation might be beneficial."

In a note dated 24 March 2001, Ms D recorded that Mrs A had been reviewed by Dr C. Dr C did not make any note of the consultation. Ms D recorded:

"She was reviewed at clinic by Dr C. [Ms B] reports concerns about length of time that it is taking to stabilise mental state. It appears to be 'taking its toll' on the family. Request for increased assistance.

Plan, crisis. Home visits to continue monitoring BP and offer support over the weekend.

Seen at home today. [Mrs A] experiencing increased 'voices' about being taken away. Children are finding the outbursts of swearing and aggression difficult to cope with. According to [Ms B] children are becoming upset and behavior has deteriorated. More fighting between the children is increasing stress.

[Dr C] has increased the rate of medication to speed up recovery

- Organise Respite care
- Continue monitoring BP as protocol
- Continue offering support."

Ms D appears to have completed the application for respite care over two days on 24 and 25 March 2001.

On 25 March 2001, Ms D visited Mrs A in her capacity as a Duly Authorised Officer under the Mental Health (Compulsory Assessment and Treatment) Act 1992. The DAO/Crisis-Intervention Record of Clinical Contact completed by Ms D noted:

"Presenting Problem

Commenced on Clopixol medication regime, 2 weeks ago.

- Reduction of usual medications, Cipramil and risperidone occurring at same time.
- Had become increasingly difficult to cope with. Not able to look after herself, irritable, verbally abusive, preoccupied with auditory hallucination, paranoid ++. Upsetting children in house. Not sleeping at night. Family requesting increased support. ...

Current medication regime has not reached therapeutic levels, hence deteriorating mental state.

Description — Disheveled and unkempt

Appearance/behaviour — Irritable and suspicious, able to hold a conversation

Orientation/sensorium — Poor recall

Mood/affect — Irritable and miserable

Thought processes — Reports break through voices accusing and paranoid. Preoccupied.

Insight/judgement — Limited insight, Impulsive judgement — poor

Suicide potential — Denies suicidal ideation

Violence potential — Some potential

Level of consciousness — Full consciousness

Estimate of intelligence — average

Intervention plan — Home visit — to review mental state. Support; counsel and reassurance for family. To use Imovane for sleep

Outcome/resultant action — Home visit Sunday 25/03/01. Organise, crisis respite →29/03/01."

Ms H visited Mrs A on 28 March 2001 and noted her to be feeling tired and wobbly on her feet.

Ms D saw Mrs A again on 29 March 2001. Ms D again completed a DAO/Crisis-Intervention Record of Clinical Contact which noted:

“Presenting Problem: Recent changes to medication. Clonazepam and risperidone: changed to Clozaril. Slow titration to increase Clozaril. As medication currently not at therapeutic level deteriorating in mental state. Reports increase in auditory and visual hallucination. Level of functioning has decreased. Not caring for herself i.e. showering or changing clothes. Currently [Mrs A] lives [with] her daughter in [a rural township]. Increased social stressors — requiring respite care for [Mrs A] and her family. D/W staff/doctor [the rural hospital] respite for [Mrs A] initially for 72 hours then review for ?72 hours. Diagnosis Paranoid Schizophrenia. ...
 Appearance/behaviour — slightly irritated
 Orientation/sensorium — Orientated to time, place, person
 Mood/affect — Flattened affect, appears low in mood
 Thought processes — reports increase in auditory + visual hallucinations →fluctuates in intensity, preoccupied. Problems [with] thought blocking
 Insight/judgement — insight — fluctuates
 Suicide potential — Has attempted in past
 Violence potential — May act on thoughts
 Level of consciousness — Fully conscious
 Estimate of intelligence — average
 Intervention plan — Admit to [the rural hospital respite care]
 Daily blood pressure and temperature
 Support through MHS. Review MS daily
 Request Crisis Respite Funding.”

Mrs A was admitted to the rural hospital for respite care on 29 March 2001. She remained there for five days.

There are no entries in the rural hospital’s records between 31 March 2001 and 10 April 2001. On 17 April 2001 Mrs A was noted to be light headed on waking.

On 23 April 2001 Ms J, a rural hospital CMHN, completed a needs assessment.

The pathology laboratory reported the results of Mrs A’s blood tests on 24 April 2001.

On 26 April 2001 the rural hospital’s records note:

“Re difficulty in achieving [Mrs A’s] needs i.e. appropriately funded accommodation while [Mrs A] attends [the city hospital] for tests. Given the difficulties encountered thus far obtaining accommodation and options substantial discussion concluded that [Dr C] will arrange admission for [Mrs A] to [a ward at the city hospital].”

When visited by Ms J on 9 May 2001 Mrs A presented as well, although she continued to hear derogatory voices.

On 16 May 2001 Ms B advised Ms J that her mother was as unwell as she had been when she returned from overseas in January 2001. Mrs A was having visual and auditory

hallucinations, seeing and hearing people who were not present, and thought that people were coming to take her away. Ms B asked for her mother to be admitted to the city hospital.

Ms J discussed the situation with Ms D and contacted Dr C, who agreed that admission to the city hospital was necessary but was unable to arrange a bed. Ms J then liaised directly with the mental health unit at the city hospital, which agreed to admit Mrs A.

The City Hospital

Mrs A was admitted to the city hospital's mental health unit late on 16 May 2001. During her admission her clozapine was titrated down and stopped, and she was started on olanzapine. Her diagnosis was changed back to paranoid schizophrenia and she has since been treated on that basis. She was prescribed olanzapine 10mg daily, Cogentin 2mg daily, Imovane 15mg daily, haloperidol 5mg bd and imipramine 50mg daily. She was discharged on 29 June 2001.

August 2001 — Dr K's investigation

Before making a complaint to my office, Ms B made a complaint to the rural hospital in May 2001. As Dr C was employed by the DHB, which is contracted to provide mental health services throughout the area, the rural hospital forwarded the complaint to the DHB.

Dr K, who was the DHB's Clinical Director of Mental Health Services from the end of July 2001, investigated the background to the complaint. When conducting an initial review of Mrs A's clinical records Dr K identified some areas of concern and addressed these in a report dated 14 August 2001. The report stated:

“Complaints by [Ms B] about the treatment of her mother, [Mrs A], and by [the rural hospital] with regard to documentation.

The patient was new to the service, having been transferred from [the CMHC] in October 2000. She had a long history of illness treated as an outpatient, was reasonably stable though with continuing derogatory auditory hallucinations. Her past was well documented in the referral letter from [Dr G]. The diagnosis over a period of thirty years has been Paranoid Schizophrenia. There have been only two admissions to hospital in '81 and '82. She complies with medication although may have limited insight and she usually lives with one or other of her daughters.

Change of diagnosis

In a letter dated 19 October 2000 to [Dr E], [Dr C] states that her diagnosis is Major Affective Disorder (illusionary melancholia), result remit.

Later in the same letter he states ‘in view of the changing of her diagnosis I am phasing out the risperidone as well as the nortriptyline and introducing Cipramil gradually’.

Entry in [the rural hospital's computer system] for 26.10.00 ([Ms F]) states:
‘seen by psychiatrist’

Outcome of assessment was ‘? Diagnosis of schizophrenia not appropriate. Provisional diagnosis Major Depression with psychotic features.’

This is clear documentation of the fact [that] [Dr C] did not agree with the longstanding diagnosis of Paranoid Schizophrenia, had made a diagnosis of Major depression with psychotic features and proposed to reduce and phase out the antipsychotic despite acknowledgement of the psychotic symptoms. ...

Conclusions

... I find [Ms B's] concerns regarding the change of diagnosis and management in October 2000 to be justified. ...

I do not think that [Dr C] displayed appropriate clinical judgement in his management of this case. I am not clear that he accepts that, as he has told me that the problem was that the patient became non compliant whilst [overseas]. He has also told me that his only change of diagnosis was to question whether she had dementia. Psychological testing has shown cognitive impairment but this [may] be on the basis of a life long psychosis.

Furthermore the absence of clinical notes by him is totally unacceptable. I could find only two items of correspondence from him but even they fell well short of acceptable clinical standards.

I have discussed this case with [Dr C]. He acknowledges the deficiency in clinical records on this patient and probably on the other forty, which have been reported from [the rural hospital]. If there are systemic or process difficulties which have contributed to this then they should be addressed by him in the various venues he attends. However that cannot be an excuse for failure to keep adequate records which is a fundamental and core requirement of medical practice. If he is unable to use computerized records then he must provide written and legible notes.

Recommendations

[Dr C] has stated that he will attend to the documentation problem. I would suggest that this should be audited in say two months' time. ...”

Dr C was given copies of Ms B's complaint and Dr K's report and then met with Dr K to discuss the complaint on 3 September 2001. Dr K's notes of the meeting are as follows:

“3 September 2001

Meeting with [Dr C] to discuss the complaint by the daughter of [Mrs A]

[Dr K] has read the clinical files.

[Dr C] has also had the opportunity to review the files.

[Dr C] states that when he first saw [Mrs A], he had the opportunity to read [Mrs A's] clinical records from [the CMHC] where her previous history was well documented. ...

The records of [Mrs A's] contact with [Dr C] indicate that he disagreed with the previous diagnosis. Today he states that this was on the basis of what he saw as the periodicity of her illness, that her delusions were no more than realistic fears that she would be returned to [the psychiatric unit]. He states that by convention ... the diagnoses of schizophrenia and depressive disorder cannot coexist, although he would entertain schizoaffective disorder. He does not accept the co-morbidity of schizophrenia and depression.

At his first assessment he considered her to be depressed with psychotic symptoms. Since she was at that time on a relatively high dose of risperidone he concluded that either the treatment was wrong or the diagnosis was wrong. He revised the diagnosis to that of depression with psychotic features, changed her antidepressant and gradually reduced her antipsychotic although she remained on a very low dose of risperidone 1mg. I did not understand the rationale for this.

He reports that she made considerable improvement on the change of antidepressant and this confirms his view that his revised diagnosis was correct. He maintains that the diagnosis of paranoid schizophrenia is on the 'outer fringe of diagnosis'.

He does not agree that the great reduction in antipsychotic medication might have been responsible for her marked deterioration whilst [overseas] where apparently her hallucinations and delusions became much worse. He attributes this to her being non-compliant with her drugs whilst there. He also states that this was predictable, in which case this begs the question as to why he did not attempt to address that possible problem earlier.

In summary, he agrees that he changed the diagnosis and treatment. He feels that this was a justifiable decision.

The issue of documentation is also a problem. In my reading of the records, I found no clinical notes as such by [Dr C]. There are two letters written by him and reference to his seeing the patient in nursing notes. This is not an adequate clinical practice.

[Dr C] is not inclined to meet the daughter's request for an apology.

Recommendations

1. As has been discussed in an earlier meeting, [Dr C] must attend to his clinical note taking as it falls well short of recognized standards of medical records. This is an issue of patient safety as well as a primary responsibility of a medical practitioner. He agrees to do so.

This should be reviewed by clinical audit in say two months.

2. In cases of diagnostic and/or treatment difficulty, it is useful to present the case to a peer review meeting. In changing the diagnosis in this patient's case, [Dr C] was disagreeing with many clinicians who had known [Mrs A] for many years. That is a bold step which should not be undertaken lightly."

Dr C wrote to Dr K following the meeting on 3 September. His letter read as follows:

“Re [Mrs A]

I respond to her daughter’s questions seriatim.

1. When I saw her initially she was hallucinating and very depressed, while on very high dosages of medication. (Risperidone up to 12mg and amitriptyline 100mg nocte, for the entertained diagnosis of paranoid schizophrenia.)

So, something could perhaps be improved.

I saw in her file that the diagnosis of major depression had already in the past been made by three drs: [Drs G and two other doctors], Since the diagnosis of major depressive (affective) disorder with psychotic and melancholic features was certainly one of the differential diagnoses, I utilized this diagnosis as another avenue to treatment and prescribed Cipramil, another antidepressant (previously she was taking [nortriptyline] 100mg nocte) and started phasing out the risperidone. (If such a high dose of risperidone was not helping it did not make sense to retain it). I however did not stop it altogether before she went [overseas]. I also started phasing out the [nortriptyline].

The improvement was dramatic.

It is so that she developed mild symptoms before she went [overseas], but I felt we had to be a bit conservative. Maybe she needed a new antipsychotic with mood stabilizing effect; (as it seemed) that there may be a periodic element to her illness, because when depressed the voices became very bad, and she became depressed periodically ... or maybe lithium? And rehabilitation ... not just doing the washing at her daughter’s place ... that was my thinking.

What happened was she went [overseas] and stopped taking her medication.

Maybe the family did not make arrangement for someone to see that she took her medication. She surprisingly did not relapse immediately, but after a while she relapsed.

Predictably.

I then tried to get her back on track but she did not react well on the Clozaril and I decided to seek admission to exclude an organic lesion because she became slightly confused.

I have not seen her since.”

Dr K's concerns about Dr C's management of Mrs A's treatment and his failure to keep adequate clinical records for a number of patients caused her to require Dr C to undergo a period of reorientation and supervision for four weeks starting on 12 November 2001. The arrangements for Dr C's reorientation and supervision included a requirement for the current history, mental status examination, diagnosis, management, follow-up and medication changes (including their rationale) to be recorded for every patient seen, weekly supervision, and active participation in the psychiatrists' weekly meeting.

Dr K also wrote to the Medical Council requesting that Dr C undergo a competence review under the Medical Practitioners Act 1995.

Outcome of Medical Council's competence review

By letter dated 19 May 2004 the Medical Council advised as follows:

"I advise that the Medical Council has reviewed [Dr C's] competence to practise under the competence provisions of the Medical Practitioners Act 1995.

The terms of reference of [Dr C's] review included:

'Whether [Dr C's] competence in psychiatry, with specific regard to prescribing, boundaries, record keeping and diagnosis and patient management meets the standard reasonably to be expected of a medical practitioner with his type of registration.'

The outcome of the review was that [Dr C] has the skills and knowledge required to practise medicine in accordance with his registration and meets the standard reasonably to be expected of a medical practitioner who holds registration of the type held by [Dr C] except in the area of record keeping and report writing. Following the review, Council ordered [Dr C] to undertake an educational programme focusing on record keeping and report writing. No conditions have been placed on [Dr C's] practice of medicine."

Dr C's response to Health and Disability Commissioner investigation

On 11 November 2002 Dr C's barrister provided the following response to notification of my investigation:

The Diagnosis

... In making the diagnosis [Dr C] took all the available information into account as well as his personal observations, knowledge and experience. In considering/evaluating the standard of service in so far as it relates to his diagnosis, the following is to be [borne] in mind:

1. Diagnostic criteria have evolved since DSM1 was first published in 1952; this is particularly so in the case of schizophrenia, schizoaffective disorder, mood disorders with psychotic features, etc.
2. Patients' conditions do not remain static.

3. Certain of this patient's symptoms are atypical of schizophrenia and in particular the nature of her auditory ... hallucinations (strong indications of depressive thoughts rather than of accusatory or mandatory nature) and the absence of the deterioration normally associated with this condition particularly of such long standing.
4. There had on a number of previous occasions been diagnoses of depression.
5. The delineation between schizophrenia, schizoaffective disorders and mood disorders with psychotic features are less than clear cut.

The diagnosis at the time the patient presented to [Dr C] was justified by her then condition, the current state of knowledge and not inconsistent with her history.

The Medication Protocol

Over the years the patient has been treated with the antipsychotic medication, risperidone — at times this was administered in very high dosages. She also received high dosages of nortriptyline, an antidepressant. Despite the very aggressive medication regime the patient remained gravely ill with marked extra pyramidal symptoms [caused] by the antipsychotic ...

In [Dr C's] view it was necessary to concentrate the treatment on the depression but to address it with a different medication and to reduce the antipsychotic medication. [Dr C] prescribed Cipramil (a serotonin reuptake inhibitor in conjunction with but with a reduced dosage of an adrenaline reuptake inhibitor like nortriptyline) while gradually reducing the risperidone dosage. It must be noted that it was not a sudden change in medication but a gradual one. The patient responded very well to the change to the extent that her family and her medical advisors considered her fit to go on holiday [overseas].

At the time of her visit [overseas] she was taking:

Cipramil	40 milligrams daily
Nortriptyline	25 milligrams daily
Risperidone	1 milligram daily
[Clonazepam]	5 mgs PRN

The improvement in the patient's condition clearly vindicated the change in the medication. The apparent relapse suffered by the patient [while overseas] appears to be due to the fact that she did not take her medication as prescribed.

Clozaril was introduced after her return from [overseas]. This drug is never introduced and maintained without initial blood tests and monitoring thereafter. The testing regime including blood pressure monitoring was implemented. The full implications of the prescription were discussed with the patient and her caregiver and ... there are several nursing notes to confirm this. It is inconceivable that the testing and monitoring regime would not have prompted the patient or her daughter to ask questions.

The [overseas] trip

At the time [Dr C's] opinion was sought about the trip there were no clinical reasons why the patient should not have gone.

According to [Mrs A] the trip was scheduled to last for six weeks and did last for six weeks.

If there had been any relapse while the patient was on holiday it was more probably due to her [not] taking her medication as recorded in the nursing note of 15/01/01 ...

Summary of services rendered

[Dr C] held an appointment as consultant; he [was] available to the nursing staff, the patient's general practitioner and the patient on request. He did not make his own appointments and saw patients as deemed necessary by the nursing staff. Where he deemed further consultation necessary he would convey that to the staff who would make necessary arrangements. The psychiatric nurse remained the principal caregiver who had intimate and regular contact with the patient and her family. When the principal caregiver considered that a psychiatrist's intervention was necessary, he or she would call on him or some other practitioner on duty at the time.

[Dr C] was not called upon to arrange for the patient's admission after her return from [overseas] and it was not his function to arrange support to allow her daughter to care for her at home. The nurse in charge responded to the situation and when [Dr C] saw the patient a few days later she was much improved.

[Dr C] is a member of the Institute of Australian Psychiatrists New Zealand Division as well as [an overseas] Institute of Psychotherapy."

Dr C's barrister wrote a further letter on 3 October 2003. Excerpts from the letter are set out below:

"... The lapse of time and the nature of the diagnostic process makes it ... impossible to attribute every relevant bit of information which [Dr C] had taken into account to a particular source. What is set out below is the best that can be achieved but should be sufficient for the Commissioner's purposes.

As previously indicated [Dr C] had regard to the patient's records ...

[Dr C] saw the patient on four occasions that he can recall. The first occasion was at her daughter's ([Ms B]) house where the patient was living with her daughter, her daughter's partner and her teenage children. The patient's daughter and the Mental Health nurse were present during the consultation and contributed information. The Mental Health nurse and [Ms B] were also present on a second occasion when [Dr C] saw the patient at [the rural hospital clinic]. The third occasion was just before the patient left [to go overseas] and the last occasion was after her relapse when [Ms B] stormed out of [Dr C's]

office blaming him for the relapse. [Dr C] cannot recall the name of the Mental Health nurse who attended the last two consultations.

[Dr C] was aware that subsequent to her husband's death about 20 years ago, the patient had been admitted to [the psychiatric unit] with feelings of depression; subsequently she had developed derogatory auditory hallucinations and has been involved in the Mental Health system ever since.

At the time of the first consultation the patient was living in sub-optimal conditions: there was conflict in the household, the patient had to shoulder the major portion of a heavy housework load and the teenagers were hostile towards her. The patient complained about feeling depressed and of derogatory auditory hallucinations. She reported mood fluctuations with periods of depression with hallucinations followed by periods of wellness and then periods of hyperactivity with accompanying hallucinations. The main complaints related to the hallucinations and the depressions. She reported that the derogatory hallucinations had given rise to suicidal ideations and there had been a suicide attempt. At the time of the consultation it was reported that she coped well with the housework.

[Dr C] observed that she was very anxious and that she suffered from anhedonia and insomnia. Although she was initially withdrawn, she was friendly and a good rapport was established. Eye contact was good and her speech was normal. Her affect was congruent with normal reactivity taking into account the extra pyramidal side effects. There were no praecox feelings present. Her thought flow was smooth and centred around her feelings of worthlessness. Although her cognition appeared to be intact, her insight was limited and her judgement could be clouded by her depression. There was no evidence of neurological or systemic disease other than the extra pyramidal side effect of the medication.

As indicated in my letter of 11 November 2002, diagnostic parameters have changed over the last 20 years. Base[d] on the latest DSM IV TR [Dr C] concluded that a diagnosis of paranoid schizophrenia and/or schizoaffective disorder was untenable and that a diagnosis of a mood disorder with psychotic episodes was more in keeping with the patient's history and current symptoms.

The medication she was taking was not only ineffective but dangerous: both [nortriptyline] and Melleril are cardio toxic and unsafe where there is a suicide risk. Notwithstanding very high dosages of risperidone the patient was still experiencing auditory hallucinations; in the circumstances it was pointless to continue this medication. A change to a serotonin reuptake inhibitor was indicated and citalopram was prescribed which is safer and more effective than risperidone. A phased withdrawal of risperidone was indicated with it being replaced by olanzapine which is a serotonin-dopamine antagonist with antipsychotic and mood stabilizing effects.

The changes in the patient's medications were necessary in her own best interests and had a beneficial effect. At the next consultation it appeared that the patient's mood had lifted

and the hallucinations disappeared. In these circumstances, it appeared to be safe for her to go on holiday provided she continued her medication.

The changes in the patient's diagnosis and the adjustment to her medication had nothing to do with her relapse; she was still taking the same type (just a safer) medication. She had shown such improvement on the new regime that it was considered safe for her to go [overseas] with the obvious proviso that she continued her medication. She had a relapse because she stopped her medication."

On 1 June 2004 Dr C provided his own response as follows:

"A: The diagnosis

1. The nurse, together with [Ms B] requested a further opinion from me as to [Mrs A's] diagnosis because she became very unwell at times, and had a longstanding (30 years) diagnosis of schizophrenia.
2. During the past 30 years the diagnosis and treatment of schizophrenia has changed considerably: there is even a discrepancy between the American and the British diagnostic criteria, as I referred to in the course of the interview. It is important to review all patients including those where a diagnosis has been made. In [Mrs A's] case, I held genuine concerns that her longstanding change did not readily fit with the nature of her symptoms. I did not categorically change her diagnosis, and I regret that it may have been interpreted in that way.
3. I have **enclosed** a diagram of what I perceive as [Mrs A's] mood changes, from 1998 to February 2003 (the last medical records I have seen), to illustrate that she has mood changes, which I consider must be taken into account in her diagnosis and treatment. Recognition of these mood changes could well lead to the diagnosis of a mood disorder with psychosis (melancholia), which would influence and improve treatment options.

B: The Medication

1. It is fundamental that at the time she chose to travel, [Mrs A] was not sufficiently unwell to be prevented from traveling. That is, even had I considered it unwise I was not in a position to prevent her from going. In that situation, I consider I could only do my best to ensure [Mrs A] (and her daughters) were aware of the need for [Mrs A] to maintain her medication, and who to contact should they experience any difficulties — which I did.
2. It is an obvious point that if [Mrs A] had not stopped her medication she would not have had such a total relapse. I gave clear instructions about the need for compliance.
3. I consider that if she or her daughter had acted on my instruction to contact her GP or another psychiatrist [while overseas], a total relapse could have been prevented.

4. If her daughter [Ms B], with whom she was staying had advised me as soon as she found that her mother had left all her medication behind we could have taken steps to remedy the situation. However I was not advised.
5. [Mrs A's] daughter [overseas] likewise made no contact (that I was aware of) in regard to [Mrs A's] medication. I had advised [Ms B] that she should ensure her sister's cooperation as to the taking of medication before [Mrs A] travelled [overseas].
6. With reference to changing [Mrs A's] medication. [Mrs A] was on [nortriptyline], which is a dangerous drug for a patient with suicidal tendencies as it is easily fatal in overdose. [Mrs A] had previously taken an overdose and remained a suicide risk — although I did not consider that a high possibility, it could not be discounted given her history. I therefore began to reduce the dose of [nortriptyline] to replace it with another antidepressant which would not be dangerous in the event of an overdose. In [Mrs A's] case I elected citalopram. It has a good side effect profile and is recommended in depression with psychosis. It has also been reported as being of benefit in psychosis by itself.
7. Secondly, [Mrs A] had been prescribed risperidone in doses of up to 12mg/daily. When I consulted her she was on 8mg. Despite this, she remained ill. Risperidone in such a high dose gives patients extra pyramidal side effects which include restlessness, and a mask face — both of which [Mrs A] exhibited. It also carries a risk of tardive dyskinesia, which can cause disfigurement, which is [an] increased problem in more elderly patients.
8. Accordingly I decreased the dose slowly. It was my intention to commence [Mrs A] on a mood stabilizing antipsychotic when she returned from [overseas]. I considered that the citalopram and risperidone would be sufficient to keep her reasonably well until her return.

C: The use of Clozaril

1. The decision to prescribe Clozaril for use by [Mrs A] while she remained in the community was made because I considered it would be of most benefit in the circumstances. Those circumstances were that my attempt to hospitalise her was against the wishes of her daughter; and further, there were no beds available at the time.

I unequivocally offer my apology to all the family. I am sorry that they are not happy with my treatment of Mrs A. I was at all times doing what I thought was best for her.”

Dr C's table of Mrs A's mood changes appears below:

“Explanation:

Dates — These are representative and do not purport to be each and every consultation.

The 'Comment' column reflects what is in the notes, either using the exact words or accurately paraphrasing. It is not intended to be an exhaustive definition.

The Summary column reflects [Mrs A's] relative state: 'Very ill' denotes admission or an attempted suicide: Improved, Unwell, Well and Very Well are self explanatory.

Date	Comment	Who	Summary
5-2-81	<i>Admitted — paranoid Schizophrenia</i>	<i>[Dr G]</i>	<i>Very ill</i>
1982	<i>Admitted — depression</i>	<i>[A doctor]</i>	<i>Very ill</i>
9-4-96	<i>Relapse. Angry, paranoid with hallucinations</i>	<i>[Dr G]</i>	<i>Unwell</i>
July 1998	<i>Derogatory voices; delusions and depressive symptoms; suicidal and ideation</i>	<i>[Dr G]</i>	<i>Very ill</i>
17-8-98	<i>Calm euthymic; auditory hallucinations less troublesome</i>	<i>[Dr G]</i>	<i>Well</i>
October 1998	<i>Refractory psychotic symptoms plus depressive symptoms</i>	<i>[Dr G]</i>	<i>Unwell</i>
December 1998	<i>Symptoms remitted</i>	<i>[Dr G]</i>	<i>Well</i>
25-2-99	<i>Depression — overdose (suicide attempt)</i>	<i>[Dr G]</i>	<i>Very ill</i>
3-5-99	<i>Depressive symptoms</i>	<i>[A doctor]</i>	<i>Unwell</i>
13-5-99	<i>Bright and reaction</i>	<i>[A doctor]</i>	<i>Very well</i>
July 1999	<i>Schizophrenia/depression — remission</i>	<i>[A doctor]</i>	<i>Very well</i>
August	<i>Schizophrenia/depression — remission</i>	<i>[A doctor]</i>	<i>Very well</i>
December	<i>Schizophrenia/depression — remission, 'remarkably well'</i>	<i>[A doctor]</i>	<i>Very well</i>
27-1-00	<i>Overdose — suicide attempt</i>	<i>[Dr G]</i>	<i>Very ill</i>
10-2-00	<i>Voices (night)</i>	<i>[Dr G]</i>	<i>Improved</i>
22-2-00	<i>Voices — managing</i>		<i>Improved</i>
24-2-00	<i>Voice and tears</i>		<i>Unwell</i>
June 2000	<i>Depressive symptoms and suicidal thoughts, insomnia — respite care</i>		<i>Very ill</i>
17-8-00	<i>Calm, euthymic, less voices</i>	<i>[Dr G]</i>	<i>Well</i>
6-9-00	<i>Pleasant, amicable, interactive</i>	<i>Nurse</i>	<i>Well</i>
19-9-00	<i>Tearful, depressive</i>	<i>Nurse</i>	<i>Unwell</i>
9-10-00	<i>Responds to voices, agitated</i>	<i>Nurse</i>	<i>Unwell</i>
16-10-00	<i>Euthymic, blunted affect — voices more intense when mood low</i>	<i>Nurse</i>	<i>Unwell</i>
19-10-00	<i>?Mood disorder. No apparent psychosis</i>	<i>[Dr C]</i>	<i>Well</i>
26-10-00	<i>Slightly anxious; depressed for short periods</i>	<i>Nurse</i>	<i>Well</i>
2-11-00	<i>Nurse considers well</i>	<i>Nurse</i>	<i>Well</i>
7-11-00	<i>Feeling well, mood and energy levels improved</i>	<i>Nurse</i>	<i>Well</i>
14-11-00	<i>Bright mood, no obvious agitation</i>	<i>Nurse</i>	<i>Well</i>

22-11-00	<i>Cheerful: voices mainly at night</i>		<i>Well</i>
27-11-00	<i>Voices more persistent. Clonazepam removed</i>		<i>Unwell</i>
29-11-00	<i>Well/cheerful</i>		<i>Well</i>
15-1-01	<i>Very unwell (overseas) — incessant talking, voices, hallucinations and paranoia</i>	<i>Daughter</i>	<i>Very ill</i>
18-1-01	<i>Sleeping long periods. Managing voices better but auditory hallucinations persisting</i>	<i>Nurse</i>	<i>Improved</i>
23-1-01	<i>Increasing auditory hallucinations, flat affect, irritable. Respite</i>	<i>Nurse</i>	<i>Very ill</i>
30-1-01	<i>Almost back to well state</i>	<i>Nurse</i>	<i>Improved</i>
1-2-01	<i>Dramatic improvement</i>	<i>Nurse</i>	<i>Improved</i>
5-2-01	<i>Irritable, suspicious ?black out</i>	<i>Nurse</i>	<i>Unwell</i>
7-2-01	<i>Suicidal thought, irritable, distrustful</i>	<i>Nurse</i>	<i>Unwell</i>
14-2-01	<i>Euthymic with restricted affect; voices at times</i>	<i>[A doctor]</i>	<i>Unwell</i>
25-3-01	<i>Hallucinations, abusive, insomnia</i>	<i>Nurse</i>	<i>Unwell</i>
26-4-01	<i>Dr C seeks admission</i>		<i>Unwell</i>
9-5-01	<i>Presents well but still voices</i>	<i>Nurse</i>	<i>Well</i>
16-5-01	<i>Auditory hallucinations, paranoia. Admitted to mental health unit</i>	<i>CMH nurse; ward assessment</i>	<i>Very ill</i>
21-5-01	<i>Sleeping well: daughter reports improvement</i>	<i>Nurse</i>	<i>Improved</i>
22/23-5-01	<i>Very settled, no paranoia</i>	<i>Nurse</i>	<i>Well</i>
25-5-01	<i>Voices but settled</i>	<i>Nurse</i>	<i>Well</i>
29-5-01	<i>Tearful and anxious, paranoia</i>	<i>Nurse</i>	<i>Unwell</i>
26-6-01	<i>Bright and reactive; voices</i>	<i>Nurse</i>	<i>Well</i>
6-7-01	<i>Responsive and appropriate</i>	<i>Nurse</i>	<i>Well</i>
25-7-01	<i>Increased paranoia; voices</i>	<i>Nurse</i>	<i>Unwell</i>
7-8-01	<i>Auditory hallucinations</i>	<i>[A doctor]</i>	<i>Unwell</i>
18-9-01	<i>Behaviour difficult, verbally aggressive</i>	<i>Nurse</i>	<i>Unwell</i>
9-10-01	<i>Auditory hallucinations, crying</i>	<i>[A doctor]</i>	<i>Unwell</i>
25-10-01	<i>Engaging and generally well</i>	<i>Nurse</i>	<i>Well</i>
9-11-01	<i>Periods of unsettled behaviour</i>		<i>Unwell</i>
27-11-01	<i>Generally well</i>	<i>Nurse</i>	<i>Well</i>
4-2-02	<i>Paranoid thinking, verbally abusive</i>	<i>Nurse</i>	<i>Unwell</i>
26-2-02	<i>Euthymic, affect reactive, insight poor</i>	<i>[A doctor]</i>	
11-3-02	<i>Crisis respite care; agitated and persecutory thoughts</i>	<i>Nurse</i>	<i>Very ill</i>
27-3-02	<i>Calm</i>	<i>Nurse</i>	<i>Very well</i>
22-4-02	<i>Normal affect and reactivity, happy, no suicidal ideation or psychotic symptoms</i>	<i>[A doctor]</i>	<i>Very well</i>
5-7-02	<i>Mildly depressed but no hallucinations</i>	<i>[A doctor]</i>	<i>Well</i>
25-7-02	<i>Auditory hallucinations controlled by haloperidol</i>	<i>[A doctor]</i>	<i>Well</i>
9-8-02	<i>Quite well</i>	<i>[A doctor]</i>	<i>Well</i>

12-8-02	<i>Warm, friendly, contented. Some voices</i>	<i>[A doctor]</i>	<i>Well</i>
13-11-02	<i>Auditory hallucinations</i>	<i>[A doctor]</i>	<i>Unwell</i>
5-12-02	<i>Increasing hallucinations and paranoia</i>	<i>Nurse</i>	<i>Unwell</i>
25-2-03	<i>Hallucinations</i>	<i>[A doctor]</i>	<i>Unwell</i>

Independent advice to Commissioner

Psychiatric advice

The following expert advice was obtained from Dr Felicity Plunkett, an independent psychiatrist:

“Responses to the questions and issues on which I have been asked to comment:

In responding to these, I need to state that I have found it difficult to incorporate [Dr C’s] perspective, as he has not responded to the Commissioner’s request for a response to the complaint personally, but through a lawyer’s letter. The wording of this letter leaves me uncertain whether the views expressed in it are indeed [Dr C’s] views, or whether these were reframed legally in a defensive reaction to the complaint or were in fact those of [Dr C’s lawyer].

1. With regard to [Dr C’s] rediagnosis of [Mrs A] in October 2000, what standards apply and were those standards met?

What Standards Apply?

There are no formal documents containing standards or guidelines regarding the process of rediagnosis, for New Zealand psychiatrists. In my opinion, the standards which apply to a consultant psychiatrist making such a rediagnosis are:

- a. The need to carry out a careful clinical assessment and review of the patient’s history and mental state prior to any rediagnosis
- b. The need to be fully conversant with the main diagnostic systems in use in the country where the psychiatrist is working, and to apply these appropriately in making the diagnosis
- c. Particularly prior to altering a longstanding diagnosis, the need to obtain as much collateral information as possible:
 - i. from past clinical records
 - ii. and (with the patient’s permission) from the patient’s key family members, particularly the primary caregiver
- d. Where there is conflict or disagreement regarding the diagnosis between different members of the treating team or different teams within the local mental health service involved in a patient’s care, it is good practice to discuss the case and the diagnostic issue in a peer review setting with other psychiatrist colleagues, and/or

to resolve these differences in a case conference with the key clinical staff involved.

- e. When a rediagnosis is made, there needs to be careful documentation of this with the reasons for the rediagnosis being recorded fully so as to explain the change.
- f. Having made a significant rediagnosis which has implications regarding changes to treatment, there is a need to set in place a careful management plan with ongoing re-assessments involving the follow-up team and (with the patient's permission) the patient's primary caregiver, to monitor the results of any treatment change and ensure that the patient's clinical state does not deteriorate. As medication changes can take 3 to 6 months to lead to clinical effects such as a relapse, this plan needs to be in place for several months after any rediagnosis and treatment change.

Were Those Standards Met?

- a. [Dr C] appears to have made the rediagnosis on the basis of two initial out-patient contacts only. [Mrs A's] daughter stated that the first (on 19th October) lasted only 20 minutes, and the length of the second on 26th October is not documented. As [Dr C] has not made any clinical notes it is impossible to be reassured that he did carry out a full and careful assessment of [Mrs A] in these two appointments. Her daughter [Ms B's] account indicates to me that a detailed exploration of [Mrs A's] history, mental state and symptoms did not occur, and (as below) it is unclear whether [Dr C] had the past psychiatric records and history available to him on either occasion. [Mrs A's] daughter [Ms B] states that he only had a faxed letter on 19th October. The typed assessment letter to the GP [Dr E] is dated 19th October, so followed the very brief initial 20 minute appointment. Twenty minutes would not be sufficient time for a careful assessment to have occurred. Given that [Dr C] in the letter of 19th October to [Dr E] records the rediagnosis and that he was 'phasing out the risperidone', he had clearly rediagnosed her on the basis of the initial 20 minute appointment. In my opinion [Dr C] thus did not meet a reasonable standard in this respect.
- b. It is difficult for me to be reassured that [Dr C] was fully conversant with the main diagnostic systems in use in New Zealand mental health, or that he applied these appropriately to [Mrs A]. The term he used in rediagnosing her is not part of any recognised diagnostic system (neither the DSM-IV nor ICD-10 systems, both of which are in use in NZ). In the lawyer's letter of 11th November 2002, there appears a justification of the rediagnosis which appears to state that diagnostic criteria have evolved since DSM-I was published in 1952, and of course this is correct but irrelevant, as the system in current use in NZ is DSM-IV, far more recently published. In later discussions with [Dr K] during the complaint investigation process, he appears to have verbally clarified that what he meant by the term 'Major affective disorder (illusionary melancholia)' was in fact a psychotic depression, and this also appears the case from the lawyer's letter of 11th November. His treatment plan was however not appropriate for such a diagnosis, as antipsychotic medication is required to treat psychotic depression,

rather than antidepressant medication alone. His treatment plan indicates either that he lacked basic knowledge about the appropriate treatment for psychotic depression, or that he had misdiagnosed [Mrs A] as having a mild to moderate major depression without psychosis, despite the presence of documented psychotic symptoms. These issues overlap into discussions of his overall treatment plan (continued below), but in my view [Dr C] did not make a competent rediagnosis within a recognised and appropriate diagnostic system. I thus do not feel that he met a reasonable standard in this respect.

- c. Due to the paucity of his documentation, we have only the brief typed letter to [Dr E] determine this, and information provided by [Mrs A's] daughter. Information gathered in the later complaint enquiry states that he did have [the file from the day clinic and CMHC's] available at the time of rediagnosing [Mrs A], but [Ms B] disputes this, saying he just had a faxed letter on 19th October. It is additionally unclear (even if [Dr C] did have the files available) whether he had read these files in any detail or taken note of their contents. Again, [Ms B] states that the clinic was running at least half an hour late so there may not have been time prior to the 20 minute assessment on 19th October for a proper review of the past files. [Dr C's] letter to [Dr E] of 19th October does not allude to any details from the past clinical records, but only to brief and patchy historical details which sound to have been gathered from [Mrs A] herself (important but insufficient information by itself), and to his current assessment of her mental state and symptoms. [Ms B] states that [Dr C] did not gather any collateral information from her as the primary caregiver, despite her being present at both initial appointments. She also states that her mother tended to hide psychotic symptoms such as 'voices' from doctors due to a fear of readmission to hospital, but did display these symptoms to her family. Collateral information from [Ms B] would thus have been an important way to gather information about the frequency and nature of these symptoms. In my opinion [Dr C] thus did not meet a reasonable standard in terms of adequately gathering and taking into account collateral information, prior to making the rediagnosis.
- d. The issue of resolving conflict between treating clinicians does not apply to the initial rediagnosis, as at that point there were no other treating teams involved and the other team members involved in her care have not recorded any conflicting views. There is thus no strong reason why [Dr C] should have arranged a peer review discussion or case conference at that early stage of [Mrs A's] care with [the rural hospital].
- e. Regarding careful documentation of the reasoning for a major rediagnosis, [Dr C] clearly did not meet a reasonable standard. He made no clinical notes of the consultation in the file, and a remedial process was later implemented by [the DHB] regarding recurrent deficits in his clinical documentation. The brief typed letter to [Dr E] states brief details of history and mental state, and then the rediagnosis and planned treatment change, but gives no actual explanation as to the reasoning for this, so as to explain the changes. In my opinion [Dr C] did not

meet a reasonable standard in terms of documenting the reasoning for the rediagnosis.

- f. Regarding the need to accompany a major rediagnosis with a careful management plan and ongoing re-assessments, especially where the rediagnosis leads to a significant treatment change, it is difficult to know whether [Dr C] met a reasonable standard, as there is no documentation of a management plan regarding the involvement of her family, frequency of community nurse reviews or of psychiatrist reviews, or of a relapse-prevention plan. [Dr C] did however himself review [Mrs A] at appropriate intervals after the change of medication, and on 16th November again wrote to [Dr E]. He discusses the medication changes but records no evaluation of her progress or mental state at all. [Mrs A's] daughter [Ms B] later stated that within one week of the initial medication change her mother's mental state began to deteriorate, with auditory hallucinations and paranoid thinking, but there is no mention of this being assessed or detected. By 7th December when [Mrs A] flew [overseas] to visit family, only about six weeks had passed since the treatment change. [Dr C's] last appointment with [Mrs A] was on 16th November, three weeks before the trip. It is possible that [Dr C] would not have been able to prevent this journey as [Mrs A] was a voluntary patient, but apparently [Ms B] informed him two weeks before the flight that she was concerned for her mother and felt her symptoms were worse. There sounds to have been a difficult and angry interaction due to [Ms B] becoming distressed that [Dr C] appeared not to be taking note of her concerns, and [Dr C] sounds to have been insistent that her mother was on a suitable treatment plan and was fit to travel. Given the short time-frame since the medication change (only six weeks) and the concerns expressed by [Mrs A's] daughter, even had [Dr C] been certain that his assessment and advice was correct, it would have been necessary to have provided [Mrs A] with a letter to take with her for any mental health crisis team or GP [overseas], outlining her history, mental state and treatment, in case a relapse occurred. A brief letter was provided by psychiatric nurse [Ms H] from [the rural hospital], rather than by [Dr C], but the letter is extremely brief and makes no mention at all of the 30 year prior diagnosis of schizophrenia/schizoaffective disorder or of the recent medication changes. In my opinion [Dr C] should have written this letter, and it should have contained psychiatric detail regarding her past and current diagnosis and treatment. On balance, it is thus my opinion that [Dr C] did not meet a reasonable standard in respect to setting in place a proper management plan following the rediagnosis and treatment change.

2. What is 'Major affective disorder (illusionary melancholia) result remit' and was this diagnosis appropriate?

The DSM-IV is the diagnostic system in widest use in New Zealand and is the official diagnostic system for Ministry of Health statistics regarding mental disorders. A few European-trained psychiatrists prefer to use ICD-10 terminology (the system is used in Britain). Either system would be acceptable, although use of the DSM-IV system would reduce the possibility of miscommunication with other clinicians. 'Major

affective disorder (illusionary melancholia)' does not exist as a recognised diagnostic entity either of the above diagnostic systems. The term 'major affective disorder' is at times used less formally to mean a serious mood disorder — either a major depression or a bipolar disorder. 'Illusionary melancholia' does not exist as a diagnostic concept. Melancholia as such is a term for a subtype of major depression — a severe form of major depression with changes in physical symptoms and motor activity/thinking (usually marked slowing although agitation can occur). 'Illusionary' is not a recognised or appropriate psychiatric term. I do not know what Dr C meant by 'result remit' and this is not a qualifying term in the DSM-IV or ICD-10 diagnostic systems. The lawyer's letter of 11th November is not helpful in clarifying these points and does not explain the strange terminology used. In this letter [Dr C] stresses [Mrs A's] past history of depression, and appears to be arguing that the delineation between schizophrenia, schizoaffective disorders and mood disorders with psychotic features is less than clear-cut, although this is not in itself a reason for the change in diagnosis and treatment. Given that [Dr C] used unusual and idiosyncratic terminology to record the rediagnosis, we are left guessing as to what he actually meant. Evidence for this varies according to the different sources. [Ms B] stated that [Dr C] told her and [Mrs A] on 26th October that he believed she in fact had a bipolar disorder (with depressions). The entry made in [the hospital database] as a clinical record of the assessment on 26th October by the community nurse [Ms F] reads: 'outcome of assessment was ? diagnosis of schizophrenia not appropriate. Provisional diagnosis Major Depression with psychotic features.'

In her investigation of the complaint, [Dr K] records her view that the entry in [the hospital database] indicates that '[Dr C] did not agree with the prior diagnosis of Paranoid Schizophrenia, had made a diagnosis of Major Depression with psychotic features and proposed to reduce and phase out the antipsychotic despite acknowledgement of the psychotic symptoms.' I would agree with this interpretation of [the hospital database] record. [Dr K] then met with [Dr C] to discuss the complaint. In her records of their discussion on 3rd September 2001, she documents that he stated he disagreed with the past diagnosis and considered [Mrs A] to be depressed with psychotic symptoms. At that interview [Dr C] apparently also stated that at the first assessment he had had the opportunity to read [Mrs A's] past clinical records from [the CMHC]. I concur with [Dr K's] summary of these records, that [Mrs A] had in the past had documented delusions of reference, persecutory delusions, and derogatory auditory hallucinations. I also note that [Dr G's] referral letter to [Dr C] dated 28/8/00 (which I assume was the 'faxed letter' [Dr C] is likely to have had at the first assessment) states that [Mrs A] had been treated for 'schizophrenia, paranoid type or schizoaffective disorder for over 30 years'. [Dr G] also states that [Mrs A] had experienced 'passivity delusions' when more unwell. This pattern of symptoms is not indicative of a major depression, even one with psychotic features, as passivity delusions are far more likely to occur in schizophrenia or a schizoaffective disorder. There was also a clear history of intermittent depressive symptoms which had required antidepressant treatment in the past, and [Dr C] apparently told [Dr K] that he did not accept 'co-morbidity of depression and schizophrenia', so as he believed [Mrs A] to be depressed he did not agree with the

diagnosis of schizophrenia. He also, however, told [Dr K] that he would ‘entertain schizoaffective disorder’ as a diagnosis. (Schizoaffective disorder is a long-term condition which includes mood symptoms as well as symptoms of schizophrenia.) However, he appears not to have actually made a diagnosis of a schizoaffective disorder (which would require treatment with both antipsychotic and antidepressant medication).

In saying that depression and schizophrenia could not ‘by convention’ be ‘co-morbid’, [Dr C] is probably referring to the DSM-IV criteria for diagnosis of a Major Depression. The DSM-IV states that a diagnosis of Major Depression should not be made if a Schizoaffective Disorder diagnosis in fact explains the episodes of depression better. It also states that a diagnosis of Major Depression cannot be made if the depressive episodes are superimposed on Schizophrenia. In fact, symptoms of depression are common (and widely documented in the literature) in schizophrenia and often do require treatment, even if they cannot ‘by convention’ according to the DSM-IV be termed episodes of ‘Major Depression’. It is of concern to me that [Dr C] appears to have misinterpreted the DSM criteria in this matter such that rather than diagnosing a Schizoaffective Disorder, or Schizophrenia (in which depressive symptoms commonly do occur) he opted to rediagnose [Mrs A] as having Major Depression and to taper off her antipsychotic medicine, effectively ignoring her long history of psychotic symptoms. In my opinion, based on the clinical records available to me and, apparently, to [Dr C] when he made this rediagnosis, ‘Major Depression with psychotic features’ was not an appropriate rediagnosis based on [Mrs A’s] documented past history and symptoms. I think it far more likely that her diagnosis was that of Schizophrenia (paranoid type) with intermittent episodes of depressive symptoms, or a Schizoaffective Disorder.

3. In rediagnosing [Mrs A], what information should [Dr C] have taken into account and did he take the appropriate information into account?

This issue has been covered in 1(c) above, and it remains unclear whether he did in fact have all the [the CMHC] records on 19th October at the first assessment, after which he made the rediagnosis. Certainly he does not appear to have taken the information from these into account if it was available.

4. Please comment on [Dr C’s] reasoning for his rediagnosis.

This is largely covered above. We have little evidence as to his reasoning, due to his poor documentation of this, but in the interview with [Dr K] as above he appears to have held to the rigid and misguided view that patients with schizophrenia cannot also develop depression. This view is not upheld in the psychiatric literature, where management of depression occurring in patients with schizophrenia is frequently discussed. [Dr C] appears to have based this rediagnosis on a brief and inadequate cross-sectional assessment on 19th October, at which time [Mrs A] gave some history of intermittent depressive symptoms. In fact, [Dr C] records that although depressed the previous day she was not depressed on the 19th when he assessed her. Despite the

fact that a true Major Depression with psychotic features is a serious illness and does not fluctuate day-to-day in this fashion, he nonetheless altered her diagnosis to this. In the lawyer's letter of 11th November he appears to mainly be arguing that she had depressive symptoms and history, as the main justification. His reasoning is thus extremely unclear and does not appear to be based on a sound knowledge of important psychiatric syndromes or of basic DSM-IV diagnostic criteria.

I will deal with the technical questions about medications next, including [Mrs A's] prior antidepressant nortriptyline, in place of which [Dr C] substituted Cipramil.

5. What is Cipramil and when is it indicated?

Cipramil is the trade name for citalopram, a Selective Serotonin Reuptake Inhibitor or SSRI antidepressant. It is indicated particularly in mild to moderate Major Depression, and would generally be prescribed alone (without an antipsychotic drug) only in Major Depression without psychotic symptoms. It is well documented that Major Depression with psychotic symptoms requires treatment either with electro-convulsive therapy or with combined antidepressant and antipsychotic medication. There are several Reviews, Treatment Guidelines and Case Reports in the literature attesting to this. Citalopram is also indicated in anxiety disorders. Unlike other SSRIs, it does not cause drug interactions with many other psychiatric medications, so can be useful where use of more than one drug simultaneously cannot be avoided. The common dose range is 20 to 40 mgs daily.

6. What is Nortriptyline and when is it indicated?

Nortriptyline is a tricyclic antidepressant. Tricyclics are also indicated for mild to moderate Major Depression, but are traditionally also preferred in severe and psychotic depression. However, in psychotic depression, as with SSRIs, they are given alongside an antipsychotic medication, not alone. Nortriptyline is a common and effective tricyclic and is relatively short-acting, leaving the body rapidly on cessation. After a major dose-reduction the blood levels would drop rapidly in a matter of days, before re-stabilising. Nortriptyline is also indicated in anxiety disorders. It interacts with some SSRIs so as to cause elevated tricyclic blood levels, but not with citalopram. The common dose range is 100 to 200 mgs daily, for treatment of depression.

7. What is Risperdal and when is it indicated?

Risperdal is the trade name for risperidone, a new-generation or 'atypical' antipsychotic drug. It is indicated for any mental disorder involving psychotic symptoms, including schizophrenia, schizoaffective disorder and major depression with psychotic features. The common dose range is 3 to 8 mgs daily, but resistant longer-term psychotic illnesses sometimes require higher doses. While there is some indication that risperidone can improve depressive symptoms occurring in schizophrenia, there is more evidence for other atypical antipsychotics in this respect, such as olanzapine or clozapine. Similarly, there is more evidence for efficacy of clozapine in resistant schizophrenia or

schizoaffective disorder, rather than risperidone. Risperidone is a relatively short-acting medication, and the blood levels would drop rapidly after a major dose change. It is usual to taper risperidone over at least one month when making a medication change.

8. With regard to [Dr C's] prescribing of Cipramil and reduction of Risperdal, what standards apply and were those standards met?

In making medication changes of this sort, the main standards are as follows:

- a. The reasons for the change, possible benefits and side-effects of any new medication need to be explained to the patient and to their primary caregiver beforehand, so that they can engage in an informed consent process.
- b. It is unwise to alter more than one medication group simultaneously, unless there is a medical emergency requiring this.
- c. Psychiatric medications which are shorter-acting (i.e. leave the body fairly rapidly after cessation) need to be tapered off across at least one month to reduce the risk of withdrawal effects. Again, this applies except in a medical emergency.
- d. The new medication should be started at an appropriate initial dose, taking into account possible drug interactions with other medications still present in the body.
- e. The patient's coping with these medication changes needs careful monitoring by clinical staff on a regular basis — at least twice weekly, and the patient's primary caregiver needs to be involved in the monitoring plan and aware of possible side-effects or withdrawal effects so as to alert the treating team should these occur.

Were these standards met?

- a. It is difficult to believe that adequate and accurate information was given to [Mrs A] and [Ms B] about the planned changes in medication, the likely effects of Cipramil and its possible side-effects, and possible effects of tapering and cessation of nortriptyline and risperidone. This is partly as [Dr C's] reasoning for the rediagnosis on which the change was based was, as above, flawed, and as [Ms B] when interviewed about these appointments said that she believed [Ms F] the community nurse was to visit them at home and explain the process of weaning off the risperidone. This does not suggest that [Dr C] gave detailed information so as to engage [Mrs A] and her daughter in an informed consent process, at the second appointment on 26th October. I thus doubt that this standard was met.
- b. There were no emergency reasons for altering several medications simultaneously. In the lawyer's letter of 11th November, [Dr C] states that [Mrs A] suffered marked extra pyramidal symptoms on her risperidone (e.g. Parkinson's-disease-like effects and restlessness). However, he made no mention of these at all in the letter to the GP of 19th October 2000, nor are such severe side-effects mentioned in the referral letter from [Dr G]. I thus find this hard to credit as an 'emergency' justification. Despite this lack of an emergency cause for rapid drug changes, as well as tapering nortriptyline and commencing citalopram, [Dr C] also tapered the risperidone to an extremely low dose of 1 mg daily (an ineffective dose in a patient with a severe

chronic psychotic illness). It is usual to alter an antidepressant by reducing one while adding the other, but unwise to simultaneously reduce antipsychotic medication. Should symptoms recur (as they did), [Dr C] would be unsure which of the medication changes had caused this deterioration. In addition, there is always a risk of relapse of symptoms with any medication change, no matter how carefully managed. This risk increases considerably if any additional medications are simultaneously altered. [Dr C] thus did not meet this standard.

- c. Nortriptyline is a relatively short-acting medication and it is advisable to taper it off over one month to avoid withdrawal effects which could cause distress or even a relapse. The same tapering period applies to risperidone. The [database] records written by community nurse [Ms F] on 26th October state that [Dr C's] plan was to gradually decrease nortriptyline and Risperdal, and there is a prescription record dated 19/10/00 (after the brief initial assessment) for a gradual tapering of risperidone to 2 mgs daily across three weeks. Prior to the medication change [Mrs A] was prescribed 8 mgs risperidone and 100 mgs nortriptyline daily (according to the clinical notes, although [Dr C] told [Dr E] in his letter of 19th October that she was on risperidone 12 mgs daily, which appears to have been incorrect). However, according to the [database] record of the subsequent appointment, and despite the tapering plan noted in [the database] and on the prescription record, in one week (by 2nd November) her medication had apparently been reduced to 1 mg risperidone and 25 mgs nortriptyline daily, which is an extremely rapid and sudden reduction. For the risperidone it is virtually the same as cessation, as a 1 mg dose would have been ineffective given her chronic illness and prior much higher doses. In managing the appropriate tapering off of the prior medications, [Dr C] thus did not meet a reasonable standard of care, and by a too-rapid taper would have placed [Mrs A] at greater risk of a relapse, especially as two medications were rapidly reduced simultaneously.
- d. At the same time as this rapid dose reduction on 26th October, [Dr C] prescribed citalopram, probably initially at 10 mgs daily. This is a normal starting dose for this medication, which is not usually tapered much if at all on commencement. Drug interactions with the other medications were not a factor as citalopram does not interact with nortriptyline or risperidone. [Dr C] appears to have increased the dose to 20 mgs daily on 2nd November, and by the time of her trip [overseas] on 7th December, [Mrs A's] Cipramil dose was 40 mgs daily. To increase to 40 mgs daily across six weeks is quite rapid, especially as other medications were being rapidly reduced simultaneously. However such an increase in citalopram is not unknown in treating a resistant depression.
- e. Regarding the setting in place of a careful follow-up plan to monitor [Mrs A's] coping with these medication changes at least twice weekly, [Dr C] saw her again one week after the initial dose change, and then a fortnight after this. In addition, her community nurse [Ms F] visited her six days after the initial dose change, and then once weekly across the next two weeks. In most weeks [Mrs A] thus received two reviews, but often these were close together so that she was not seen for 5 to 6 days at

a time, in the weeks after the major dose change. I am unsure if this was considered an adequate level of review by [Dr C] as he has written no management plan. I would regard it as inadequate in view of her chronic psychotic illness and the rapid near-cessation of her risperidone, together with a 75% drop in her nortriptyline dose. [Ms B] gives an account of her mother becoming more unwell quite rapidly after the initial large dose reductions, and does not appear to have been adequately supported and involved in the follow-up plan. In organising this aspect of her treatment plan I thus feel that [Dr C] has not met an adequate standard. In the lawyer's letter of 11th November, he appears to argue that he merely visited [the rural hospital] intermittently and saw whichever patients the nurses had scheduled for him, and that primary responsibility for organising patient care rested with the main community nurse. I entirely disagree with this abdication of clinical responsibility and find the argument specious. [Dr C] was the identified psychiatrist for [Mrs A] and as such, even as a psychiatrist visiting weekly, he had clear responsibility for overseeing her treatment plan on his regular contacts and for ensuring that this was safe and adequate. He was not responsible for every detail of practical implementation of the plan — that rested with the local clinic staff, but a responsible psychiatrist has a definite overarching role to establish, document and keep an eye on a management plan as treatment proceeds. [Dr C] failed to carry out that overseeing role.

9. Was [Dr C's] prescribing of Cipramil and reduction of Risperdal appropriate?

No, as detailed above, [Dr C] in my opinion misdiagnosed [Mrs A] as having a major depression with psychosis. He then, in addition, proceeded with an inappropriate treatment regime for such a diagnosis. In major depression with psychotic symptoms combined treatment with antidepressant and antipsychotic medication is required, and [Dr C] in fact reduced and nearly ceased the antipsychotic risperidone. Use of citalopram in a major depression with psychosis is not unknown, but it is not a common choice to treat such a condition, and is certainly not reported to have been used alone in this condition. To treat a Schizoaffective disorder or Schizophrenic disorder with depressive symptoms, the treatment of choice is increasingly to change antipsychotic medication to an atypical drug such as olanzapine, although concurrent antidepressants are often used as well. They are not used alone and without antipsychotic medications in these conditions, however.

10. Comment on [Dr C's] reasoning for changing [Mrs A's] medication regime.

This is difficult to determine, but must be linked to his reasoning for changing the diagnosis. He appears to have felt that major depression with psychosis could be treated without antipsychotic medication, which is not a view traditionally held or based on evidence from the psychiatric literature. Alternatively, he possibly believed that a 1 mg risperidone dose was adequate antipsychotic treatment — again, I do not concur with this view in [Mrs A's] case. In the interview with [Dr K], he appears to be arguing that [Mrs A's] prior treatment was in his view ineffective thus needed changing. He also in the lawyer's letter of 11th November 2002 for the first time stated that she suffered extrapyramidal symptoms (nowhere else documented). I

cannot comment on the rationale for the extremely rapid reductions in both the nortriptyline and the risperidone across the initial week, as there is no sensible rationale for such a sudden change and [Dr C] has not recorded any management plan.

11. Do you consider that [Dr C] adequately took into account concerns expressed by [Ms B] about her mother's mental health and new medication regime? What action should a psychiatrist take in response to the concerns of family members who are primary caregivers?

No, as discussed above, I do not believe that [Dr C] adequately took into account the concerns expressed by [Ms B] about her mother's mental health and new medication regime. These appear to have been most forcefully expressed by [Ms B] about two weeks before her mother left [to go overseas], but there are no clinical notes by any staff documenting this exchange, which may have occurred at the clinic review with [Dr C] on 16th November, for which appointment there are no [database] records. [Dr C] did write a brief typed letter to [Dr E] after this appointment but no mention of her daughter's concerns are made. It is thus unclear when [Ms B] saw [Dr C] to express her concerns. Whatever the exact date, on this occasion, [Ms B] became distressed about her view of her mother's worsened symptoms (increased paranoid thinking, not sleeping properly). She reports that [Dr C] said he 'knew what he was doing'. [Ms B] apparently confronted him angrily saying he was wrong, and he is then alleged to have told her 'either you do it my way or you find another psychiatrist'. [Ms B] states that she had felt unable to arrange an alternative psychiatrist, being new to the district herself, so ceased challenging [Dr C].

This sounds to have been a difficult and acrimonious exchange for both parties, but whatever the level of distress in a concerned relative, it is the responsibility of the psychiatrist as a trained professional to listen carefully to the concerns and to respond to these appropriately. It seems clear that [Dr C] did not do this, if [Ms B's] account is accurate. [Dr C] has of course left no records to disprove her version of events. On [Dr C] and the community nurse [Ms F's] brief contacts they appear to have largely felt that [Mrs A] was improved on the medication change, but her daughter alleges that she did display increased symptoms at home, between contacts. This led to the dispute about the wisdom of the treatment plan. In my opinion a psychiatrist should take careful note of reports from family members, especially the primary caregiver, regarding a patient's symptoms. Family commonly do see symptoms that patients keep hidden from health professionals during brief reviews. If a relative expressed strong concerns that a patient was deteriorating after a medication change, an urgent clinical review should be arranged. As far as I can determine this did not occur, in the two weeks prior to [Mrs A's] overseas trip. When travel of this sort is planned, there is even more reason to ensure that a careful reassessment occurs.

12. Please comment on [Dr C's] advice that there were no clinical reasons why [Mrs A] should not travel [overseas]. In your opinion, was [Mrs A's] trip contraindicated?

In my opinion this trip was contraindicated, or at least extremely unwise, so soon after such major medication changes. Even if there had not been any signs or reports of deterioration there would have been a risk that the stress and excitement of an overseas trip would further destabilise matters, together with even mild jetlag affecting sleep. In fact, [Ms B] did forcefully express her concerns about her mother's mental state, but these were ignored a mere two weeks before the trip was due. This was even more of concern as this was clearly not a financially well-off family, and when the relapse occurred [while overseas] the family were shocked to be told that psychiatric care there would cost \$800 a day. [Ms B] had to borrow money for the air ticket so as to fly [overseas] to retrieve her mother. [The rural hospital] later reimbursed her, but at the time this dilemma was clearly extremely stressful. In the lawyer's letter of 11th November, [Dr C] appears to argue that 'the patient responded very well to the change to the extent that her family and her medical advisors considered her fit to go on holiday [overseas]'. This is flatly contradicted by the reports of serious concerns forcefully expressed by [Ms B] to the contrary, two weeks prior to the planned trip.

A further matter to consider is that after a marked reduction in medication there can be an initial, relatively brief 'window' of improvement, due to rapid fading of side effects such as sedation. However, this is often then followed by a subsequent deterioration in mental state and then relapse, as more time passes without effective treatment. This may have occurred in [Mrs A], and [Dr C] should have been aware of this common pattern and anticipated it by using caution when supporting an overseas trip during a time when she was still vulnerable to deterioration.

13. When [Mrs A] consulted Dr C on 18 January 2001 on her return from [overseas], do you consider that hospital admission was indicated? If so, what was [Dr C's] responsibility?

The reports from [Mrs A's] daughters appear to indicate that her psychotic symptoms deteriorated [while overseas], with poor sleep, increased voices and persecutory delusions and delusional fears that [Ms B] and other family members had died. Apparently [Mrs A] refused to go into the local respite facility ([at the rural hospital]) at the review on 18th January, so only admission or home respite care were possible. In a distant rural area, arranging home respite care is always difficult and this proved to be the case, as below. [Mrs A's] medications were not fully reinstated, as far as I can gather as there are as usual no clinical notes by [Dr C] regarding treatment plans and medication changes, nor are there any typed letters covering this important post-relapse review. The [database] records do not fully tally with the prescription photocopies or reported information from [Ms B], but it appears that risperidone was recommenced, and the dose raised fairly rapidly to about 6 mgs daily. No mention is made of Cipramil so I am unclear whether this was continued. Additional sedation with clonazepam was arranged. [Dr C] may not have fully reinstated the risperidone to the former dose as he appears to have believed that it was her cessation of the last 1 mg of risperidone [while overseas] that had caused her to relapse, rather than the overall treatment changes. [Mrs A's] insight into her illness was probably not ideal at

the best of times, and was likely to have worsened prior to her trip due to the rapid dose reductions destabilising her and increasing her paranoid thinking. This probably led to her ceasing the last 1 mg of risperidone during the trip, so I believe that [Dr C] also bears responsibility for this and do not agree that the relapse was entirely Mrs A's 'fault' for having ceased the 1 mg risperidone. Under all these circumstances, admission to hospital would have been the wisest course, even if this required a period of treatment under the Mental Health Act. [Mrs A's] past history of suicide attempt when unwell and in relapse was in my opinion a reason to have insisted on a compulsory admission if a voluntary admission could not be arranged. In my opinion [Dr C] should have made this clinical decision and attempted to persuade [Mrs A] to accept informal admission, or, failing this, to have begun the Mental Health Act process via a Section 8 Medical Certificate. It would also be his responsibility to liaise with [the city hospital psychiatric unit] so as to convey clinical information, and possibly to assist with arranging the bed, although nursing staff often assist with this aspect.

14. Was the plan put in place for [Mrs A] on 18 January 2001 appropriate in the circumstances? Do you consider that [Mrs A] received appropriate support and what was [Dr C's] responsibility in terms of providing support?

On [Mrs A's] return with her daughter on 18th January they were both extremely tired, and after the assessment with [Dr C], [Ms B] appears to have been presented with a plan for respite care at home as an alternative to admission without having been properly consulted as to whether she could cope with this. They were apparently promised up to 70 hours weekly home care with respite workers. This was however clearly difficult for [the rural hospital] to arrange in such a far-flung rural area, and the main respite worker assigned was untrained and was reported to do little but knit and have meal breaks, then leave. This worker also appears not to have assisted in supervising [Mrs A's] medication doses, and apparently brought her two children under age 4 with her during respite duty, on a day when [Mrs A] was agitated and suicidal. When [Mrs A] walked out onto the road so as to kill herself the respite worker stayed with her children and did not assist [Ms B]. Home-based respite assistance appears to have been withdrawn thereafter.

Following the assessment on 18th January, the plan from [the database] was for daily community nurse reviews, but it is unclear whether these were in person or by phone, and no daily reviews are documented in the [database] records. [Ms B] reports that she had visits from either [Mrs A's] community support worker or community nurse about once to three times weekly. These appear not to have been recorded, and community support worker (CSW) visits would have been inadequate to review [Mrs A's] mental state, as CSWs are not trained nurses. The respite care plan was thus inadequately implemented and was insufficient to maintain [Mrs A] safely at home in a state of relapse, especially as [Dr C's] medication plan was inadequate as well. [Dr C's] part in this plan was to ensure appropriate medication, which in my view he failed to do, and to set out a clear management plan for daily visits and respite care and maintain an overview of the plan, checking that this was being followed. Given

[Mrs A's] unwell state he should have checked on this by telephone from [the city hospital] at least weekly, but appears not to have done so (at least nothing of this sort is documented).

15. What is clozapine and when is it indicated?

Clozapine is an 'atypical' antipsychotic medication which is most used in treatment-resistant chronic schizophrenia or schizoaffective disorders. It is also used where severe side-effects preclude the use of other 'traditional' antipsychotic medications (e.g. Parkinson's disease-like symptoms or dyskinesias — involuntary muscle movements). Clozapine is given orally, across a wide dosage range, and must be preceded by careful physical screening as it can cause serious medical side-effects in a small proportion of patients. During clozapine use, regular medical monitoring and blood tests are also required.

16. With regard to [Dr C's] decision to prescribe clozapine in February 2002, what standards apply and were those standards met?

Standards in a decision to prescribe clozapine:

- a. The patient should have a treatment-resistant long-term psychotic illness, generally schizophrenia or a schizoaffective disorder, or should be unable to take alternative antipsychotic medications due to side-effects or medical complications.
- b. Treatment-resistance is usually defined as: the patient needs to have tried three different antipsychotic medications from at least two different therapeutic groups, when given at adequate therapeutic doses for adequate duration (usually a minimum of six weeks each) in the past.
- c. The possible benefits and risks of clozapine use need to be carefully explained to the patient and their caregivers, and should also be given in the form of a written information sheet. Informed consent must be obtained for all voluntary patients.
- d. The patient needs to be physically examined and screened medically via blood testing, history, an electrocardiogram (ECG) and any other investigations indicated, to ensure that there are no medical conditions present which would mean clozapine prescription was contraindicated, e.g. a history of suppression of white blood cell production, significant cardiac disease, epilepsy, etc.

Were these standards met?

- a. [Mrs A's] initial diagnosis was appropriate for use of clozapine, but regarding [Dr C's] rediagnosis, clozapine is not indicated for Major depression with psychotic features. It must be assumed that he had revised the diagnosis back to schizophrenia or schizoaffective disorder, but there is no clinical note or GP letter which clarifies this. In a 'to whom it may concern' letter of unclear purpose dated 23rd March 2001, [Dr C] discusses his reasons for prescribing clozapine, but fails to mention her diagnosis at all. It is thus difficult to know whether he met this

standard in terms of a rational reason for clozapine prescription based on a re-revision of her diagnosis.

- b. In the letter of 23rd March as above, [Dr C] states ‘she has been prescribed many other medications, without any response and in view of that I have started her on Clozaril’. He thus implies that the reason for clozapine prescription was treatment-resistance to other medications. However, [Mrs A] did not meet the usual criteria defining treatment-resistance. She had a history of having been relatively stable, with a moderate response of her psychotic symptoms to treatment, on her medication prior to transferring to [Dr C’s] care. It is, in my opinion, partly due to this that [Dr C] was unable to elicit marked psychotic symptoms on his first assessment on 19th October thus largely discounted the past severity of these, and altered her diagnosis. Past medications on which she appears to have done reasonably well appear to have been thiothixene and risperidone, in that she was stable on this prior to moving to [a rural township]. In my opinion the records indicate that [Mrs A] had had reasonable responses to antipsychotic medications, but that her mental state at times worsened due to psycho-social stressors related to moving accommodation and difficulties within her family. It is likely that the adjustment to living in a new environment within her daughter’s family was more responsible for any worsening of her symptoms at the time of the initial assessment in October, rather than resistance to the risperidone prescribed. After altering her diagnosis, [Dr C] in fact nearly ceased the risperidone, rapidly lowering this to 1 mg from 8 mgs daily. After this and other medication changes as above, she relapsed, with a return of psychotic symptoms. The records indicate that [Mrs A’s] mental state fluctuated after her return from [overseas], with intermittent worsening of the psychotic symptoms. [Dr C] did not trial any other antipsychotic medications, nor did he reinstate the prior full dose of risperidone 8 mgs daily so as to treat these symptoms. Instead, he eventually prescribed clozapine in March 2001. I thus do not feel that [Mrs A] met the criteria for treatment resistance or that [Dr C] met the standard by using this as a reason to prescribe clozapine, a medication which carries significant medical risks and which as a result needs to be prescribed carefully and with good reasons.

The diagnosis of treatment-resistance is not straightforward, as clinicians vary as to what level of residual symptoms can be called a ‘failure to respond’. Some would define treatment-resistance as the continuation of any, even low-grade symptoms, while others would see only more serious and distressing symptoms or a clear relapse as indicating treatment-resistance. [Dr C] appears to have based his view that [Mrs A] was treatment-resistant on her failure to restabilise fully on 6 mgs dose of risperidone after the [overseas] relapse, plus her prior account of low-grade persistent auditory hallucinations across the years. However, given the risks and difficulties attendant on clozapine use in a far-flung rural area and in an older patient, I do not agree that there were grounds to start a medically risky drug on the basis of mild chronic symptoms despite which [Mrs A] had previously managed a reasonable quality of life when stable on appropriate prior medication.

- c. As ever, due to the paucity of clinical records it is extremely difficult to know whether a true informed consent process was carried out with [Mrs A] and her daughter, but overall I doubt this. Her community nurse [Ms D] noted in the [database] records that a discussion about starting clozapine occurred at an appointment with [Dr C] on 15th February 2001, but no details of the content are noted, other than the details of drug doses to be altered and that there would be ‘daily monitoring’ for a number of symptoms, some of them highly unlikely to occur on clozapine.

In the lawyer’s letter of 11th November, [Dr C] states ‘it is inconceivable that the testing and monitoring regime would not have prompted the patient or her daughter to ask questions.’ This is an extraordinary statement as it appears to indicate that rather than providing proper information at the start of the process, [Dr C] expected the patient and family to take the initiative to ask questions based on the monitoring regime set in place, so as to obtain information. This contravenes all normal standards of the provision of adequate information as part of an informed consent process.

A further discussion about the new medication occurred at a home visit on 19th February with [Ms D]. Some discussion about the need to monitor with blood tests and daily physical recordings clearly did occur. Also, discussion of the possible risks of lowered white blood cells probably occurred, as [Ms B] later phoned the clinic, concerned prior to the agreed start date that her mother had a cold and ‘might come to some harm’. Commencement of clozapine was thus slightly postponed, on [Ms D’s] advice. It is unclear if [Dr C] gave any of this practical information, or if this was largely left to [Ms D]. [Ms B’s] account is that they were given no real information about the risks and benefits of clozapine, but that [Dr C] reassured her it would ‘work’. She said that she subsequently obtained an information booklet on clozapine, but she and her mother do not sound to have been provided with written information initially when the treatment decision was made. [Ms D] mentions in the clinical record of 5th March that [Ms B] herself obtained written information on clozapine ‘through the drug company’. Family members should not have to locate such information themselves but should have it provided as part of the process of informed consent. [Dr C] was primarily responsible for carrying out the informed consent process and in ensuring written information was provided, especially as it was unlikely that a rural outreach clinic would often commence clozapine de novo in out-patients, so the clinic staff were unlikely to have been experienced in this process. In my opinion a reasonable standard was not met as regards informed consent, in the prescribing decision.

- d. [Mrs A] was not adequately medically screened prior to clozapine commencement. There are no records that any such screening occurred as regards a proper medical history and full physical examination. Screening blood tests were clearly arranged, but there is no mention of referral to her GP for physical evaluation or to check the history. As she was new to the district [Dr C] would

have had little or no medical background available — certainly no medical history was given in the referral letter from [the CMHC], although the more distant psychiatric records mention a history of raised blood pressure. Due to the risk of cardiac side-effects as below, and especially given her age, [Mrs A] should have had an ECG as well as blood tests before clozapine was started. There is no evidence that this was done. The manufacturers provide a special form to document all the pre-screening history-taking and tests, to assist doctors with the process. This has been left entirely blank and uncompleted, apart from a tick noting that [Mrs A] was not pregnant. This is a poor standard of medical screening as part of the decision to prescribe clozapine.

17. What are the side effects and warnings associated with clozapine?

a) Medically serious potential adverse effects caused by clozapine (and warnings):

Agranulocytosis: suppression of white blood cell production, occurs in 1–2% of patients and has caused fatalities particularly in the early, pre-monitoring days of clozapine use (due to life-threatening infections). The risk is higher in the initial three months of clozapine use and is considerably reduced thereafter. Patients should not be given clozapine if they have a history of bone marrow suppression or blood dyscrasia (abnormal production of blood cells or of platelets). Warnings are given about reporting any fever or flu-like illness immediately.

Seizures: seizures can occur in 5% of patients, especially at high doses of clozapine. They occur generally at doses above 600 mgs daily, but some patients may be idiosyncratically vulnerable, especially older patients. Patients with pre-existing seizure disorders are most at risk and in general clozapine is not used in such patients unless essential. Anticonvulsant medication (sodium valproate) is used with clozapine to treat this adverse effect, if needed. It is recommended that patients are warned not to engage in activities that would be dangerous during a seizure, such as operating heavy machinery or driving.

Myocarditis: inflammation of the heart muscle, extremely rare and the rates reported have varied considerably, but the rate is definitely higher in clozapine-treated patients than in patients not taking clozapine. Even more rarely this has caused fatalities. Patients should be warned to see their doctor for any cardiac symptoms such as palpitations, chest pain, or difficulties breathing.

Severe hypotension with falls, fainting or cardiac arrest: Very low blood pressure can occur, at times causing falls, fainting and in rare cases (0.03% of cases of low blood pressure on clozapine) respiratory or cardiac arrest with a fatality has occurred. Patients should have the risk of low blood pressure explained, with suggestions on managing this, and be asked to inform staff if it occurs so that it can be monitored. Severe cases may be more of a risk in patients also on a benzodiazepine sedative and it is advised that these medications not be combined if possible.

Neuroleptic malignant syndrome (NMS): NMS is a serious syndrome of: fever, sweating, blood pressure, pulse or breathing abnormalities; confusion, delirium or coma; and muscular side effects such as stiffness. Muscle tissue breaks down and can cause kidney failure and in severe cases the syndrome can be fatal. There have been several reported cases on clozapine, but the rates appear to be extremely low. Patients are not generally warned about NMS due to its rarity, but it should be considered by medical staff if symptoms as above occur during routine monitoring.

Increased risk of deep vein thrombosis and pulmonary embolism: blood clots in the leg veins, leading to a clot lodging in the lung. Fatal pulmonary embolism is reported in patients taking clozapine at 27 times the rate of that in the general population, but is still extremely rare so is not generally included in warnings to patients.

Drug-induced hepatitis: inflammation of the liver can occur and clozapine should generally not be prescribed in patients with liver disease. This should be screened for prior to starting clozapine. It is very rare, but patients are generally warned to see a doctor urgently if they feel generally unwell with nausea, vomiting or develop jaundice.

Exacerbation of glaucoma: raised pressure inside the eye, which can cause visual impairment if untreated. Clozapine can worsen this in predisposed individuals. Again, it is rare, but patients should be warned to report side-effects such as blurred vision, and clozapine is generally not prescribed in patients known to have the condition.

Gastrointestinal slowing with ileus or gastric dilatation: clozapine often causes constipation and, rarely, this can be severe enough to cause bowel blockage and dilatation of the nearby stomach or bowel. In rare cases this has proved fatal. Patients should be warned to see a doctor urgently if they develop abdominal distension, vomiting and discomfort.

Hyperglycaemia and increased risk of developing diabetes: impaired handling of sugar by the body can occur, and rarely can cause elevated blood glucose with a coma, as in diabetes. Increased incidence of later-life onset of diabetes is also reported on clozapine. Patients should be monitored for their weight and girth, and asked to see a doctor if they develop thirst and excessive urination.

b) Less medically serious potential adverse effects caused by clozapine:

These all occur in at least 10% of people so are at a frequency where patients should be warned about them prior to treatment.

Hypersalivation: Increased saliva in the mouth, sometimes with dribbling at night so that a towel is needed on the pillow. Occurs in almost half of patients.

Sedation: drowsiness, worse in the initial 2–3 weeks of clozapine use and a reason for the slow tapering up of initial doses. Clozapine is also usually given at night once established, where possible. Occurs in almost half of patients.

Weight gain: this varies, but a moderate weight gain is not uncommon on clozapine. Occurs in $\frac{1}{3}$ of patients.

Tachycardia: racing heartbeat. This occurs in $\frac{1}{4}$ of patients in the initial 2–3 weeks of treatment, and generally settles, but can occasionally cause distress. It can be a medical risk in patients with prior cardiac disease.

Dizziness: this occurs in $\frac{1}{4}$ of patients, especially in the initial 2–3 weeks.

Constipation: this occurs in $\frac{1}{4}$ of patients, and laxatives may be needed.

Insomnia: this occurs in 20% of patients, sometimes linked with the increased salivation as patients feel choked with saliva when lying down. Advice about managing this is needed.

Nausea: occurs in 17% of patients.

Vomiting: occurs in 17% of patients.

Dyspepsia: Acid stomach. occurs in 14% of patients.

Urinary incontinence: occurs more rarely (1%) but can be exacerbated by sedation or confusion, if these occur.

Note regarding warnings and adverse effects: These are many and complex, so patients and families need both verbal explanation and reassurance (as most are rare and are monitored for by staff), and written information to keep as a reminder about the most important problems and warnings. The risks of falls and low blood pressure are greater in older patients.

18. Was [Dr C's] prescribing of clozapine appropriate?

The manufacturers' recommended clozapine dosage regime at the start of treatment is:

Week One	Morning Dose (mg)	Evening Dose (mg)	Week Two	Morning Dose (mg)	Evening Dose (mg)
Day 1	nil	12.5	Day 8	50	100
Day 2	nil	25	Day 9	100	100

Day 3	25	25	Day 10	100	100
Day 4	25	25	Day 11	50	200
Day 5	25	50	Day 12	50	200
Day 6	50	75	Day 13	100	200
Day 7	50	100	Day 14	100	200

As above, clozapine is commenced in gradual increments across the first two weeks, so as to minimise problems with side-effects. Thereafter it tends to be checked via a blood level, then increased (in an older person) by at most 50 mg increments about every 7 days according to clinical response and blood levels. The average dose range in a 62 year old would be up to 200–300 mgs daily.

In contrast to this, on 22nd March 2001 [Dr C] prescribed the clozapine titration in a highly unusual manner. His initial charting of clozapine on the prescription sheet is merely as ‘Clozaril regime as documented in her notes. Increase Clozaril to 100 mgs nocte, then 200 mgs nocte then 300 mgs nocte then 400 mgs nocte with 5 day intervals between dose increases.’ This is imprecise charting as no starting dose is specified, nor is it clear when the dose is to be increased to 100 mgs nocte. The clinical note from the [database] with details about the Clozaril regime was again made by the nurse [Ms D] not by [Dr C], and was not signed ([the database] records cut and pasted into the notes do not ever appear to be signed). It is dated 15th February 2001, when [Ms D] records the starting dose as Clozaril 25 mgs for 3 days, then to increase to 50 mgs for one week. Due to [Mrs A] developing a cold it is however unclear exactly when this regime commenced, but it was probably on 5th March when the [database] record states ‘Commencement of Clopixon’. No mention of Clopixon (a traditional long-acting depot antipsychotic drug) occurs from any other sources (nor was any prescribed) and I believe that this is an error in terminology made by Ms D, who wrote down a drug with a somewhat similar name. The error is repeated again later in the note of 5th March, but the following [database] record of 7th March (again by [Ms D]) states ‘Commencement of Clozaril.’ The notes thereafter continue the errors, with the name Clopixon again being mistakenly used on 12th March and on 24th March. Finally, on 29th March [Ms D] refers to the drug as ‘clozapine’, a clear fusion of Clopixon and clozapine and another error. This causes me serious concern, as [Dr C] delegated documentation of the exact drug regime prescribed to the nurse [Ms D], who appears so unfamiliar with clozapine that she repeatedly recorded it using an incorrect name. There must have been a more accurate prescription used at the local pharmacy to actually obtain the clozapine supply (copies of outpatient prescriptions were largely not included with the documentation), but [the rural hospital database] records are seriously inaccurate and show an extremely poor standard regarding the most basic prescribing principles, for which [Dr C] is responsible as only psychiatrists are registered so as to prescribe clozapine medication.

It thus appears that [Mrs A] probably commenced 25 mgs clozapine on 5th March, then increased this to 50 mgs on about 8th March, after which it was increased to 100 mgs on 22nd March and then up to 400 mgs daily via weekly increments of 100 mgs.

For a 62 year old woman this is an extremely rapid and coarse dose titration, and at variance with the much more gradual regime recommended by the manufacturing company and adhered to in all other mental health services where I have worked. I would expect even a young fit patient to experience distressing side-effects on such a regime, and far more so in an older person. [Ms B] describes her mother's physical health as having gone 'down hill dramatically', with vomiting, diarrhoea and incontinence and worsening of her psychotic symptoms. The [database] records note [Mrs A] to have been mildly 'woozy' even prior to increasing to 50 mgs daily on 8th March, with morning sedation probably occurring by 12th March, and increased hallucinations and reduced sleep by 19th March (the risperidone was being simultaneously rapidly tapered off again). At the review with [Dr C] on 22nd March [Mrs A's] continuing disturbed mental state with paranoia, hearing voices, swearing and aggression was raised by [Ms B] who pointed out the toll this was taking on her family. As a result a crisis respite admission to [the rural hospital] was organised from 29th March for one week. By 28th March (prior to respite care) [Mrs A] reported tiredness and some unsteadiness (dose increased to 100 mg 5 days before). On 14th April [Dr C] reduced her clozapine from 400 mgs to 200 mgs at night, but as ever made no clinical note to explain this. On 17th April [Mrs A] complained of light-headedness. By 26th April the clinical team including [Dr C] had begun to feel that her care was too difficult to manage in the community and that she required admission to [the city hospital], and she was eventually admitted on 16th May 2001. The admission notes document that urinary incontinence had continued, and that she had developed sedation and low blood pressure.

As above, the correct dose is partly determined by serum levels of clozapine. These were done regularly from 21st March. By 28th March the level was just below 1000 nmol/L which is very close to the level aimed at to treat resistant psychosis. If the initial planned titration regime was followed as laid out by [Dr C] (there are no records of this, but also none to indicate that the plan deviated) then [Mrs A's] clozapine was again increased by 100 mgs even after this quite good serum level in a 62 year old woman, and by the next test on 5th April the serum level had risen to 1590 nmol/L. A young person might tolerate this, but as the level for toxicity is 2000 nmol/L and [Mrs A] was not young, she is highly likely to have experienced significant side-effects at this level, and in my opinion was at risk for more serious medical side-effects as well. At his next review on 14th April [Dr C] reduced the dose by half to 200 mgs daily, probably partly as he was concerned by this high serum level of clozapine. Again, there are no clinical notes and also no evidence that the significance of these levels was recognised by the clinic nurses and conveyed to [Dr C] by phone, so dose adjustments only occurred belatedly, at his weekly visits. This demonstrates a poor standard in the overall management of the clozapine prescription and treatment plan by [Dr C].

In summary, [Dr C's] decision to prescribe clozapine was inappropriate, as above, and his practical prescribing of clozapine was at a very poor standard and led to significant side-effects. This appears to have been compounded by inexperienced clinic staff unused to managing a clozapine commencement process in the community, which is not surprising as this is always logistically difficult even in large urban centres and it was unwise and inappropriate for [Dr C] to attempt out-patient commencement of a complex and somewhat risky drug such as clozapine at a distant rural outpost.

19. When clozapine is prescribed, what monitoring is required and why?

- e. Weekly blood testing for the first 18 weeks of a clozapine trial:
 - i. A full blood count especially to check white cells is mandatory prior to the trial and weekly in the first 18 weeks of the trial. Thereafter this is checked monthly.
 - ii. Liver function tests, electrolytes and renal function are checked prior to commencement and thereafter each month in the first 18 weeks.
 - iii. Serum clozapine levels are needed between weeks two to four so as to determine whether the serum level is adequate or a larger dose is needed. Once the desired serum level is achieved, these are done only occasionally, to check that the serum level remains stabilised and appropriate.
- f. Daily physical recordings for the first three weeks of a clozapine trial: All patients need daily pulse, blood pressure and temperature recordings taken for the first three weeks. This is often logistically difficult to manage in out-patient clozapine trials, and is one reason these are generally not attempted in isolated areas. As any lowering of blood pressure is generally orthostatic (posture-related) blood pressure should be checked both lying and standing so as to detect this symptom.
- g. An ECG (electrocardiogram) is required prior to the trial, at the end of the first two weeks to screen for myocarditis, and thereafter only if cardiac symptoms develop, e.g. palpitations, chest pain or a marked tachycardia (rapid heart rate).
- h. General monitoring e.g. for side-effects and to ensure the dosage regime is understood:
Daily visits are required for an out-patient clozapine trial, to support the patient and caregivers, ensure the rather complex dosage titration is understood and organised, and to monitor the person's mental state and for any side-effects. Continuing explanation of the treatment programme and of possible side effects is carried out at these visits, and weekly blood tests are ensured so that weekly clozapine supplies can be delivered. (The supply of clozapine weekly from any pharmacy is dependant on an adequate white cell count from the latest blood test taken that week.)

20. Was [Mrs A's] clozapine adequately monitored and what was [Dr C's] responsibility in terms of monitoring?

- i. Weekly blood testing for the first 18 weeks of a clozapine trial:
 - i. Full blood counts to check white cells appear to have been done correctly pre-trial and thereafter weekly. Clozapine dispensing depends on this so acts as a double-check that this monitoring does occur. [Dr C] would have been responsible for commencing testing or for arranging this with [Mrs A's] GP. A number of doctors' names appear on the pathology forms as the requesting doctor so I am unclear which doctor routinely overviewed and checked the results, but assume [Dr C] did so. I am unsure if this testing was delegated to the GP practice, or alternatively whether the names are those of local GPs working as medical officers at [the rural hospital]. I assume that this checking of the results was managed adequately, but in the absence of any clinical records by [Dr C] detailing the management plan, this is of course hard to determine with certainty.
 - ii. Liver function, electrolytes and renal function tests. These appear to have been arranged appropriately.
 - iii. Serum clozapine levels appear to have been requested almost weekly from the start of the trial, which is a higher frequency than usual but probably wise in terms of the inappropriately rapid dose titration and [Mrs A's] older age. I suspect they were routinely added to the weekly blood test forms. Unfortunately, the results do not appear to have been responded to appropriately, as noted above, in that the titration occurred despite quite high levels, until [Dr C] decided to halve her dose after the 1590 nmol/L level. There does not appear to have been an adequate system set up by [Dr C] for clinic staff to phone him with results between his visits, or perhaps clinic staff were not experienced enough with clozapine trials to realise that the level was becoming quite high and to act appropriately. In the absence of any written management plan we are left guessing.
- j. Daily physical recordings for the first three weeks of a clozapine trial: Daily blood pressure and temperature recordings were taken for the first three weeks. However, there is no evidence that nursing staff were asked to check blood pressure both lying and standing so as to detect postural drops in blood pressure (often the cause of falls). The pulse, an important recording as clozapine can cause tachycardia initially, and to monitor for myocarditis, was not recorded at all by clinic staff but was only taken by hospital staff in week 4 when [Mrs A] had respite at [the rural hospital]. [The database] records in the early days of the trial refer at times to the need to check blood pressure and temperature but not the pulse, and no clear plan regarding recordings is set out anywhere in the clinical notes.

Given the practical difficulties in managing these recordings I am not surprised that occasional days were missed, and in itself this is not crucial. However, [Ms B] alleged that on several days she had to do the blood pressure and temperature recordings herself as staff could not attend. This is obviously not an adequate standard as she was not a trained nurse as far as I know.

The inadequate blood pressure recordings and lack of pulse recordings are another indicator that clinic staff were unfamiliar with the routine recordings needed during a clozapine trial, and it was [Dr C's] responsibility to order the

necessary recordings clearly as part of an overall management plan, and to check the charts so as to ensure that the recordings were not becoming abnormal. This was not adequately managed, especially as [Mrs A] did have a past history of mild hypertension which increases the risk of blood pressure abnormalities during clozapine trials.

k. ECG recordings: no ECG is recorded in the [the rural hospital] records so I conclude that this was not organised at any stage. This is not adequate, especially given [Mrs A's] age and history of hypertension. [Dr C] should have arranged ECGs with her GP.

l. General monitoring e.g. for side-effects and to ensure the dosage regime is understood:

[Mrs A's] community nurse [Ms D] noted in the [database] records that a discussion about starting clozapine occurred at an appointment with [Dr C] on 15th February 2001. [Ms D] noted the need to observe for 'neuroleptic symptomatology (daily) during this period' with observation 'for signs of muscle rigidity, increased temperature and excessive sweating'. I suspect these instructions came from [Dr C] as [Ms D] does not appear to have been very familiar with clozapine trials. I am baffled by these instructions as although a low-grade fever and possibly sweating could occur in the early weeks on clozapine and is checked for via recordings, muscular side-effects such as rigidity or 'neuroleptic symptomatology' (an unclear term probably meaning extrapyramidal side-effects) are extremely unlikely to occur at all on clozapine, which is remarkably free of side-effects such as stiffness or other extrapyramidal side-effects. The mixture of symptoms mentioned sounds almost like screening for neuroleptic malignant syndrome which although a remote possibility was highly unlikely to occur. Common and likely problems such as sedation, dizziness, salivation and racing heart are not mentioned at all. This passage from [the database] thus adds weight to the view that neither [Dr C] or [Ms D] were familiar with likely clozapine side-effects and that [Dr C] was unlikely to have given [Ms D] appropriate instructions as to what side-effects to watch out for on her daily visits. [Dr C's] 'to whom it may concern' letter (possibly a means of liaising with her GP and any other doctors) dated 23rd March two weeks into the trial, mentions only a risk of low blood pressure regarding possible side-effects. The lack of a written management plan, as ever, does not assist. Daily visits were intended and attempted, but as above, could not always be managed. In my view [Dr C] did not meet a reasonable standard in organising the general monitoring.

21. What information should a patient be given about clozapine and is it appropriate for a psychiatrist to delegate this task to a community mental health nurse?

The potential benefits need to be explained as well as the risks and side-effects, with practicalities of follow-up, monitoring and the titration of doses. It is usual to inform patients about any side-effects which occur more frequently — for example the listed side-effects in 17(b) which occur with at least a 10% frequency. In addition, it is

necessary to discuss rare but potentially very serious side-effects. The main warnings discussed are agranulocytosis (suppression of white blood cell production), but also the possible risk of seizures, cardiac symptoms, abdominal pain or gastrointestinal symptoms, visual side-effects and symptoms of raised blood sugar. For all these side-effects the information needs to be explained in straightforward terminology so as to be easily understood. It is difficult for patients and families to retain all these details, so written information must be provided and a clear plan to call the clinic or to see their GP if symptoms occur needs to be arranged, including weekend and after-hours back-up. The treating psychiatrist has considerable initial responsibility to convey this information and to ensure that a written version is provided. This task cannot be delegated to nursing staff as it forms a key part of a proper informed consent process. The community nurse however has an important role in that she must continue to explain this information and to answer questions on subsequent visits. Clozapine is on the face of it, looking at the long list of potential side-effects, a medically risky medication. In fact most patients tolerate it fairly well provided it is titrated properly and they are reasonably robust, as the more serious side-effects are rare. It has great value in otherwise untreatable resistant illnesses, which can make the risks worth taking, but the decision always needs to be taken carefully with patients and families, weighing up the pros and cons with the treating doctor. This process, and the provision of information, was not carried out adequately by [Dr C].

22. From March to May 2001, when she was on clozapine, did [Dr C] provide an appropriate standard of care to [Mrs A]?

Much of this question has been covered in the sections above. In summary, [Dr C] did not, in my opinion provide an adequate standard of care to [Mrs A] during her clozapine treatment. He documented no management plan, prescribed inappropriately and in an unsafe manner, failed to ensure that rural clinic staff were adequately experienced and informed so as to manage an out-patient clozapine trial, titrated doses up far too steeply and rapidly, allowed the blood level to become unduly elevated and failed to arrange reviews mid-week between his clinics, by telephone with clinic staff, of blood test results. In addition, [Dr C's] frequency of direct clinical reviews was inadequate across the clozapine trial period. He appears to have seen [Mrs A] and [Ms B] on 15th February 2001 to discuss the change to clozapine, then next saw them on 22nd March after she had been taking the clozapine for almost three weeks. There is then no record of any further clinical review with [Dr C] at all throughout the rest of the clozapine course in April and May in the [database] records, despite [Mrs A's] continuing poor mental state and difficulties with behaviour and side-effects. Whether he reviewed her when he halved her clozapine on 14th April is unclear — it is not recorded in [the databse] if so, and of course [Dr C] made no clinical notes. He may have recharted the clozapine purely on the basis of her reported side-effects or the serum level result. His documentation failure is addressed below. This is an entirely inadequate level of clinical overview by the treating psychiatrist, especially as [Mrs A] was aged 62, was not doing well and was deteriorating, culminating in an acute admission. There are failures in multiple aspects of his care and clinical decision-making, as has been fully documented.

23. Please comment on [Dr C's] documentation. Does it meet appropriate standards? If not, in what manner and to what extent does it depart from standards?

[Dr C's] documentation was grossly inadequate. He failed to make any clinical notes at all, instead relying on the community nurse to make all of these via [the database] system, despite her probable lack of experience with commencing clozapine in the community. A clinical note by the responsible psychiatrist documenting every patient contact, as well as every significant decision he makes, is required. Thus, if he reduced her clozapine on 14th April without seeing [Mrs A], there should have been a brief note detailing why. Significant and abnormal blood tests results should be noted and briefly discussed. A detailed management plan is required in all patients, but even more so during such a difficult clinical task as an out-patient clozapine trial in a 62 year old woman living in a distant rural area. As a result of the lack of clinical records [Dr C's] reasoning for the diagnosis and medication change is unclear and has largely been gleaned belatedly, during the complaint investigation. He failed to provide an adequate letter to mental health staff or GPs [overseas] during [Mrs A's] ill-advised trip, and failed to complete the clozapine forms to document that an adequate medical history and physical screening had been undertaken. He arranged for clozapine to commence in mid February 2001 (in fact this occurred 5th March) but failed to write any letter informing her GP of this until 23rd March. At that point he wrote the 'to whom it may concern' letter, which presumably went to [Dr E], but this is unclear. Close liaison with the GP is essential in a clozapine trial, due to the need that the GP assist with pre-treatment physical screening, with monitoring for side-effects, and avoids prescribing any drug that could exacerbate white blood cell suppression. No letter with information about possible medical side-effects or listing drugs the GP should avoid prescribing appears to have been written. Thus apart from three brief typed letters to the GP or other doctors, all other aspects of [Dr C's] documentation were inadequate to a degree likely to compromise patient care and safety.

24. Any other matters which need to be brought to the Commissioner's attention.

- a. I have formed the impression from reviewing the records that [Mrs A's] daughter [Ms B] increasingly came to be perceived as 'difficult' by mental health staff from [the rural hospital]. There is evidence of increasingly hostile interactions as matters deteriorated with [Mrs A's] care and progress, especially after her return from [overseas]. I cannot comment on the personality styles of those involved in this situation, but in my opinion [Ms B] was throughout this period given good reason to be concerned and angry, frequently excluded from treatment planning and given inadequate support and information. In addition she was attempting to care for her unwell and behaviourally disturbed mother and several children, in a financially stressed household. I thus think that it is not surprising that she became increasingly antagonistic towards the local mental health services. In my opinion all the staff involved had the responsibility as health professionals to take note of caregiver concerns and to show more understanding as to why [Ms B] was reacting in this manner, rather than blaming her and seeing her as part of the

problem. Certainly [Dr C] appears to have had an unhelpful attitude. I also suspect that this poor relationship was not assisted by changes in other staff involved, shortly after [Mrs A's] care was transferred to [the rural hospital] at a time when new therapeutic relationships were being established.

Mental health services usually have protocols guiding clinicians in prescribing clozapine and arranging the logistical aspects of monitoring and follow-up. No such protocol was provided so I assume that neither [the rural hospital] [n] or [the DHB] have such a document. I would strongly recommend that they develop such a protocol, especially in view of [Mrs A's] experiences.”

Additional psychiatric advice

Dr Plunkett provided the following additional advice on 12 June 2004:

- “1. Is [Dr C] correct in his assertion that Criterion D of the DSM-IV definition of schizophrenia requires the exclusion of mood disorder before a diagnosis of schizophrenia can be made (page 4 of transcript)?**

Yes, the DSM-IV states as Exclusion Criterion D that:

Schizoaffective Disorder and Mood Disorder With Psychotic Features have been ruled out because either (1) no Major Depressive, Manic, or Mixed Episodes have occurred concurrently with the active-phase symptoms; or (2) if mood episodes have occurred during active-phase symptoms, their total duration has been brief relative to the duration of the active and residual periods. (see photocopy attached)

- 2. Do you agree with [Dr C] that [Mrs A's] symptoms and history could support a diagnosis of mood disorder/major affective disorder with psychosis (page 5 of transcript)?**

As in my prior report, I think it is unlikely that [Mrs A's] symptoms and history can be explained entirely by a diagnosis purely of mood disorder. However, a diagnosis of schizoaffective disorder is possible. Clarifying this diagnosis would require a careful assessment and history-taking with [Mrs A], and a detailed review of her past records. The referral letters and past records that were available to me at the time of preparing my initial report were clear that her past diagnosis was of schizophrenia or of a schizoaffective disorder, and while episodes of depression were mentioned, a mood disorder per se was not felt to be her sole diagnosis. In the case notes and even in the current Transcript¹ she is at times described as well in her moods yet still experiencing hallucinations. This does not occur in a pure mood disorder — either in a bipolar disorder or a major depression with psychosis. In a schizoaffective disorder, the patient has features of schizophrenia as well as of mood disorder, and

¹ Pages 20–21 (Dr C): “... and then on the 29th, then they say Mrs A seems well ... cheerful ... getting all ready for her trip [overseas], talked about the voices ...”.

schizoaffective disorder is distinguished from a mood disorder or from pure schizophrenia by the following criteria:

‘During the same period of illness, there have been delusions or hallucinations for at least 2 weeks in the absence of prominent mood symptoms.

Symptoms that meet criteria for a mood episode are present for a substantial portion of the total duration of the active and residual periods of the illness.’

In my judgement, from the records that have to date been provided to me, [Mrs A] is most likely to have had a diagnosis either of a schizoaffective disorder or of schizophrenia as such. She certainly had, it appears, periods when her moods were relatively normal yet psychotic symptoms persisted. I am unable to determine whether her bouts of depression were sufficiently frequent to meet the criteria for schizoaffective disorder, or whether these indicated schizophrenia complicated by intermittent depressed episodes.

The main reason for elaborating this issue regarding the diagnosis is that in my opinion [Mrs A] did have a significant chronic psychotic illness — either schizophrenia or a schizoaffective disorder. Such an illness cannot be effectively treated solely with an antidepressant or a mood stabiliser, but requires adequate doses of antipsychotic medication as well.

3. What is involution melancholia?

‘Involitional melancholia’ is an outdated concept which was a subcategory of the DSM-II but had been deleted in the previous DSM-III version, and which was in ICD-9, but is no longer in the current ICD-10 version. This means that it was removed from the DSM diagnostic system after 1980, and from the ICD diagnostic system after 1992.

The term ‘involitional melancholia’ referred to a moderately severe depressive illness, occurring later in life. It was believed partly to be caused by hormonal changes in women in the post-menopausal phase, but was also occasionally diagnosed in males, so thinking about the cause appears to have been unclear at times. Studies and reviews have been published discussing whether it should exist as a specific diagnostic entity (see ‘The Myth of Involitional Melancholia’ — Weissman, 1979; and page 1419 of ‘Psychiatric syndromes linked to reproductive function: a review of current knowledge’ — Gitlin and Pasnau, 1989). In Weissman’s study, for instance, no distinct clinical difference could be found between patients with major depression as such and so-called ‘involitional melancholia’. Following similar reports and reviews in the late 1970s this diagnosis was removed from the DSM system.

4. Is involution melancholia the same thing as mood disorder with psychosis or something different?

Yes, essentially. As above, the literature does not support a diagnostic entity called ‘involuntional melancholia’ which is distinct from major depression. As the old concept of ‘involuntional melancholia’ generally implied a more severe depression, it was said to be associated with melancholic symptoms or with psychosis. It thus might have been used to refer to a major depression with psychosis, generally in a post-menopausal woman. Please note however that there is no diagnostic entity in the DSM called ‘mood disorder with psychosis’. The DSM specifically divides Mood Disorder categories into major depression or bipolar disorder, either of which can be associated with psychosis, if they are severe.

5. Do you agree with [Dr C] that the use of citalopram in patients suffering from mood disorder with psychosis is well documented (page 6 of transcript)?

No, I do not agree that this is well documented. Any effective antidepressant can be used to treat a severe major depression with psychosis along with antipsychotic medication — although in fact the treatment of choice for severe psychotic depression is ECT. The treatment of choice of a psychotic bipolar disorder is antipsychotic medication and a mood stabiliser ± an antidepressant (in a depressed phase). Citalopram alone is not recommended as a treatment of ‘mood disorder with psychosis’ or of psychotic illnesses as such. Even in combination with an antipsychotic, the recommendation currently for treating a major depression with psychosis is to use a tricyclic antidepressant, rather than an SSRI antidepressant such as citalopram.

Comment on references regarding citalopram provided by [Dr C]:

[Dr C] has provided some articles which he appears to feel support his claim that the use of citalopram in patients suffering from mood disorder with psychosis is well documented.

1. Kallioniemi and Syvaelahti, Nordic J Psych 1993: Citalopram, a specific inhibitor of serotonin reuptake in treatment of psychotic and borderline patients:

The abstract makes it clear that citalopram was used in only 8 patients, 4 of whom appear to have been diagnosed with borderline personality disorder rather than psychosis. The exact diagnoses of the 4 ‘psychotic’ patients are not given. Little detail is provided e.g. the use of other medication is not clarified although concomitant use of neuroleptics (antipsychotics) is mentioned. Methodologically the study appears from the abstract to be of poor quality, and the numbers are small. This study also reports only that citalopram in the authors’ opinion helped with anxiety, impulsivity and aggression, not with core treatment of any ‘psychosis’ or ‘mood disorder’ as such.

2. Pollock et al, Am J Psych 2002: Comparison of citalopram, perphenazine and placebo for the acute treatment of psychosis & behavioural disturbances in hospitalised, demented patients:

This study compares citalopram, perphenazine (a traditional antipsychotic) and placebo in treating psychosis and behavioural disturbance in hospitalised patients with dementia. It shows some benefit with citalopram and perphenazine. I do not however believe that the results can be generalised to treatment of ‘mood disorder with psychosis’ as this study looked at a completely different patient and diagnostic group. Some patients had psychosis (due to their dementia) and others did not. The addition of citalopram may actually have been treating underlying anxiety or an unrecognised mood disorder, not psychosis at all — the authors are cautious and do not actually claim that citalopram was working as an ‘antipsychotic’. This study does not confirm [Dr C’s] assertion that the use of citalopram in patients suffering from mood disorder with psychosis is ‘well documented’.

References which do not support the claim that the use of citalopram in patients suffering from mood disorder with psychosis is well documented:

I was unable to locate any national Treatment Guidelines for major depression with psychosis which recommended the use of citalopram. Instead, the RANZCP ‘summary of guideline for the treatment of depression’ (page 37) states that first-line treatment is an adequate trial of a tricyclic (TCA) and antipsychotic, or to consider ECT. If this fails, use of an SSRI such as citalopram is not suggested as an alternative. This recommendation (TCA plus antipsychotic) is supported by at least one adequate randomised controlled trial (a reasonable level of scientific evidence).

The Canadian ‘Clinical Guidelines for the Treatment of Depressive Disorders’ (pages 40–41) recommend use of ECT or of olanzapine (antipsychotic) plus antidepressant. They go on to emphasise that monotherapy with selective serotonin reuptake inhibitors (SSRIs) is not recommended in Major Depressive Disorder (MDD) with psychosis. Citalopram is an SSRI.

USA Guidelines from the American Psychiatric Association recommend treatment with ‘antidepressants plus antipsychotics, or ECT’. Again, citalopram is not mentioned as having any ‘well documented’ role in treatment of ‘mood disorder with psychosis’.

There are studies² & ³ which do document use of citalopram in major depression with psychosis — but in these it is always used together with adequate doses of an antipsychotic drug.

Finally, a report by Navarro et al in Acta Psychiatr Scand (2001) looked at treatment of late-life depression (patients aged over 60) and concluded that there

² Konig et al, Neuropsychobiology 2001 — citalopram plus olanzapine (antipsychotic) was used.

³ Bonomo and Fogliani, Am J Psych 2000 — low numbers but is an early report of use of citalopram plus 4–9 mg haloperidol daily (this haloperidol dose is equivalent to 4–8 mg risperidone daily).

was a significantly higher remission rate to nortriptyline than to citalopram, especially for ‘those with endogenous or psychotic features’.

6. Is [Dr C] correct in asserting that citalopram is safer than nortriptyline where there is a risk of suicide (page 6 of the transcript)?

Yes. Citalopram is relatively safe in overdose whereas all tricyclics including nortriptyline are relatively toxic in overdose.

7. Is 12 or 13mg daily of risperidone an extremely high dosage as [Dr C] suggests (line 20, page 8 of the transcript)?

Yes, I agree that this is a high dose. The usual treatment range in adults according to the ‘*New Ethicals*’ reference catalogue is about 4–6mg daily, and *New Ethicals* gives the upper limit as 16mg daily. Higher doses of about 8–10mg are however at times used in patients with more chronic and resistant psychotic illnesses, and it is possible that [Mrs A’s] prior psychiatrist [Dr G] felt that her illness was of this type as from my reading of the letters previously provided by HDC he referred her to [Dr C] on a daily dose of 8mg risperidone.

I do not think that it would have been unreasonable for [Dr C] to be somewhat concerned a) that this was a relatively high dose and might have been causing [Mrs A] some extrapyramidal side-effects and b) that if she nonetheless had psychotic symptoms on this dose then it appeared the risperidone was relatively ineffective for her resistant psychosis. I do however think it was unreasonable and unwise for him to then reduce her risperidone dose down as low as 1mg daily across a relatively short time-frame. I do not believe that this was an effective antipsychotic dose for [Mrs A].

8. Please review the studies for which [Dr C] has provided abstracts and advise whether they support [Dr C’s] assertion that 1mg daily of risperidone is effective in reducing psychotic symptoms. (See line 19, page 9 of the transcript).

As above, the issue is not really whether in some instances of the treatment of psychosis 1mg risperidone daily can be an effective dose, but whether this was likely to be the case for [Mrs A]. Studies over the past 10–15 years have indeed shown that lower antipsychotic doses can often be used effectively to treat patients with schizophrenia. The main message from these studies however is that this is the case in readily responsive patients, for example first-episode patients who do not have a long history of chronic illness. In patients (like [Mrs A]) who do have a long history of a chronic, resistant psychotic illness an extremely low dose such as 1mg risperidone is very unlikely to be an effective antipsychotic dose. She had in fact been treated with a higher-than-average dose (8mg daily) and would thus have become somewhat acclimatised to this higher dose. As above, the fact that moderate to high doses of risperidone across an extended period of time (from the past psychiatric records) had not fully controlled her symptoms indicates that her illness was resistant and hard to treat. A change to a different antipsychotic drug would thus have been more sensible,

rather than reduction to an ineffective dose of the existing (apparently already relatively ineffective) antipsychotic medication.

Regarding the study provided by [Dr C]:

The only paper provided which appears to address this to some degree is by Bhana and Spencer, from 'Drugs and Aging' (2000). This study reports benefit from the use of 1mg risperidone in the management of dementia-associated behavioural and psychological symptoms in the elderly. However, as with the article provided about citalopram, this study refers specifically to a very different patient population: elderly patients with a definite diagnosis of dementia and with associated psychosis, aggression or behavioural disturbance. Despite [Dr C's] linkage of this (in the Transcript, line 20 page 10) to [Mrs A's] later CT-scan abnormalities detected after her psychiatric admission to [the city hospital], it is clear that at the time he initially assessed her he had not made any such diagnosis. Nor can [Mrs A] — a patient he later supported in making a trip [overseas] all by herself — reasonably be equated to elderly patients with significant dementia as in the Bhana study. I thus do not regard this study as providing useful guidance in her treatment.

[Mrs A] was however aged 62 and it is indeed true that lower medication doses are generally preferred in older patients. However, this is would be particularly the case were she being treated for the first time, when it would be reasonable to exercise caution in commencing risperidone by gradually increasing her dose from 0.5mg daily to between 2–4mg daily. [Mrs A] however had been taking 8mg of risperidone daily so her ability to tolerate the medication was clearly established and was in fact quite robust. From the Transcript (page 9) [Dr C] felt she had some degree of a 'mask face' (possible bradykinesia) and 'irritability' — which he appears to have interpreted as definite akathisia, although in my view this is not certain. However, even these possible side-effects appear to have been only mild to moderate and she had tolerated them for some time. In my view it would have been reasonable to consider changing her antipsychotic medication to a new drug, or to reduce it to a more normal dose for adults (about 4mgs daily), while following her carefully across the subsequent three months to assess any benefit and ensure she did not relapse. Physically and functionally [Mrs A] does not appear to have been a frail, antipsychotic-naïve patient falling clearly into the 'elderly' category for whom very low doses like 1mg daily are appropriate. To place [Mrs A] in this category would indicate poor clinical judgement, were it in fact the basis for the treatment plan undertaken by [Dr C].

9. Is citalopram effective in reducing psychotic symptoms?

No, not as such. See the response to question 5 above. It is an antidepressant not an antipsychotic agent. In severe depression with psychosis, the use of citalopram (or any antidepressant) by itself is in fact highly likely to worsen the illness, thus it is always given with effective antipsychotic medication if used in such conditions.

10. Do you agree that citalopram was a better choice of medication than nortriptyline for [Mrs A]?

Citalopram's main advantage was its greater safety should she take an overdose. This is not an unreasonable basis to make a change for an out-patient, although [Dr C] does not appear to have been particularly worried initially about [Mrs A] being a high suicide risk. If [Dr C] made the change as he had rediagnosed her as having a major depression with psychosis then in fact there is evidence to the contrary: that nortriptyline is likely to be more effective than citalopram (see question 5 response above). If her diagnosis was in fact schizophrenia or a schizoaffective disorder with a depressive episode (as is my view) there is no good evidence that any one antidepressant is to be preferred, although in general the tricyclics are recommended in more severe depressions. It might have been reasonable to change [Mrs A's] antidepressant to citalopram, hoping that she would experience an idiosyncratic improvement on the SSRI, as long as other medication was kept stable — e.g. as long as the antipsychotic medication was maintained at its usual dose. The concurrent changes in both the antidepressant and in the risperidone dose were ill advised, in my opinion.

11. Would 1mg daily of risperidone have been sufficient for citalopram to have had a beneficial effect in reducing [Mrs A's] psychotic symptoms as [Dr C] alleges is indicated in the study (line 1, page 12 of transcript).

I do not agree that the studies provided by [Dr C] offer any evidence to support this view. As above, in my opinion this is too low a dose of risperidone to be effective for [Mrs A] as a treatment for both psychosis and depression when used alongside an antidepressant. As in my question 9 response above, the use of citalopram by itself (without adequate concurrent treatment with antipsychotic) is in fact likely to worsen the illness. The very low risperidone dose of 1mg would not in my view have been sufficient to prevent her psychotic illness from relapsing across the subsequent 2–3 months after the change was made. I do not agree that there is any good evidence in the literature that citalopram has in itself any antipsychotic efficacy.

12. Do you agree that [Mrs A's] history indicates that she suffered from episodes of major depression?

I agree that [Mrs A] appears to have suffered from significant episodes of depression. As in my initial report, this appears to have led to some confusion regarding the diagnosis, as [Dr C] appears to have felt that [Mrs A] had to have either schizophrenia per se, or major depression (or possibly a bipolar disorder). Technically this is correct, as the DSM-IV states that significant episodes of what appear to be major depression occurring in a patient with definite schizophrenia should not be called 'major depression' but rather called 'depression NOS' (not otherwise specified). In fact, as in my initial report, significant episodes of depression occurring in patients with schizophrenia are quite common, and do not necessarily mean that the patient does not have schizophrenia or that the diagnosis should be altered.

I would need considerably more collateral information and probably directly to assess [Mrs A] in order to determine whether she did in fact have schizophrenia with occasional significant episodes of depression, or a schizoaffective disorder (with recurrent depression). As stated in my initial report and in the response to question 2 above, I do not however feel (from the information provided to me to date) that her symptoms can be explained entirely by a pure mood disorder such as major depression or bipolar disorder.

13. Do you agree that [Mrs A's] condition could be adequately treated with a mood stabilizer with antipsychotic properties alone?

[Dr C] variously uses the term 'mood stabiliser with antipsychotic properties' (line 12 page 13) or alternatively 'antipsychotic with mood stabilizing properties' (line 12 page 14). He is probably referring to the newer antipsychotic agents, the so-called 'atypicals'. In New Zealand the available atypicals include risperidone, quetiapine, olanzapine and clozapine. The strongest evidence in the literature is for olanzapine as a mood stabilising agent in bipolar disorder, although all the others have been tried⁴. Olanzapine is listed as an option to use as a mood stabiliser in the acute treatment of manic and mixed affective episodes and (when used in combination with fluoxetine) as a treatment option for bipolar depression.⁵ The atypical antipsychotics are also first-line treatment for schizophrenia and schizoaffective disorder, as in general their side-effects are better-tolerated than the older, typical antipsychotics, and as they are often more effective. Treatment with an atypical antipsychotic other than risperidone would thus have been appropriate for [Mrs A] — especially as relatively high-dose risperidone treatment appeared not to be managing her symptoms. However, there is in my opinion no evidence from the material provided to me to date that [Mrs A's] diagnosis was that of a bipolar disorder. Bipolar disorder can only be diagnosed if the patient has a clear history of manic or hypomanic episodes, which I have seen no record of in [Mrs A's] case. The atypical antipsychotic medications (especially olanzapine) appear to have some role in treating resistant depressions however so it is likely that this would have been worth trying both for her chronic psychotic illness and her tendency to depressions.

14. What is your opinion of [Dr C's] plan to stabilize [Mrs A's] mood with citalopram and then use lithium or perhaps olanzapine or clozapine (line 25, page 12 of the transcript)?

I have commented in question 10 above on the decision to change her antidepressant from nortriptyline to citalopram. As in 13 above, a change to a different atypical antipsychotic agent from risperidone was reasonable. In my opinion lithium would not have been as appropriate as it is specifically a mood stabiliser used in bipolar

⁴ Muzina, Current Psychiatry Online (2004) Bipolar maintenance: Are atypical antipsychotics really 'mood stabilizers'?

⁵ In the RANZCP Summary of Guideline For The Treatment Of Bipolar Disorder.

disorder — and as above I do not think that this was [Mrs A's] diagnosis. Lithium is also considerably more toxic, especially in overdose. Although no kidney disease is reported in [Mrs A's] case, there is somewhat more chance at her age of mild renal impairment leading to accumulation of lithium with serious toxicity. I am unsure why [Dr C] in the end chose clozapine rather than olanzapine. The evidence is far stronger for olanzapine in treating resistant depression and as a mood stabiliser, and clozapine carries considerably more medical risks and requires very careful monitoring. Clozapine is also generally less well tolerated than olanzapine, often causing more sedation. It also needs to be titrated after commencement much more slowly and carefully and across a longer period of time.

In summary, I do not believe that more than one of [Mrs A's] medications should have been altered significantly all at once, and in my opinion if risperidone were to be altered I would have recommended olanzapine as the alternative antipsychotic drug, not clozapine.

15. In your opinion, is there any evidence supporting [Dr C's] theory that [Mrs A] may have been suffering from a bipolar illness (line 8, page 16 of the transcript)?

As already discussed above in question 13, I am not aware of any convincing evidence from the Transcript or the records previously sent to me, that [Mrs A] had a diagnosis of bipolar disorder. Certainly her prior doctor, [Dr G], did not record this as her diagnosis, and he had followed her up across a longer time period than [Dr C]. As above, bipolar disorder can only be diagnosed if the patient has a clear history of manic or hypomanic episodes, which I have seen no record of in [Mrs A's] case. A history of psychosis per se is insufficient to make a diagnosis of bipolar disorder, especially as there is evidence that the psychotic symptoms occurred at times when [Mrs A's] moods were stable. This points rather to a schizophrenic or schizoaffective disorder.

16. Is major affective disorder with involution melancholia an accepted DSM-IV diagnosis (line 21, page 17 of the transcript)?

No. This is answered in question 3 above. The concept of 'major affective disorder' or 'major mood disorder' is used at times to encompass both bipolar disorder and serious or psychotic major depressions, but it is not a diagnostic category as such.

17. Was it appropriate for [Dr C] to expect the community mental health nurses to write up the notes of consultations held in patients' homes (line 27, page 18 of the transcript) and to make no notes himself?

No, in my opinion this was not appropriate as a routine, although it does sometimes occur. If a follow-up visit has been uneventful and has involved no reassessment nor any changes to the patient's management, the doctor will sometimes arrange for the nurse present to make notes regarding the visit, especially if there is pressure of other work. This is not however particularly wise in terms of best clinical practice, as errors

may be made and aspects of the review may not be recorded. In my opinion it was not appropriate for all such reviews to be documented by the community nurses, as [Dr C] would have been reassessing [Mrs A] and reviewing her progress and management at times in the course of such home visits. Indeed this is clear, as the HDC summary records that at the clinical review on 15th February 2001 [Dr C] made a major management decision (to commence clozapine) yet delegated documentation of this to the accompanying nurse. Psychiatrists have a different level of training compared to community psychiatric nurses and cannot expect the nurse to record all details of an assessment accurately from the perspective of the treating doctor. Medico-legally this is also unwise. The Commissioner has himself commented in 'New Zealand GP' (1999): 'The other significant issue that arises due to the complexity of services provided to mental health consumers relates to the standard of record keeping. This is consistently a problem in the sector and must be addressed. However in the case of mental health, the need to provide accurate summary care plans and good notes is extremely important and its absence has been documented in almost every mental health enquiry ever undertaken in this country.'

18. Is [Dr C's] description of [Mrs A] as elderly appropriate (line 3, page 21 of the transcript)?

[Mrs A] was 62 years old. In NZ Mental Health Services, the age demarcation for services for the elderly (now generally referred to as 'services for older people') is age 65. However, [Mrs A's] chronological age is less relevant than her biological age, in the context of her response to medication. Some older people are physically robust and require very similar doses as younger adults for effective treatment, and this is more often the case when, like [Mrs A], they have been treated for a chronic mental illness for many years and have become acclimatised to the medication. [Mrs A] apparently had mild hypertension but no serious medical condition which would have rendered her frail and 'old for her age'. To treat her as a vulnerable 'elderly' patient thus seems inappropriate.

19. Is [Dr C's] assertion that elderly people are not usually given more than 2 mgs of risperidone daily correct (line 3, page 20 of the transcript)?

This has largely been addressed under question 8 above. In an older patient of [Mrs A's] age (62) who was being started on risperidone for the first time, quite small doses would be normal, ranging from 0.5 mgs up to about 2mgs as [Dr C] suggests. However, as in no. 18 above, many older patients who have been treated long-term since younger adulthood with medications will tolerate a higher dose. Indeed, they may well need a higher dose unless they are developing medical conditions that affect the handling of medications. [Mrs A] is not reported to have had such conditions to my knowledge. In summary, physically and functionally [Mrs A] does not appear to have been a frail, antipsychotic-naïve patient falling clearly into the 'elderly' category for whom very low doses like 1mg daily are appropriate. To place [Mrs A] in this category would indicate poor clinical judgement, were it in fact the basis for the treatment plan undertaken by [Dr C].

20. In your opinion, how likely is it that [Mrs A's] deterioration during her trip [overseas] was due solely to the fact that she had stopped taking her medication (line 22, page 20 of the transcript)?

This is unlikely, as a number of factors are likely to have placed her at greater risk. Air travel is itself a stressor, especially for a somewhat older person, and even a trip [overseas] involves some jetlag of about 2 hours which can worsen sleep disturbance. There was also evidence in the records I previously reviewed that [Mrs A] was not as well two weeks prior to travelling, with sleep disturbance and increased paranoid thinking reported by her daughter [Ms B], who forcefully expressed concerns about this. In my opinion [Mrs A's] dose of risperidone was too low at 1mg to protect her from relapse, and she was probably beginning to relapse just before travelling (about two months after the medication reduction commenced, which would be the likely time for a relapse to occur). Cessation of her medication on top of this would of course hasten the relapse, but is unlikely to have been the sole cause.

21. To what extent should a psychiatrist allow the wishes of a patient's family to dictate his or her treatment decisions (see line 15, page 22 and line 23, page 23 of the transcript)?

This is a difficult question. The patient's wishes should be paramount if they are competent to give informed consent. It seems unlikely that [Mrs A] was in fact well enough to do so following her return from [overseas], as she was suffering a relapse of her psychosis and her condition was not stable. In such circumstances the informed consent process is carried out with the immediate next of kin instead. Legally, however, a patient who is not competent to give informed consent cannot be compulsorily treated purely via discussions with their family. The patient has to be placed under the Mental Health Act and treated compulsorily. As a general rule, unless a competent patient opposes family contact, it is best practice to involve family as an important part of the team involved in the patient's care.

In theory then, immediate family should have a major role in treatment decisions where a patient is not competent to make these. I do not believe that family should 'dictate' these against the psychiatrist's better judgement, and if necessary the views of family can be overridden by invoking the Mental Health Act, if the patient's welfare demands it. In the real world, however, matters are often not so clear. Where patients have fluctuating degrees of competency and of illness severity, a treating psychiatrist may continue trying to compromise with the patient and family rather than alienating them by invoking the Mental Health Act against their wishes. This sometimes results in less than optimal treatment plans having to be followed for a period of time. [Dr C's] relationship with [Mrs A's] daughter [Ms B] at this time was poor and this would further have complicated matters.

22. Was [Dr C's] decision to reintroduce risperidone after [Mrs A's] return from [overseas] on 18 January 2001 rather than continue with citalopram reasonable (see page 23–24 of the transcript)?

As above, it was not optimal as she had previously been relatively resistant to even 8mg of risperidone daily. The decision to reinstate antipsychotic medication rather than antidepressant medication was appropriate however, as [Mrs A's] relapse sounds primarily to have been a psychotic relapse rather than an episode of mood disorder.

I suspect that [Dr C] had little choice as [Ms B] sounds to have been disillusioned with her mother's medication changes and to have insisted on a return to her 'old' medication. In the absence of an inpatient bed to admit [Mrs A] to for a full review of her treatment, [Dr C] had reduced care options and appears to have felt that a return to 'square one' for a period of restabilisation was a reasonable next step. Lack of appropriate service resources thus also restricted treatment options.

23. Does clozapine act as a mood stabilizer as [Dr C] suggests (pages 24–25 of the transcript)?

Clozapine can be used as a mood stabiliser. See the previously mentioned reference.⁶ As mentioned in question 14, I feel however that olanzapine would have been a safer option rather than clozapine, especially in a 62 year old woman who was an out-patient and living in a rural area, in terms of the difficulties monitoring her closely enough regarding likely side-effects. Olanzapine was not quite as readily available but could have been obtained even in 2001 within at most two weeks via application for a special authority number, on the basis of [Mrs A's] diagnosis of schizophrenia and history of poor response to risperidone.

24. Would it have been appropriate for [Dr C] to refer [Mrs A] back to her GP for monitoring after the introduction of clozapine or should [Dr C] have overseen the monitoring himself? What kind of instructions should a psychiatrist give to a GP when requesting him or her to monitor a patient who is commencing on clozapine?

It is less common in New Zealand for GPs to be directly involved in shared care for clozapine treatment, but this may occur at times, once patients are stable. However, is extremely uncommon for a GP to be involved in shared care from the very beginning, during the initial weeks of titration of the clozapine dose. GPs might assist with the initial physical screening via blood tests, ECG and a physical examination, but would generally only be reinvolved in monitoring thereafter once the clozapine titration had been completed and the patient was stable on the final dose. One difficulty is that [the DHB] do not appear to have had a clozapine Policy in 2001 to guide clinicians.

The best example of shared care with GPs is from the UK's National Health Service, where this occurs far more frequently. Please see the attached reference 'Draft General Guidelines On Setting Up A Shared Care Agreement For Clozapine'. This is

⁶ Muzina, Current Psychiatry Online (2004) Bipolar maintenance: Are atypical antipsychotics really 'mood stabilizers'?

of a particularly high and detailed standard but serves to convey the complexity of the logistics, due to the serious nature of clozapine's potential side-effects. Even if a less detailed proforma were used it is apparent that it would be impossible to arrange even partially shared care as regards monitoring arrangements with a GP, without clear written instructions. In my opinion [Mrs A] should not have been referred back to her GP for monitoring until her clozapine was fully titrated and stable at the final dose, and until she was clearly tolerating this without significant side-effects or medical problems.

The appropriate communication with the GP would thus have been an initial notification about the plan to commence clozapine with important information for the GP about this. Many medications are contraindicated alongside clozapine and unless provided with lists of these, GPs are not likely to be aware of all such interactions — especially in rural areas. See the attached sample of a basic GP letter regarding clozapine commencement.⁷ In my opinion [Dr C] should have personally overseen the clozapine monitoring until it was clear that [Mrs A] was fully stabilised and doing well on this new medication. If this point had been reached, a detailed management plan would then need to have been discussed with the GP and then recorded clearly. Monitoring is one of the most important aspects of clozapine treatment plans, and there must be clear arrangements as to who is responsible for checking all blood results, and what steps are to be taken in the event of an abnormal haematology result falling outside the 'green' or safe range. I have not provided a sample of instructions which a psychiatrist should give to a GP when requesting him or her to monitor a patient who is commencing on clozapine, as I do not feel this to be clinically appropriate under any circumstances.

25. Was it appropriate for [Dr C] to delegate the provision of information about clozapine to a community mental health nurse when [Mrs A's] daughter [Ms B] terminated discussions with him (line 29, page 26 of the transcript)?

[Dr C] appears to have had few options in the matter if as he states, [Ms B] thereafter refused to meet with him to discuss her mother's treatment. As I have made clear, in my opinion the whole plan to commence clozapine for [Mrs A] as an out-patient in a far-flung rural community was unwise. This was obviously further complicated by [Dr C's] poor relationship with the primary caregiver, [Ms B]. It was unfortunate that the provision of information had to be delegated, and it appears that [Dr C] did not oversee this to the degree required — i.e. he did not ensure that [Ms B] and [Mrs A] received detailed written as well as verbal information about clozapine treatment, before this was commenced.

26. If you regard the delegation as inappropriate, please advise what you would regard as an appropriate course of action in these circumstances.

⁷ Reference: 'Information For General Practitioners Regarding Clozapine Treatment' — Sample of a basic GP letter to alert a GP that their patient is commencing clozapine (note that this is not a shared care agreement with the GP, nor is the GP being asked to provide monitoring).

It would have been preferable to have involved [Mrs A's] GP, especially as [Dr C] planned for her GP to have a major role in the monitoring process. Dr C could have conveyed the information about clozapine in detail and in writing to the GP who hopefully had a better relationship with [Mrs A] and [Ms B] at that point. A joint appointment with the community psychiatric nurse and the GP both present would have been preferable to delegation of this task solely to the nurse. If involvement of [Mrs A's] GP in this way were impossible, [Dr C] would have had little choice but to work through the community psychiatric nurse to provide the necessary information about clozapine. I reiterate however that my opinion the whole plan to commence clozapine for [Mrs A] as an out-patient in a far-flung rural community was unwise.

27. Please provide comment on any other aspects of [Dr C's] interview which you feel are noteworthy.

I was struck by [Dr C's] worrying discussion of his planned prescription and monitoring regime for commencing clozapine. From the Transcript (page 25, line 19):

'There are basically two regimes that ... one could use. One is a regime as advocated by Clozaril ... by the manufacturers, Novartis, of Clozaril. ... And the other is to use a fairly low dose for a while and see how the patient does on the low dose, and if there are any complications to that, to react on the complications to see how the patient reacts. Because some people use 300mg, they're quite happy on 300mg, and some have to use something like 600 or 700mg, so the thing is to keep close contact with the patient and if there are any problems. And the problem is usually in the beginning that you do get this bit of high, low blood pressure. Low, lowish blood pressure, they feel a bit dizzy. And then what usually happens is they ring me up and say "I feel a bit dizzy" etc. etc. And then you do blood checks to see where we are, and we reduce the dose and that would usually, that would be ... Touch wood, I've never had any worse side effect than that.'

In this, [Dr C] appears to be describing his personal regime for commencement of clozapine in which (unlike that recommended by the manufacturers Novartis) the patient is put straight onto a 'low dose' and then in some unspecified way increased to between 300–700mg of clozapine daily. [Dr C's] discussion appears to suggest that his method of determining the final clozapine dose is to wait until the patient contacts him complaining of side effects such as low blood pressure causing dizziness, and then to reduce the dose to a safer level. This in fact bears a close resemblance to what appears to have actually occurred with [Mrs A], in that in my opinion she was titrated far too rapidly onto clozapine and in an idiosyncratic manner which did not conform to the Novartis recommended regime. She then developed side-effects of tiredness, urinary incontinence, sedation and low blood pressure and a blood level showed that her serum clozapine was too high, at which point it was reduced. The reason for the extremely slow and gradual titration onto clozapine recommended by Novartis is that side-effects such as [Mrs A] experienced are otherwise highly likely, but these can be minimised if the titration occurs slowly and in small increments.

Later in the Transcript (page 29 line 30) [Dr C] states that had never previously commenced any patient on clozapine in the community before [Mrs A] and his description of the process bears out his inexperience in this and his lack of knowledge about the safe way to manage clozapine commencement under any circumstances. It also suggests that he had a worryingly poor grasp of the full extent of clozapine's potential side-effects.

Despite the lack of a local DHB Clozapine Policy, [Dr C] could easily have consulted [the city hospital] pharmacist for guidance regarding the clozapine titration and monitoring, but he appears not to have done so. This adds further weight to my opinion that [Dr C's] plan to treat [Mrs A] with clozapine in the community as an out-patient was both extremely ill advised and poorly managed.

References Attached:

- (a) Weissman M, JAMA, 1979: The Myth of Involutional Melancholia
- (b) Gitlin and Pasnau, Am J Psych, 1989: Psychiatric syndromes linked to reproductive function: a review of current knowledge (see page 1419)
- (c) DSM-IV definitions of Schizophrenia and of Major Depression diagnosis when occurring in Schizophrenia (pages 342–345) and Major Depression — melancholic features.
- (d) Kallioniemi and Syvaelahti, Nordic J Psych 1993: Citalopram, a specific inhibitor of serotonin reuptake in treatment of psychotic and borderline patients (from Dr C)
- (e) Pollock et al, Am J Psych 2002: Comparison of citalopram, perphenazine and placebo for the acute treatment of psychosis and behavioural disturbances in hospitalised, demented patients (from Dr C)
- (f) RANZCP Summary of guideline for the treatment of Depression (page 37)
- (g) The Canadian Clinical Guidelines for the Treatment of Depressive Disorders (pages 40–41)
- (h) Practice Guideline for the Treatment of Patients with Major Depression (American Psychiatric Association)
- (i) Navarro et al, Acta Psychiatr Scand, 2001: Citalopram vs nortriptyline in late-life depression: a 12 week randomised single-blind study
- (j) Konig et al, Neuropsychobiology, 2001: First experiences in combination therapy using olanzapine with SSRIs (citalopram, paroxetine) in delusional depression
- (k) Bonomo and Fogliani, Am J Psych, 2000: Citalopram and haloperidol for psychotic depression
- (l) Bhana and Spencer, Drugs and Aging 2000: Risperidone: a review of its use in the management of the behavioural and psychological symptoms of dementia (from Dr C)
- (m) Muzina, Current Psychiatry Online, 2004: Bipolar maintenance: Are atypical antipsychotics really 'mood stabilizers'?
- (n) Draft General Guidelines On Setting Up A Shared Care Agreement For Clozapine (sample of an NHS shared care agreement)
- (o) Information For General Practitioners Regarding Clozapine Treatment — Sample of a basic GP letter regarding clozapine commencement.”

Nursing advice

The following expert advice was obtained from Mr Tom Woods, an independent mental health nurse:

“Preamble

This report is the result of a request by the Commissioner’s office for independent expert nursing opinion in regard to the complaint involving [the rural hospital] and the care given to [Mrs A] [Health and Disabilities Commission case number 02/01804/AM].

1. With regard to [the rural hospital’s] management of [Mrs A] when she returned from [overseas] in crisis in January 2001, what professional standards applied? Were those standards met by [the rural hospital’s] community mental health nurses?

The Nursing Council of New Zealand [NCNZ] provides the basis for professional standards for registered nurses in the Code of Conduct for Nurses and Midwives [NCNZ, 1999]. Best practice for mental health nurses working in the area for two years or more is outlined in the Australian and New Zealand College of Mental Health Nurses’ [ANZCMHN] Standards of Practice for Mental Health Nursing in New Zealand [1995]. Community Mental Health Nurses [CMHNs] are typically those working at this level.

Standard III of the guide [ANZCMHN, 1995] states that ‘The Mental Health Nurse provides nursing care that reflects contemporary nursing practice and is consistent with the therapeutic plan’ (p.10). From the photocopied records provided it appears significant elements were absent, making it hard to identify a therapeutic plan. I was unable to find a comprehensive nursing assessment subsequent to [Mrs A’s] referral from [...] early in September 2000. Assessment and planning appears limited to the letter from [Dr C] to the GP [Dr E] [19/10/2000], and the nursing notes that record [Dr C’s] initial assessment [26/10/2000]. Mostly these relate to a change of diagnosis [to major affective disorder] and medication.

The nursing assessment documented around the time of [Mrs A’s] return from [overseas] was completed before staff back in [the rural hospital] saw her. It was completed as a result of discussion with daughter [Ms B] via telephone. I refer to [Ms H’s] clinical note of 15/01/01 and [Ms D’s] Clinical Assessment Form of the same date. Four days after [Mrs A’s] return a Respite Clinical Assessment and Treatment Care Plan was completed by [Ms D], which noted a return to the original diagnosis of schizophrenia.

While the notes show a high degree of concern on the part of nursing staff prior to the client’s return, subsequent crisis assessment was not fully done. Intervention planning was limited to daily review by the CMHN, increased Community Support Worker [CSW] input, and an increase in medication. Nursing evaluation of this ongoing plan of respite care does not appear in the notes. Nursing visits are alluded to in [Ms B’s]

account of the care received after her mother returned from [overseas], however these are not documented for the period between 18/01/2001 and 30/01/2001.

Standard III [ANZCMHN, 1995] states that the nurse be able to ‘Facilitate the process of comprehensive nursing assessment’ and ‘Document assessment outcomes, nursing management plan, strategies for care and outcomes’ (p.11). Performance criteria includes that ‘The nursing management plan accurately reflects the outcomes of ongoing nursing assessment, collaboration with the consumer, family or whanau and consultation with other members of the mental health team’ (p.12). This standard does not appear to have been met.

2. What support would a provider using reasonable care and skill have provided to [Mrs A] and her family by [the rural hospital] when [Mrs A] returned from [overseas] in January 2001? Did [the rural hospital] provide the support which a provider using reasonable skill and care should have provided?

Crisis assessment by a psychiatrist was indicated, and [Mrs A] was seen. [The rural hospital’s] response to the situation should have been based on a comprehensive assessment by the multidisciplinary team. Given the level of concern expressed by [the family] it seems remiss that a comprehensive assessment was not done, which could have outlined [Mrs A’s] mental state, risk factors, and the family’s coping ability. As mentioned above, assessment was limited to [Ms D’s] reportage of the psychiatric consultation.

[Ms B’s] account indicates that clinical opinion was her mother would be better managed in the home, with assistance from a respite caregiver present overnight, for some nights. The interview with [Dr C] is at variance with this indicating his preference was for hospital admission, however there were no beds at [the city hospital]. The notes do not indicate what was done to support the client and the family between 18/01/01 and 23/01/01, though plan was for the CMHN to review daily, with increased support from the CSW. The evidence suggests the support provided was inadequate.

3. When [Mrs A] consulted [Dr C] on 18 January 2001 on her return from [overseas], do you consider that a community mental health nurse using reasonable care and skill would have assessed [Mrs A] as requiring hospital admission? If so, what steps should [the rural hospital’s] community mental health nurses have taken to arrange her admission?

The Clinical Assessment done by [Ms D] for the purposes of crisis respite [dated 23/01/01] notes an increase in the [passive-like] ‘negative’ symptoms of schizophrenia and an increase in auditory hallucinations. Other nursing notes at that time state that the voices [Mrs A] was hearing were of a persecutory nature and that she believed members of her family were being harmed. Suicidality did not appear to be a concern, though impulsivity was present. It is also noted that along with non-compliance there had been a change in the diagnosis and the medication prescribed,

which may have contributed to the deterioration. Given this picture and the family's situation, admission was indicated. However [Mrs A] was refusing both admission and respite placement, and it is debatable whether she would have met the requirements for admission under the Mental Health Act [MHA] 1992. Notes indicate family would have also been reluctant to support formal admission.

Usual practice for informal admissions to hospital by community teams requires the community consultant to request this via a written assessment of the client, as only doctors have admission rights. If admission was not possible due to the lack of a bed, then the CMHN would have to explore other options e.g. respite, in consultation with the team. Nursing intervention using powers as a Duly Authorised Officer [DAO] to arrange an assessment under the MHA would be most uncommon and unfeasible without the cooperation of the psychiatrist, in this case [Dr C].

4. Was the plan put in place for [Mrs A's] care on 18 January 2001 appropriate in the circumstances? What support should [the rural hospital's] community mental health nurses have provided to [Mrs A] and her family? Did [the rural hospital's] community mental health nurses act with reasonable skill and care in providing support to [Mrs A] and her family?

[Mrs A] had obviously relapsed, and due to non-compliance with her medication her treatment could only be reinstated gradually. In the absence of admission, prudent crisis care would have included daily or twice-daily nursing visits, as well as experienced respite staff in the home, to manage the client successfully. The notes do not show this level of care being provided. [Ms B's] account of the respite care provided illustrates her dissatisfaction, and it appears the staff member assigned was a nurse aide who found [Mrs A's] care somewhat beyond her.

Standard II of the ANZCMHN standards requires that the 'Mental Health Nurse establishes partnerships as the basis for a therapeutic relationship with consumers' (p.8). Consumer and family satisfaction with this process is one of the performance criteria for the standard. Standard III sees that the nurse should be able to 'Collaborate with consumer, family or whanau, and other colleagues to develop a nursing plan for care' (p.9) [ANZCMHN, 1995]. These competencies were insufficiently met.

5. When a patient is commenced on clozapine, what monitoring should a community mental health nurse acting with reasonable care and skill carry out? What standards apply to the commencement of a patient on clozapine?

The standards that apply to the commencement of clozapine therapy have been developed as a result of the recorded incidence of agranulocytosis in some users. This condition sees the lowering of white blood cell numbers that can leave the user vulnerable to the effects of infection. For this reason clozapine is only available on specialist prescription, and protocol for the management of the drug in New Zealand has been provided by the manufacturer [Novartis]. The company maintains a national

database of clients taking the drug, and requires the monitoring of neutrophil and white cell counts [WBC] for the continuation of supply.

The 'Clozaril Patient Registration' form created by Novartis appears to have been partially completed by [Ms D], though it is signed by [Dr C], as required of the consultant. Only one of the contraindications and precautions listed is ticked.

The Auckland District Health Board policy 'Clozapine — Administration of — Updated November 2003' [ADHB, 2003] and guidelines in Management of Mental Disorders [Andrews, Oakley-Browne, 2000] recommend a baseline full blood count be done, with electrolytes, renal and liver function tests also performed prior to commencement. If these are within normal limits the drug can be given, with weekly blood tests for WBC and neutrophil counts for the first eighteen weeks, monthly thereafter. ADHB policy requires daily recordings of pulse, blood pressure and temperature in the first three weeks of treatment, and thereafter as required by any adverse effects. Given these risks and conditions clozapine is seen as one of the most complex medications in use in the community.

A CMHN could be expected to monitor and record physical signs and symptoms, to ensure that the client had blood tests done, and that they were receiving and taking the medication as prescribed. The initial dose of clozapine is small [e.g. 12.5mg to 25mg daily] and gradually builds up over a period of weeks to a therapeutic dose [between 200 to 450mg]. This changing regime requires oversight to ensure the client and/or the family/supports are able to implement this. Client and family education is therefore a large part of successful treatment. [Ms B's] handwritten complaint [p.8 'A' Health and Disability Commissioner Expert Advice (HDCEA)] shows she believed her mother was being held responsible for having the weekly blood tests done and sourcing the medication, a situation she felt was unrealistic and which proved unsuccessful.

6. Was [Mrs A's] commencement on clozapine monitored with reasonable skill and care by [the rural hospital's] community mental health nurses?

[Mrs A] was commenced on clozapine on the 07/03/2001. There was a delay due to her developing a cold, which daughter [Ms B] reported [the public hospital's treatment and progress notes (progress notes) for Mrs A, entry dated 22/02/2001]. The notes provided show that blood pressure and temperature were taken twice daily for the first week, and daily after that with only two omissions during the three weeks recorded.

[Ms D's] note of 11/04/2001 [the progress notes] indicates she was aware when the required haematological test was not done for that week, and made arrangement for this to happen. [Ms B's] report also mentions problems with getting this done. The summarized laboratory results of the 18/04/01 and 16/05/01 [progress notes] would indicate that weekly blood counts did not occur initially, but were happening from the middle of April onwards. Supply was not interrupted, presumably Novartis was aware.

[Mrs A's] mental state continued to be unstable which is perhaps understandable given the risperidone was being decreased and therapeutic clozapine levels had not been reached. Blood pressure problems and light-headedness had been noticed prior to starting clozapine [progress note entry 05/02/2001]. The notes do not show this being brought to the attention of [Dr C], though his letter of 23/03/2001 [the progress notes] mentions hypotension as a possible side effect. The monitoring and clinical observations show that her blood pressure was down as a result of starting clozapine. Over the three week period of monitoring the systolic and diastolic levels dropped from around 135/80 to 120/70. This hypotension and resulting unsteadiness of gait should have been seen as significant, given that [Mrs A] [was] three weeks into the new regime, when the full dose had yet to be reached. Other factors that should have indicated concern were that her unsteadiness was not limited to getting out of bed in the morning, but occurred 'walking around the house during the day' [the progress note entry 28/03/2001] and [Mrs A's] age.

7. What responsibility do community mental health nurses have for providing information about, and obtaining informed consent to, medications such as clozapine?

Normally it is the prescribing physician's responsibility to inform the client about changes in treatment, and to seek the informed consent required. Nurses have a responsibility outlined in Standard IV of the ANZCMHN standards of practice and are required to 'Assist the consumer, their family or whanau and the community to attain access to accurate and relevant health knowledge' (p.14) [1995].

8. Did [the rural hospital's] community mental health nurses adequately discharge their responsibility for providing information about clozapine to [Mrs A] and her family and obtaining informed consent from [Mrs A] before its commencement?

[Ms D's] note of 19/02/2001 [the progress notes] indicates she home visited and spoke with [Mrs A] and her daughter about the transition to the new medication, though any specific information made available to them is not outlined. The note of 05/03/2001 [progress notes] shows that [Ms B] had obtained consumer information from Novartis. [Ms B] reported that her mother had a cold, which held up the commencement of clozapine, a fact that indicates she had some awareness of relevant risk factors. The nurse therefore knew that [Mrs A] and her family had received information about the transition, and had sourced consumer information on the drug. Consent to treatment is a medical responsibility.

9. What training should a community mental health nurse have before being assigned to monitor a patient's commencement on clozapine?

The training required of a Registered Comprehensive Nurse should be sufficient for a nurse subsequently specializing in community mental health to understand the effects of clozapine, possible adverse effects, and to monitor its use. However the protocol around the drug is sufficiently medically complex that many CMHNs might need to review their knowledge of haematology and the pharmacology of atypical

antipsychotics. The ADHB has provided a specific policy around use of the drug, which requires the collaborative effort of nursing and medical staff in seeing the drug is safely used [ADHB, 2003]. The drug companies themselves take an active role in providing information [at least in the larger centers] with presentations aimed at medical and nursing staff outlining the use of products. It is not clear whether this level of resource was available to [Ms D]. It appears she was being required to oversee the implementation of a complex change in treatment, with little medical or psychiatric support, in an isolated rural area.

10. What actions would a community mental health nurse using reasonable skill and care have taken in response to being notified by [Mrs A's] principal caregiver, [Ms B], that [Mrs A] was becoming increasingly unwell? Did [the rural hospital's] community mental health nurses respond with reasonable skill and care?

The action taken by the CMHN appears influenced by the process of starting clozapine, which required a gradual increase of the dose to therapeutic levels for a client who was unstable, in the absence of regular contact and review with the prescribing psychiatrist. Once this course of action had commenced it would seem reasonable to continue to implement the plan of care, hoping the condition would improve. [Ms D] was aware of the deterioration, and the DAO/Crisis Intervention Reports of 24/03/2001 and 29/03/2001 [the progress notes] show she believed this was because therapeutic levels had not been reached. Mention is made of some deterioration as early as the note entry of the 14/03/2001, while the note of 19/03/2001 [the progress notes] indicates [Ms B] was considering hospitalization. The increased contact with [Mrs A] allowed for ongoing monitoring of her condition, and liaison with the family. [Ms D] made nursing notes every one to five days during the three weeks from starting clozapine to [the public hospital] respite admission. According to [Ms B's] hand written report (p.10 'A' HDCEA) it was the CMHN who organized this, in response to the family's distress. I believe [Ms D] did respond with reasonable skill and care given the complexity of the circumstances.

11. What professional standards apply to documentation by community mental health nurses? Does the documentation made by [the rural hospital's] community mental health nurses in [Mrs A's] case meet those standards? If not, in what manner and to what extent does it depart from standards?

An audit tool has been developed that specifically identifies clinical indicators that demonstrate adherence to the Standards of the ANZCMHN, which has been designed for use in reviewing clients' clinical notes [O'Brien, O'Brien, McNulty, Morrison-Ngatai, Skews, Ryan, et al., 2002]. Competency VIII of nursing skills listed under Standard III of the ANZCMHN requires the mental health nurse be able to 'Document assessment outcomes, nursing management plan, strategies for care and outcome'. Competency XII in the same section says the nurse should be able to 'Evaluate and document the effectiveness of planned interventions in consultation with the consumer, and in collaboration with the multidisciplinary team' (p.11). I believe the nursing notes and the DAO/Crisis intervention reports completed by [Ms D] only

partially meet that standard. It does not appear that all client/family interactions were recorded in the clinical notes. There was no documentation outlining an ongoing plan of care. A 'Comprehensive Mental Health Assessment' and associated 'Risk and Relapse Assessment' form are included in the notes, but are only partially completed and are dated 15/06/2001 [the progress notes] — nine months after the initial referral and after the period that relates to the complaint.

It should be noted that I have had no access to other nursing and clinical notes from [the rural hospital] and therefore [am] are unable to comment on whether this level of documentation was typical and/or acceptable practice within the service at that time. Where they do appear, the nursing notes made on clinical contacts do seem of an appropriate standard. The deficiencies relate primarily to the lack of supporting documentation and planning.

12. In your opinion is it appropriate for community mental health nurses to have the primary responsibility for recording consultations by patients with a psychiatrist including changes in diagnosis and medication?

This aspect of the documentation I find unusual, and it appears to place the nurse in an unsafe position. Surely it is the psychiatrist's responsibility to record their assessment, diagnosis and treatment. The process whereby [Dr C] dictated his notes for them to be written up later in letterform and filed subsequently was inadequate and raises medico-legal issues. [A letter dated 24/05/2001] ['M' HDCEA] mentions four consultations with [Dr C] that were not documented by him in the clinical notes.

13. To what (if any) extent is it appropriate for a medical practitioner to regard community mental health nurses as responsible for assessing the need of a patient to see a psychiatrist?

Where a doctor has not been aware that a client's condition has changed, the CMHN may initiate a consult by bringing this to the doctor's attention. [Mrs A's] case included recent relapse, re-diagnosis, fundamental changes in treatment with addition of clozapine, as well as significant family distress. Knowing this and given the complexity and risk, the expectation would be for the consultant to seek client review himself.

14. Is it appropriate for a medical practitioner to regard community mental health nurses as a patient's principal caregiver?

The term 'principal caregiver' or 'primary caregiver' is more usually used referring to family members, or people involved in direct care, with whom the client may live. The relationship the nurse [Ms D] had in regard to [Mrs A] might better be described as 'key worker', 'case manager' or 'care-coordinator', which acknowledges the realities and responsibility of rural CMHN work. These terms recognize the role the CMHN has in overseeing the provision of care. The doctor prescribing would be seen as the 'responsible clinician', which acknowledges the central role the prescriber has

in the creation, and monitoring, of the medical plan of treatment and care. In health care the term ‘responsible clinician’ is not limited to the definition included in the MHA 1992. These terms imply the collaborative workings of a multidisciplinary team.

15. What responsibility do community mental health nurses have to ensure that a nurse aide employed to provide respite care is providing an appropriate level of support?

The role of the nurse aide in health care delivery has been under review in recent years. The Ministry of Health has led a process of developing competencies for the work of ‘second level nurses/health aid workers’ [Ministry of Health, 2000]. Enrolled nurses are expected to practise under the direction and supervision of a registered nurse, as outlined in the Nurses Act 1977 and Nurses Regulations 1986. Nurse aides are not enrolled nurses, and are one of a number of health worker roles now referred to as ‘Healthcare Assistants’ [ADHB, 2003b] in order to distinguish their role from that of a nurse — ‘enrolled’ or ‘registered’. However it remains a common hospital policy for a registered nurse to ‘monitor the practice of peers and less qualified staff and delegate appropriately’ (p.2) [ADHB 2004].

Mental health care has been seen as an area in which there is no role for the second level nurse [MoH, 2000] due to the difficulties of providing direction and supervision in acute settings, and concerns about client safety. Health aid workers and Healthcare Assistants are presumably seen as similarly unsuitable in this context. Community respite care for the acutely unwell carries the potential for even greater risk than inpatient settings, making it difficult or impossible for CMHNs to effectively monitor less qualified staff or delegate care. In [Mrs A’s] case the evidence from [overseas] was that her behaviour had been difficult to manage in the home environment. This attached some risk to the decision made not to pursue hospital admission in favour of respite in the home. The account given by [Ms B] of the care provided [‘A’ HDCEA] illustrates the consequences of placing an inadequately trained staff member where supervision and direction was effectively inaccessible.

[Mrs A] returned from [overseas] and was seen on the 18/01/2001, when the decision was made to treat her in the home. The plan in the nursing notes was for daily visits by the CMHN, along with changes in medication and increased support from the CSW. However there are no further entries in the record until the 30/01/2001. The documentation provided does include a crisis respite care pack with an assessment, treatment plan, and evaluation form [not completed] dated 23/01/2001 [the progress notes], five days after [Mrs A’s] return from [overseas]. They show a respite worker was to be in place in the home for four days, with daily visits from the CMHN. The only information about this episode comes from the hand written account of [Ms B] [‘A’ HDCEA] and the typed notes of a telephone conversation between the Commissioner’s office and [Ms B] [‘B’ HDCEA]. It appears the family found the respite support so inadequate that the worker was sent home, apparently on the advice of the CMHN. [Ms D] visited ‘her normal 1x –2x –3x weekly visits’ [Mrs A] in ‘A’ HDCEA].

From this it seems clear that the support provided was inadequate. In hindsight the decision to implement respite instead of pushing for admission, and the delay in doing so seem flawed. The appropriate documentation in the clinical notes relating to daily monitoring, assessment, and planning is absent. Given the general unsuitability of this kind of respite arrangement and attendant risk, the nurse would seem to have neglected her responsibility in ensuring that the care and support provided was sufficient to keep the client safe, and minimise negative effects on family.

16. What training should a nurse aide employed to provide respite care to mental health patients have?

The reference group set up by the Ministry to look at developing competencies for second level nurses found that there was no role for these nurses in mental health [MoH 2001]. While their findings acknowledged a role for ‘health aid workers’ in this context employed as ‘community mental health support workers’ [CSWs], it was in supporting service users’ wellness and in their performance of activities of daily living — not respite care for those in crisis.

17. In your opinion, what standards apply to management of a transfer of a patient’s care between community mental health nurses? Were those standards met when [Mrs A’s] care was transferred from [Ms F] to [Ms D] to [Ms J] to [Ms L]?

[The rural hospital’s] mental health nursing team at that time consisted of four CMHNs. From the time of the initial referral in September 2000 to her return from [overseas] [Mrs A’s] case was in the care of [Ms F], a period of around four months. When she returned, [Ms D] and [Dr C] assessed [Mrs A]; according to the notes neither had seen her before. CMHN [Ms H] made the notes outlining the deterioration that occurred overseas. [Ms J] made a number of notes during April and May of 2001. [Ms L] was the CSW, and her input appears to have continued from November 2000 onwards.

Nowhere does in the notes is it made clear that any change in nursing allocation took place, though it appears to have happened once, in January 2001, when [Ms D] took up ongoing care from [Ms F]. [Ms B’s] notes [p.2, ‘A’ HDCEA] mention it was ‘[Ms F’s] last day’, at the time of the consultation with [Dr C] mid November. This explains subsequent reallocation to [Ms D]. Common practice in community settings would be for a change in nurses to be discussed with the service user, and preferably with their caregivers as well. [Ms B] and presumably [Mrs A] were both aware of this change. Given the nature of [the rural hospital’s] service where the same small group of nurses did crisis work and continuing care, the fact they all contributed to [Mrs A’s] casework is not surprising, nor does it indicate significant inconsistency.

Summary

The nursing care provided shows some deficiencies when evaluated against ANZCMHN standards, particularly in regard to documentation of nursing assessment, planning and intervention. The lack of this may have contributed to an underestimation of the level of unwellness in [Mrs A] and the stress this placed on her immediate family. However a number of factors outside the nurses' control contributed to this as well, including that [Mrs A] was not well known to the service, or to the nurse caring for her after her return from [overseas]. Respite options appear to have been inappropriate and under resourced for the purposes for which they were used. What may be considered acceptable standards in metropolitan areas may be unattainable in an area that has long been seen as an isolated and disadvantaged rural area [the DHB, 2003].

My impression is of nurses 'doing the best they could' in this situation, who were not able to rely on an appropriate standard of specialist support — as evidenced by the re-diagnosis and change in medication, the decision not to admit after the decompensation overseas, the implementation of clozapine, and failures in medical documentation and accountability. These factors do not diminish the responsibility of the nurses involved to provide acceptable, professional care. It would be interesting to hear their reflections having worked largely unsupported in this situation. As would be expected the client's clinical notes do not provide these impressions, and unlike [Dr C's] comments in the interview transcript [HDCEA] I have seen no explanation of the nursing care given, in response to the complaint. Nurses in rural areas often work at a level of autonomy that exceeds the recognition, training and support provided to them. Consequently in this case some of the responsibility for any failings must lie also with [the rural hospital], and [the DHB], as funder of that service."

Additional expert advice

Dr Plunkett provided the following additional expert advice on Dr C's submission in response to the provisional opinion (see Appendix 1).

"This is a brief response to matters raised by [Dr C] after receiving the Commissioner's provisional opinion.

Documentation provided:

- HDC briefing letter
- Letter from [Dr C] to the Commissioner dated 13/10/04
- Copy of the Commissioner's full report and provisional opinion

Issue of the Change of Diagnosis:

[Dr C] argues in his letter:

- (a) That he was prompted to change the diagnosis to depression as [Mrs A] displayed some features he interpreted as indicating a mood disorder (anger outbursts, missing her dead husband, believing her children were going to take her back to hospital, agitation, irritability, loud swearing, hallucinations and poor sleep are mentioned). These were causing sufficient concern that he felt something had to be done. He goes on to say ‘her symptoms on the day that I saw her was indicative of a mood disorder (major depression with psychosis (involuntal) melancholia. In partial remission)’.

This does not persuade me that [Mrs A] was indeed displaying symptoms of mood disorder, especially depression. All the symptoms as above can occur in an exacerbation of schizophrenia, and most are not at all typical of a depression. Only her preoccupation with her dead husband, her agitation and poor sleep might possibly be depressive symptoms (but all are relatively non-specific, even so). Persecutory fears about being readmitted, hallucinations, irritability, swearing and anger are not typical.

- (b) That to rediagnose her condition ‘offered more therapeutic options’.

I do not agree that this is the case. There would have been other antipsychotic agents that could have been trialed if [Dr C] wanted to change from the risperidone. Olanzapine for example, another newer atypical antipsychotic, had not at that stage been trialed. [Mrs A] was in any event already being treated with an antidepressant (nortriptyline) so was not being deprived of treatment for possible depressed moods. More importantly, however, it is inappropriate to rediagnose a patient hoping that there may thus be more ‘therapeutic options’ available, if the diagnosis is in fact incorrect. The likely outcome is that the medication tried will be incorrect for the patient’s actual condition, will be less effective, and the patient is not in fact served by a misdiagnosis, however optimistically intended.

- (c) That schizophrenia and major depression lie at the ends of a diagnostic spectrum (presumably meaning that the change in diagnosis was thus justified). [Dr C] quotes passages from the DSM-IV-TR Guidebook regarding this.

I do not overall feel that further debating this issue at length would be particularly helpful. I remain concerned that from [Dr C’s] initial discussion of the matter, he did seem to hold a belief at that time that depression could not occur in patients with schizophrenia, thus leading him to rediagnose her and make major changes to her medication regime. The issue is not so much whether schizophrenia and major depression with psychotic features may lie at opposite ends of a spectrum, but whether a change from one diagnosis to the other was justified, and whether so marked a reduction of antipsychotic medication as a result of this diagnostic change was also justified. As in my prior reports, I do not agree that this was the case. As I have further pointed out in prior reports, even with such a rediagnosis, a major depression with psychosis requires treatment with effective doses of antipsychotic medication,

and it is this issue which is of the greatest concern, not, as the DSM-IV-TR Guidebook itself states, *'the recognized limitations of this diagnostic convention.'*

- (d) [Dr C] has written that he is surprised I did not recognize terms he had used as being typing errors. The letter he dictated regarding the rediagnosis contained the terms 'Major affective disorder (illusionary melancholia)' (by which he has now clarified he meant 'involuntional melancholia'), and 'result remit' (by which I believe he meant 'in partial remission'). I can only say that it appears the Commissioner's office was also baffled by these terms in his letter (in that I was asked to explain them), thus illustrating the problems in clear communication with other professionals that such errors and unclear terminology can cause. The letter was entered into [Mrs A's] file unchecked and uncorrected by [Dr C], and the presence of such confusing terms is thus the responsibility of [Dr C] and forms part of the concern regarding his overall documentation of the case. I have discussed the concept of 'involuntional melancholia' elsewhere and have nothing to add to that aspect of the report.

The use and discontinuation of risperidone

[Dr C] states that DSM IV requires 'the presence of deterioration' for a diagnosis of schizophrenia, and that as he believed [Mrs A] often presented well, he did not feel ongoing antipsychotic medication was required. However he also says she could be 'very ill one day and very well the next' which does not appear to indicate a consistently well state. The issue of [Mrs A] frequently concealing her symptoms from staff due to her fears of being returned to hospital has also previously been mentioned. [Dr C] also mentions his wish to change nortriptyline to Cipramil while discontinuing risperidone. He apparently only planned to reintroduce antipsychotic medication later, 'if needed'. I continue to feel that to risk an extended period of time off antipsychotic medication (or on so low a dose of risperidone as to effectively have ceased this) was very unwise.

I am unclear what [Dr C] means when he states 'all the antidepressants recommended by Dr Plunkett are, like nortriptyline, are fatal in overdose'. I am not aware that I recommended multiple antidepressants in any part of my reports to the Commissioner. If [Dr C] is referring to the family of tricyclic antidepressants being mentioned then I have made it clear that these can be toxic in overdose. Again, this is not the main issue — despite his decision to alter [Mrs A's] antidepressant to citalopram (Cipramil), it was still very important to maintain adequate doses of antipsychotic alongside the antidepressant, and ideally not to alter more than one drug at any one time, so as to be clear about the effects of any change. Deficiencies in these clinical decisions have already been commented on extensively.

Monitoring of Clozapine

I am concerned that [Dr C] states in this section of this letter that as regards commencing clozapine, 'The Clozaril registration sheet contains all the required safety checks requested and it falls on the nurse to make the arrangements with the GPs to do them.' I do not agree that such arrangements should be delegated to nursing staff — they require medical overview and direct contact with the GP by [Dr C] was needed. In the event,

these medical safety checks do not appear to have been properly arranged with the GP or with the nursing staff (eg regarding pulse and ECG recordings).

[Dr C] also states that [Mrs A's] pulse was taken 'on every occasion that blood pressure was recorded. Without taking the pulse, blood pressure cannot be recorded.' This is not necessarily correct. Some modern digital blood pressure devices do record pulse as well as blood pressure, and if such a device were used, recordings of the pulse should have been placed in [Mrs A's] hospital case notes — which they were not. Older models of sphygmomanometer do not automatically register the pulse, and a nurse taking blood pressure would not automatically count the pulse while listening through a stethoscope so as to record blood pressure — taking an accurate pulse requires digital palpation of the pulse whilst timing with a watch. It appears that [Mrs A's] daughter did not witness this occurring. Again, it was [Dr C's] responsibility to ensure that nursing staff knew which recordings to take, took such recordings, and that they recorded these in the file, so that he could check the recordings regularly.

These are the only comments I feel it is useful to make regarding [Dr C's] letter. Nothing in his letter would cause me to alter my prior reports.”

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 the services provided that comply with legal, professional, ethical, and other relevant standards.*

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

(b) An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs or each option; and

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

(e) Any other information required by legal, professional, ethical, and other relevant standard; ...

RIGHT 7

Right to Make and Informed Choice and Give Informed Consent

- 1) Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.*
-

Other Relevant Standards

The following standards are relevant to this complaint.

Medical Council of New Zealand *Guidelines for the maintenance and retention of patient records* (August 2001):

“Introduction

Records form an integral part of any medical practice; they help to ensure good care for patients and also become critical in any future dispute or investigation.

...

2. Maintaining patient records

- (a) Records must be legible and should contain all information that is relevant to a patient’s care.
- (b) Information should be accurate and updated at each consultation. Patient records are essential to guide future management, and invaluable in the uncommon occasions when the outcome is unsatisfactory.”

Medical Council of New Zealand *Statement on Information and Consent* (April 2002):

“ ...

Doctors must ensure that a decision not to consent, or to withhold consent is noted in the patient’s health record, with a summary of information given to the patient.

... ”

The Medical Council recognises that every aspect of a consultation cannot realistically be noted in the patient’s record. However Council also recognises the importance of full and detailed records. As a result Council recommends that doctors adopt written consultation protocols that specify what information in the form of discussion, publications and questions will be given in a specific type of consultation (eg all patients experiencing migraines). ...”

Novartis Datasheet for Clozaril (February 2001):

“Clozaril can cause agranulocytosis. Its use should be limited to patients with schizophrenia.

- who are non-responsive to or intolerant of classical neuroleptic drug treatment,
- who have initially normal leukocyte findings (white blood cell count (3.5 x 10/L, normal differential blood count), and
- in whom regular white blood cell (WBC) counts (ANC) (weekly during the first 18 weeks, at least monthly thereafter throughout treatment, and for 1 month after complete discontinuation of Clozaril) can be performed.

Prescribing physicians should comply fully with the required safety measures. At each consultation, a patient receiving Clozaril should be reminded to contact the treating physician immediately if any kind of infection begins to develop. Particular attention should be paid to flu-like complaints such as fever or sore throat and to other evidence of infection, which may be indicative of neutropenia. ...

Persons prescribing clozapine must comply with the requirements of the New Zealand Guidelines for the use of Atypical Anti-Psychotic Drugs and the requirements of local Hospital and Health Service Protocols for use of Clozapine. ...

CLINICAL PARTICULARS

Therapeutic Indications

Treatment with Clozaril is indicated in patients with treatment resistant schizophrenia only ie patients with schizophrenia who are non-responsive to or intolerant of classical neuroleptics.

Non-responsiveness is defined as a lack of satisfactory clinical improvement despite the use of adequate doses of at least two marketed neuroleptics prescribed for adequate durations.

Intolerance is defined as the impossibility of achieving adequate clinical benefit with classical neuroleptic drugs because of severe and untreatable neurological adverse reactions (extrapyramidal side effects or tardive dyskinesia).

DOSAGE AND METHOD OF ADMINISTRATION

The dosage must be adjusted individually. For each patient the lowest effective dose should be used. Dose adjustment is indicated in patients receiving drugs interacting with Clozaril, such as benzodiazepines, or selective serotonin re-uptake inhibitors ...

Starting therapy: 12.5mg ... once or twice on the 1st day followed by one or two 25mg tablets on the 2nd day. If well tolerated, the daily dose may then be increased slowly in increments of 25mg to 50mg in order to achieve a dose level of up to 300mg/day within 2 to 3 weeks. Thereafter, if required, the daily dose may be further increased in increments of 50mg to 100mg at half weekly or, preferably, weekly intervals. ...

Maintenance dose: After achieving maximum therapeutic benefit, many patients can be maintained effectively on lower doses. Careful downward titration is therefore recommended. Treatment should be maintained for at least 6 months. If the daily dose does not exceed 2000mg, once daily administration in the evening may be appropriate. ...

Switching from a previous neuroleptic therapy to Clozaril: When Clozaril therapy is to be initiated in a patient undergoing oral neuroleptic therapy, it is recommended that the other neuroleptic should first be discontinued by tapering the dosage downwards over a period of approximately one week. Once the neuroleptic has been completely discontinued for at least 24 hours, Clozaril treatment can be started as described above.

It is generally recommended that Clozaril should not be used in combination with other neuroleptics. ...

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Special precautionary measures: Because of the association of Clozaril with agranulocytosis, the following precautionary measures are mandatory: ...

WBC counts and ANC monitoring: Before starting Clozaril treatment, a WBC count and a differential blood count must be performed within 10 days prior to Clozaril treatment to ensure that only patients with normal leukocyte count and normal absolute neutrophil count (WBC count $\geq 3.5 \times 10^9/L$ and ANC $\geq 2.0 \times 10^9/L$) will receive the drug. After the start of Clozaril treatment the WBC count and, ANC must be monitored weekly for 18 weeks and thereafter at least monthly throughout treatment, and for 1 month after complete discontinuation of Clozaril. At each consultation, the patient should be reminded to contact the treating physician immediately if any kind of infection, fever, sore throat or other flu-like symptoms develop. An immediate differential blood count must be performed if any symptoms or signs of an infection occur. ...

OTHER PRECAUTIONS

... Orthostatic hypotension, with or without syncope, can occur with Clozaril treatment. Rarely (about one case per 3000 Clozaril treated patients) collapse can be profound and

may be accompanied by cardiac and/or respiratory arrest. Such events are more likely to occur during initial titration in association with rapid dose escalation; on very rare occasions, they occurred even after the first dose. Therefore, patients commencing Clozaril require close medical supervision. ...

ADVERSE EFFECTS ...

CENTRAL NERVOUS SYSTEM

Fatigue, drowsiness and sedation are among the most common side effects observed. Dizziness or headache may also occur.

PHARMACOLOGICAL PROPERTIES

PHARMACODYNAMIC PROPERTIES ...

Clinically Clozaril produces rapid and marked sedation and exerts strong antipsychotic effects. ...”

Royal Australian and New Zealand Clinical College of Psychiatrists Clinical Practice Guidelines *Summary of guideline for the treatment of depression* Vol 11, No 1 (March 2003):

“ASSESSMENT

Assessment should include full evaluation and formulation, including particularly:

- risk assessment;
- subtype, severity and duration of depression;
- comorbidity (with medical and/or psychiatric and/or alcohol and drug);
- current stressed, strengths and supports; and
- relevant personal and family history, and past history of any mental illnesses

SUMMARY OF TREATMENT EVIDENCE

The evidence supports the following treatments provided as part of an overall clinical management plan. Every person with depression is an individual facing uniquely different circumstances. Their treating clinicians should consider the extent to which the available evidence is pertinent to the treatment of this individual.

Components of an effective treatment plan include:

- a therapeutic relationship, which is essential to maximize benefits of treatment;
- treatment alliances with patient, family/friends, primary care providers, other mental health professionals; and
- access to cultural and primary language services.

Psychotic depression, severe depression with risk of suicide

Care should be provided by specialist mental health services until stabilised, and then continuing consultation liaison with primary care services. Treatment options are outlined in Figure 3.”

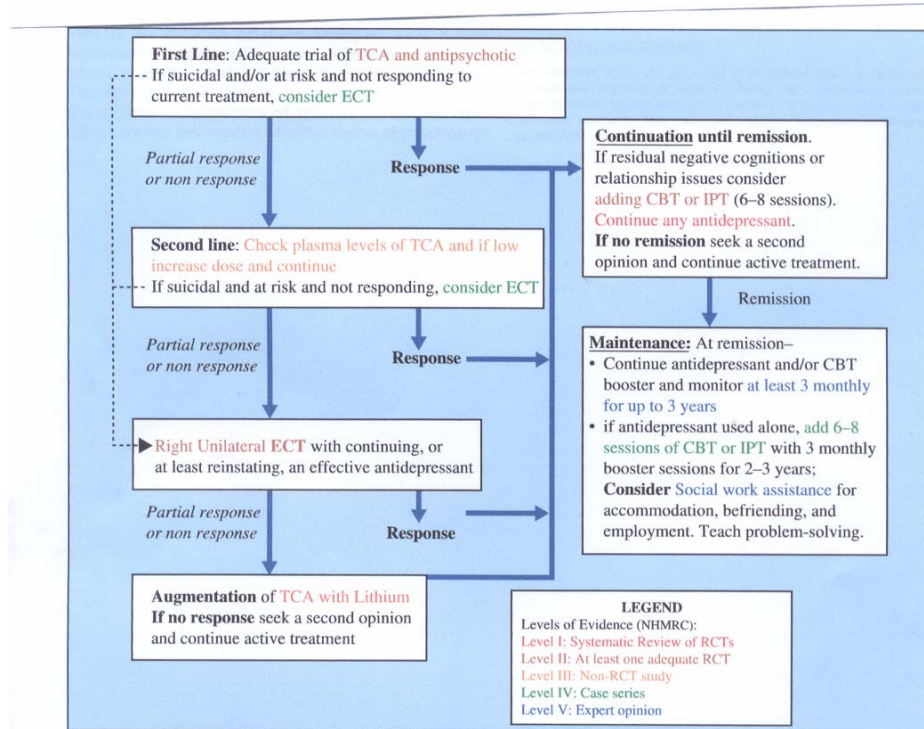


Figure 3: Main options for the treatment of psychotic depression.

A Guide to the Clinical Use of Novel (Atypical) Antipsychotic Drugs in New Zealand, (3rd ed, January 2002):

“CLOZAPINE

This antipsychotic agent has proved its place in the management of ‘treatment resistant schizophrenia’. ...

Indication

Treatment resistant schizophrenia

Patients who are non-responsive to, or intolerant to other antipsychotics. The decision to use clozapine in treatment resistant schizophrenia should be based on the severity of the illness, complications and side effects.

- a. Non-responsiveness. Clinicians often differ in their opinions as to how treatment resistance should be defined. Most agree that if a patient fails to adequately respond to two different antipsychotic drugs over a period of time, treatment resistance should be considered, providing that factors like non-compliance, negative therapeutic environment, inadequate dose, inadequate duration of treatment and coexisting organic pathology are ruled out.

- b. Intolerance: Emergence of intolerable side effects such as EPS (parkinsonism, akathisia, dystonia or tardive dyskinesia), hyperprolactinaemia. ...

Guidelines for initiating clozapine treatment:

A Steps before commencing clozapine

- i Patients should be well informed about the rationale behind the decisions to initiate clozapine treatment. The clinical benefits and potential risks involved should be clearly highlighted. Patients and caregivers should be well informed that compliance with clozapine treatment and adherence to blood monitoring programme are two conditions upon which the decision to prescribe clozapine rests.
- ii ...
- iii Physical examination — baseline full blood count (FBC), liver function tests (LFT), urea and electrolytes (U&Es), fasting blood sugar, weight, blood pressure and temperature. A baseline ECG is recommended. The initial FBC cannot be earlier than 7 days prior to initiation of clozapine treatment.
- iv ...
- v Clozapine treatment can be initiated in the hospital or community. An adequate level of monitoring and supervision must be provided. Dose titration in the community should be done slowly and patients' physical conditions should be closely monitored for at least the first 2 weeks of treatment. This includes daily monitoring of BP, pulse and treatment.
- vi ...

B Initial treatment phase (18 weeks)

- i Initial dose
12.5mg once daily on the first day, followed by 25mg on the second day. If the treatment is well tolerated, the dose may be increased by 12.5mg to 25mg per day. The rate of increase is to be guided by the level of patient tolerance and the co-existence of any physical conditions. Elderly patients may need to be started on even smaller doses and have a slower titration rate.
- ii Therapeutic dose range
In most patients antipsychotic efficacy can be expected with 200–450mg/day, given in divided doses, or a single dose at night. Some patients may be treated with lower doses and others may require doses up to 600mg/day. ... Maximum permitted dose is 900mg/day. ...
- iii Weekly FBC (white blood count and differential) must be performed for the first 18 weeks of treatment. Liver function tests (LFT's) must be performed

one month following initiation of treatment and 6 monthly thereafter unless there are clinical indications for more frequent liver function testing.

iv Physical recordings

Temperature, blood pressure and pulse should be measured and recorded at least once daily during the first two weeks of treatment. Monitoring of physical signs might need to be performed more frequently or for longer than two weeks if any abnormalities are detected during the treatment process. ECG should be performed if the clinical condition indicates.

v Liaison with the patient's General Practitioner should be established and remain in place throughout the treatment process. ... ”

Opinion: Breach — Dr C

Change in diagnosis from schizophrenia to major depression with psychotic features

Ms B complained that:

“... in October 2000 ... [Dr C] inappropriately re-diagnosed [Mrs A], on the basis of inadequate information and without adequately taking into account her almost 30-year history of paranoid schizophrenia.”

Change in diagnosis

On 19 October 2000 Dr C changed Mrs A's diagnosis from schizophrenia to a diagnosis that he has variously described as “mood disorder with psychosis (melancholia)”, “major affective disorder with psychosis” and “major affective disorder with involuntional melancholia” (the new diagnosis).

Information available to Dr C in October 2000 prior to change in diagnosis

Information available to and reviewed by Dr C is significant in determining the adequacy of his assessment of Mrs A before he changed her diagnosis on 19 October 2000.

Dr C initially said that he had reviewed Mrs A's patient records but he was uncertain whether he did so before or after his first consultation with Mrs A on 19 October 2000. He said:

“I saw two files [relating to Mrs A] in addition to her [rural hospital] file. Whether it is immediately before I saw her or immediately after I saw her, what that timeframe is, I'm not quite certain.”

Later, in response to my provisional opinion, Dr C said that he initially saw Mrs A at home and:

“since I had her notes I would have read them either before or after seeing her. It is my practice to first examine a patient and form my own opinion before I read all of the historic notes.”

Ms B said that following her first contact with the rural hospital Ms F visited and had Mrs A sign forms for the release of her files from the Community Mental Health Centre (CMHC). This probably occurred during Ms F’s visit on 6 September 2000, but there is no reference in Mrs A’s rural hospital record of the release being signed or her records being requested from the CMHC.

In my assessment, Dr C certainly had Dr G’s letter of 28 August 2000 when he first saw Mrs A, since Ms B recalls him having a faxed letter at the consultation. Dr C may also have had a copy of Mrs A’s CMHC files. I think it unlikely that he had a copy of the day clinic file since there is no record of the rural hospital requesting Mrs A’s day clinic file until 2001.

Even if Ms F did request the the CMHC’s files and they arrived before the consultation on 19 October 2000, I think it is unlikely that Dr C would have had time to review them in any depth before the consultation. Dr C would not have seen any of the material relating to Mrs A until he arrived at the rural hospital to conduct his clinic on the morning of 19 October 2000. He would have had other patients to see during the morning before seeing Mrs A. In addition, there is evidence that the morning was a busy one for Dr C as Ms B said that the clinic was running at least half an hour behind that day. It therefore seems unlikely that Dr C had the opportunity to review Mrs A’s files closely before this consultation.

I cannot determine exactly what information Dr C had reviewed before his first consultation with Mrs A on 19 October 2000 given the uncertain state of the evidence. However, Dr C’s opportunity to review whatever information was available before the consultation would have been relatively limited given the factors I have outlined above.

I note also that Dr C did not refer to any past clinical records in his letter of 19 October 2000 and the letter contains only very sparse historical details which in my own, and in Dr Plunkett’s, assessment look as though they have been gathered from Mrs A herself during the consultation. In my opinion, these two factors point to Dr C having had only a limited opportunity to review the files.

Dr Plunkett advised me that one of the standards applying to a consultant psychiatrist is:

“Particularly prior to altering a longstanding rediagnosis, the need to obtain as much collateral information as possible:

i from past clinical records.”

I am not satisfied that Dr C met this standard. It is not clear that he had Mrs A’s past clinical records or that he had the opportunity to review them carefully before taking the significant step of altering her longstanding diagnosis (which I consider Dr C was aware of, for the reasons set out below). Even if Dr C did have the opportunity to review Mrs A’s records

before the consultation, his own evidence is that he prefers to examine a patient and form his own conclusions before reviewing the patient's historical notes.

In my opinion, Dr C failed to provide services to Mrs A with reasonable care and skill when he failed to conduct an adequate review of Mrs A's past clinical records before changing her diagnosis.

Information from sources other than Mrs A

Dr Plunkett advised me that before altering a longstanding diagnosis, a consultant psychiatrist should, with the patient's permission, obtain as much collateral information as possible from the patient's key family members, and particularly from the primary caregiver.

Ms B was Mrs A's primary caregiver in October 2000 and had been closely involved in her care for more than 20 years. Ms B accompanied Mrs A to the consultation on 19 October 2000 yet Dr C, according to Ms B, did not seek any information from her about her mother's current mental state or history.

Dr C acknowledged that he may not personally have obtained a significant amount of information from Ms B, however Ms F had met with both Mrs A and Ms B and conveyed the information she gathered to him. I accept that it was appropriate for Dr C to rely to some extent on Ms F to obtain and relay information from Ms B, however he should also have sought information from Ms B himself. This would have enabled him to obtain details of Mrs A's mental state and history (including the frequency and nature of her symptoms) and to verify information passed on to him by Ms F.

Dr C also felt that it would not have been useful to seek information from Ms B in her mother's presence, particularly given the high levels of emotion Ms F had noted in the family. While I accept that the process of obtaining information from family members must be conducted with sensitivity and respect, I regard Dr C's failure to obtain information personally from Mrs A's daughter as a serious omission particularly because, as Dr Plunkett noted, Mrs A:

“... tended to hide psychotic symptoms such as ‘voices’ from doctors due to a fear of readmission to hospital, but did display these symptoms to her family. Collateral information from [Ms B] would therefore have been an important way to gather information about the frequency and nature of these symptoms.”

If Mrs A's condition made it inappropriate to seek information from her daughter in her presence, arrangements could and should have been made to meet with Ms B separately.

In my opinion, Dr C did not provide services to Mrs A with reasonable skill and care, and in compliance with the standards applying to a consultant psychiatrist, when he failed to obtain information from her daughter and primary caregiver before changing a longstanding diagnosis.

Dr C aware of longstanding diagnosis of schizophrenia

Although I have concluded that Dr C may not have had all of Mrs A's clinical records available to him and that he did not conduct an adequate review of Mrs A's past clinical records, it is clear that Dr C *was* aware that Mrs A had been diagnosed as suffering from paranoid schizophrenia for more than 20 years, with episodes of depression at various times. Dr C stated, in his response to the provisional opinion, that he was aware that Mrs A had been diagnosed as a paranoid schizophrenic 30 years before he met her.

If Dr C is right in saying that he had also reviewed Mrs A's files and it was the CMHC's files that he reviewed, then he had a substantial amount of information about her history and treatment — all of it premised on a primary diagnosis of paranoid schizophrenia. While Mrs A had been treated for depression periodically, the primary diagnosis of paranoid schizophrenia had never been displaced.

Even if Dr C had seen only Dr G's letter, he was on notice that Mrs A had a longstanding diagnosis of schizophrenia and that in changing her diagnosis he was departing from a diagnosis that had been in place for many years, because Dr G's letter described in some detail Mrs A's diagnosis and history.

Timing of change in diagnosis

In my opinion, Dr C made the change to Mrs A's diagnosis at the consultation on 19 October 2000.

Ms B stated that Dr C decided to change the diagnosis on 26 October 2000; however, I think that the evidence points to the decision being made on 19 October 2000. Dr C's letter of 19 October to Dr E records the new diagnosis as "major affective disorder ([involuntal] melancholia)" and his plan to phase out the risperidone and nortriptyline and introduce Cipramil. Dr C therefore made the decision to change Mrs A's diagnosis on the basis of a single consultation and his review of whatever records he had available to him prior to 19 October 2000.

During my investigation, Dr C said that he "did not categorically change [Mrs A's] diagnosis". In my view, however, his letter of 19 October 2000 and the substantial changes he made to Mrs A's treatment indicate that he did change her diagnosis on 19 October 2000. While Dr C may have been prepared to review his assessment depending on Mrs A's response to the new medication regime, that does not alter the fact that he changed Mrs A's diagnosis on 19 October 2000.

Assessment at consultation on 19 October 2000

Dr Plunkett advised me that before making a rediagnosis, a psychiatrist must "carry out a careful clinical assessment and review of the patient's history and mental state".

It is difficult to assess whether Dr C carried out a careful clinical assessment of Mrs A at the 19 October 2000 consultation because he did not make any clinical notes. However, Ms B said that this consultation lasted about 20 minutes and during it Dr C asked Mrs A how she was feeling.

Dr Plunkett advised me that “twenty minutes would not be sufficient time for a careful assessment to have occurred. ... Dr C thus did not meet a reasonable standard in this respect.”

In response to my provisional opinion, Dr C stated:

“It is not correct that I only spent 20 minutes, as [Ms B] has stated. I need at least 40 to 50 minutes time to build rapport and gain a patient’s confidence to the extent that [Mrs A] would tell me about missing her late husband (for example).”

There is, therefore, a conflict between the evidence of Ms B and that of Dr C as to the length of the consultation.

It seems that Dr C did obtain some background information about Mrs A’s illness, as in his letter of 19 October 2000 he noted Mrs A’s history as follows:

“... she was subsequent to her husband’s death and the passing away of both her parents ... admitted to [the psychiatric unit] with a depression. Subsequent to this she also developed voices talking to her and saying non-specific derogatory things ...

When her husband died the family went through [dire] straits and it is possible that she was annoyed with her former partner dying but also developed [guilt] feelings about it which could have formed the basis for her derogatory voices.”

In my opinion, notwithstanding the conflicting accounts of the length of the consultation, it is unlikely that Dr C carried out a full and careful assessment of Mrs A at the 19 October 2000 consultation. His letter recording the consultation contains only sketchy details of her history, and he did not obtain information from Ms B. Dr Plunkett advised that these elements — a detailed history and information from relatives/caregivers — are essential to the assessment of a new patient, particularly before making a significant change in diagnosis.

In failing to assess Mrs A adequately before making major changes in her diagnosis and treatment regime, Dr C failed to provide services to Mrs A with reasonable care and skill.

New diagnosis

In his letter of 19 October 2000, Dr C stated that Mrs A’s diagnosis was “major affective disorder (illusionary melancholia) result remit”. During my investigation Dr C said that this was a typist’s error and that the diagnosis he had dictated and intended be recorded in that letter was “major affective disorder with involution melancholia, in remission or in partial remission”.

Dr C did not suggest that the phrase “major affective disorder (illusionary melancholia) result remit” was a typist’s error when he discussed Mrs A’s diagnosis and treatment with Dr K in September 2001 or in any correspondence with my Office prior to his interview in April 2004. More recently (in his letter of 11 June 2004) Dr C said that his diagnosis was mood disorder with psychosis (melancholia).

In any event, the presence of such confusing terms in the letter is Dr C's responsibility as the author of the letter. The letter appears to have been entered into Mrs A's patient record unchecked and uncorrected by Dr C. In my opinion, this does not amount to good clinical practice and created the potential for misunderstanding and consequential risk for Mrs A.

Use of outdated diagnostic terms

Dr Plunkett specified that one of the standards applying to a consultant psychiatrist making a rediagnosis was (Dr Plunkett's emphasis):

"The need to be fully conversant with the main diagnostic systems in use in the country where the psychiatrist is working, and to apply these appropriately in making the diagnosis."

Dr Plunkett stated:

"It is difficult for me to be reassured that [Dr C] was fully conversant with the main diagnostic systems in use in New Zealand mental health, or that he applied these appropriately to [Mrs A]. The term he used in rediagnosing her is not part of any recognized diagnostic system (neither the DSM IV nor ICD10 systems, both of which are in use in NZ).

... The DSM IV is the diagnostic system in widest use in New Zealand and is the official diagnostic system for Ministry of Health statistics regarding mental disorders. A few European-trained psychiatrists prefer to use ICD10 terminology (the system is used in Britain). Either system would be acceptable, although the DSM IV system would reduce the possibility of miscommunication with other clinicians."

According to Dr Plunkett, involuntional melancholia is:

"... an outdated concept which was a subcategory of the DSM II but had been deleted in the previous DSM III version and which was in ICD-9, but is no longer in the current ICD-10 version. This means that it was removed from the DSM diagnostic system in 1980, and from the ICD diagnostic system after 1992.

The term 'involuntional melancholia' referred to a moderately severe depressive illness, occurring later in life. It was believed partly to be caused by hormonal changes in women in the post-menopausal phase, but was also occasionally diagnosed in males, so thinking about the cause appears to have been unclear at times. ...

[It is] essentially [the same thing as mood disorder with psychosis]. ... the literature does not support a diagnostic entity called 'involuntional melancholia' which is distinct from major depression. As the old concept of 'involuntional melancholia' generally implied a more severe depression, it was said to be associated with melancholic symptoms or with psychosis. It thus might have been used to refer to a major depression with psychosis, generally in a post-menopausal woman. Please note however that there is no diagnostic entity in the DSM called 'mood disorder with psychosis'. The DSM specifically divides

Mood Disorder categories into major depression or bipolar disorder, either of which can be associated with psychosis, if they are severe.”

Dr C’s diagnosis of major affective disorder with involuntional melancholia can be criticised on a number of grounds:

- The term “involuntional melancholia” was removed from the DSM diagnostic system after 1980 and from the ICD diagnostic system after 1992 so that when Dr C assessed Mrs A as suffering from involuntional melancholia in 2000, he was using a diagnostic term that had not been current for at least 8 years.
- According to Dr Plunkett the term “involuntional melancholia” was removed from the DSM and ICD systems because of concern that “no distinct clinical difference could be found between patients with major depression as such and so-called ‘involuntional melancholias’.” In continuing to use the term to diagnose his clients, Dr C gave the appearance of being either unaware of the changes in diagnostic practice and classification or of being careless of those changes.
- Dr Plunkett advised me, and Dr C accepted, that the diagnostic system in use in New Zealand in 2000 was DSM IV. In failing to give Mrs A a diagnosis provided for under DSM IV, Dr C again created the potential for confusion and misunderstanding on the part of others involved in Mrs A’s treatment, as well as for her family.
- It is axiomatic that approaches to diagnosing patients in any discipline will change during the professional lifespan of a doctor and that a doctor must continue to adapt and develop his or her practice in response to new approaches. Dr C’s use of an outdated term like “involuntional melancholia” suggests that he has failed to keep up-to-date.

In response to my provisional opinion, Dr C stated:

“The diagnosis ‘major affective disorder with involuntional melancholia in partial remission’ is a current diagnostic term with the provision that the word involuntional is not often used. I wanted to use it in this case because I wanted to illustrate her involvement with her late husband, as part of her symptomatology. I therefore put it in brackets. This, thus indicates that I am well aware of the change in the diagnostic system.”

My expert advisor, Dr Plunkett, reviewed Dr C’s response but was not persuaded that Mrs A was indeed displaying symptoms of mood disorder, especially depression. Symptoms such as Mrs A’s angry outbursts, missing her dead husband, believing her children were going to take her back to hospital, irritability, agitation, loud swearing, hallucinations and poor sleep can occur in an exacerbation of schizophrenia and most are not at all typical of a depression.

Dr C’s more recent suggestion that his diagnosis was mood disorder with psychosis (melancholia) can be criticised on similar grounds given Dr Plunkett’s advice that “there is no diagnostic entity in the DSM called ‘mood disorder with psychosis’”. Again it appears that Dr C was either unaware, or careless, of the DSM IV diagnostic system and was using

his own idiosyncratic approach to diagnosis. In doing so, he created potential for misunderstanding and confusion among Mrs A's family and other mental health professionals involved in her care.

It is also concerning that Dr C's suggestion that his diagnosis of mood disorder with psychosis was made as late as June 2004. His changing explanations indicate that Dr C had not arrived at a clear diagnosis on 19 October 2000 but nevertheless made significant changes in Mrs A's treatment.

In response to my provisional opinion, Dr C also suggested that he changed Mrs A's diagnosis so that additional options would be available for her treatment. Dr Plunkett did not agree that the change in diagnosis had this effect and advised that it is inappropriate to change a diagnosis as a means of accessing additional therapeutic options. She stated:

“There would have been other antipsychotic agents that could have been trialled if [Dr C] wanted to change from the risperidone. Olanzapine for example, another newer atypical antipsychotic, had not at that stage been trialled. [Mrs A] was in any event already being treated with an antidepressant (nortriptyline) so was not being deprived of treatment for possible depressed moods. More importantly, however, it is inappropriate to rediagnose a patient hoping that there may thus be more ‘therapeutic options’ available, if the diagnosis is in fact incorrect. The likely outcome is that the medication tried will be incorrect for the patient's actual condition, will be less effective, and the patient is not in fact served by a misdiagnosis, however optimistically intended.”

In my view, Dr C did not provide services of an appropriate standard in concluding that Mrs A's diagnosis was either “major affective disorder (illusionary melancholia) result remit” or mood disorder with psychosis (melancholia). In diagnosing Mrs A, Dr C should have arrived at a diagnosis that fitted within the DSM IV diagnostic system, or at the least, within the ICD10 system. His failure to do so and his use of outdated diagnostic terms amounts to a failure to provide services to Mrs A in accordance with relevant standards.

Appropriateness of change in diagnosis

A primary objective of my investigation has been to determine why Dr C changed Mrs A's diagnosis and whether he was clinically justified in doing so.

It has, however, been difficult to establish the grounds on which Dr C changed Mrs A's diagnosis. Not only did Dr C fail to make any notes recording his reasoning, when he was later asked to explain the change, he put forward several different reasons.

When asked to advise on Mrs A's diagnosis, Dr Plunkett noted Mrs A's documented history of delusions of reference, persecutory delusions and derogatory auditory hallucinations. She also noted that Dr G's referral letter of 28 August 2000 stated that Mrs A had been treated for “schizophrenia, paranoid type or schizoaffective disorder” for over 30 years and had experienced “passivity delusions” when more unwell. Dr Plunkett stated:

“This pattern of symptoms is not indicative of a major depression, even one with psychotic features, as passivity delusions are far more likely to occur in schizophrenia or

a schizoaffective disorder. There was also a clear history of intermittent depressive symptoms which had required antidepressant treatment in the past, and [Dr C] apparently told [Dr K] that he did not accept ‘co-morbidity of depression and schizophrenia’ so as he believed [Mrs A] to be depressed he did not agree with the diagnosis of schizophrenia. He also, however, told [Dr K] that he would ‘entertain schizoaffective disorder’ as a diagnosis. (Schizoaffective disorder is a long-term condition which includes mood symptoms as well as symptoms of schizophrenia.) However, he appears not to have actually made a diagnosis of a schizoaffective disorder (which would require treatment with both antipsychotic and antidepressant medication). ...

In my opinion, based on the clinical records available to me and, apparently, to [Dr C] when he made this rediagnosis, ‘Major Depression with psychotic features’ was not an appropriate diagnosis based on [Mrs A’s] documented past history and symptoms. I think it far more likely that her diagnosis was that of Schizophrenia (paranoid type) with intermittent episodes of depressive symptoms, or a Schizoaffective Disorder.”

In her additional advice, Dr Plunkett stated:

“... it is unlikely that [Mrs A’s] symptoms and history can be explained entirely by a diagnosis purely of mood disorder. However, a diagnosis of schizoaffective disorder is possible. Clarifying this diagnosis would require a careful assessment and history-taking with [Mrs A], and a detailed review of her past records. The referral letters and past records that were available to me ... were clear that her past diagnosis was of schizophrenia or of schizoaffective disorder, and while episodes of depression were mentioned, a mood disorder per se was not felt to be her sole diagnosis. In the case notes and even in the [transcript of an interview of [Dr C] conducted under s 62 of the Health and Disability Commissioner Act 1994] she is at times described as well in her moods yet still experiencing hallucinations. This does not occur in a pure mood disorder — either in a bipolar disorder or a major depression with psychosis. In a schizoaffective disorder, the patient has features of schizophrenia as well as of mood disorder, and schizoaffective disorder is distinguished from a mood disorder or from pure schizophrenia by the following criteria:

‘During the same two period of illness, there have been delusions or hallucinations for at least 2 weeks in the absence of prominent mood symptoms.

Symptoms that meet the criteria for mood disorder are present for a substantial portion of the total duration of the active and residual periods of the illness.’

In my judgement, from the records that have to date been provided to me, [Mrs A] is most likely to have had a diagnosis either of a schizoaffective disorder or of schizophrenia as such. She certainly had, it appears, periods when her moods were relatively normal yet psychotic symptoms persisted. I am unable to determine whether her bouts of depression were sufficiently frequent to meet the criteria for schizoaffective disorder, or whether these indicated schizophrenia complicated by intermittent depressed episodes.

The main reason for elaborating this issue regarding the diagnosis is that in my opinion [Mrs A] did have a significant chronic psychotic illness — either schizophrenia or a schizoaffective disorder.”

With respect to Mrs A’s episodes of depression, Dr Plunkett also stated:

“I agree that [Mrs A] appears to have suffered from significant episodes of depression. ... [T]his appears to have led to some confusion regarding the diagnosis, as [Dr C] appears to have felt that [Mrs A] had to have either schizophrenia per se or major depression (or possibly a bipolar disorder). Technically this is correct as the DSM IV states that significant episodes of what appear to be major depression, occurring in a patient with definite schizophrenia should not be called ‘major depression’ but rather called ‘depression NOS’ (not otherwise specified). In fact, as in my initial report, significant episodes of depression occurring in patients with schizophrenia are quite common, and do not necessarily mean that the patient does not have schizophrenia or that the diagnosis should be altered.

... I do not ... feel (from the information provided to me to date) that her symptoms can be explained entirely by a pure mood disorder such as major depression or bipolar disorder.”

In response to my provisional opinion, Dr C stated:

“There are many indications from [Mrs A’s] presentation and her medical records that would urge one to look closely at the diagnosis of one of the mood disorders (major depression or ‘*major affective disorder*’ with melancholia or depression with psychosis, terms used for the same condition, however you wish to describe it, all being ways to do so). And this leads the authors to conclude: There is an on-going debate ‘*about the degree to which Schizophrenia and Psychotic Mood Disorders are qualitatively distinct conditions versus being different aspects of the same dimension.*’ DSM IV Guidebook P173 Para 4.

Dr Plunkett’s suggestion of a schizoaffective disorder is one way of attacking a diagnosis of schizophrenia. While I agree with her to that end, I refer you to page 173 of the DSM IV Guidebook (Copy attached). ‘*The decision in DSM IV was to restrict the diagnosis of schizo-affective disorder to a given (single) episode. This was intended to increase the reliability of the diagnosis but can result in a somewhat strange situation of an individual sequentially presenting with fairly similar symptom patterns that are nonetheless labeled as episodes of Schizoaffective Disorder, episode of Schizophreniform Disorder or as psychotic mood episodes.*’ (And Dr Plunkett says there are not such terms in the DSM IV!)

To say that I hold the view that patients with schizophrenia cannot become depressed is quoting me wrongly. I said that a patient with schizophrenia who becomes depressed is a red light because of the caveat in DSM IV re diagnosing depression and schizophrenia simultaneously, and because they tend to commit suicide.

The difficulties attached to the diagnosis Dr Plunkett suggested, schizoaffective disorder, is referred to above. It is *inter alia* supposed to be a diagnosis restricted to a single episode. It however often offers an easy way out ... 'just call it both', but it is difficult in a longitudinal perspective to be correct because you do not know how long the previous episodes were."

Dr Plunkett reviewed Dr C's response to the provisional opinion but was not led to change her advice that Dr C's rediagnosis of Mrs A was inappropriate. Dr Plunkett emphasized that, in any event, a rediagnosis of major depression with psychosis requires treatment with effective doses of antipsychotic medication and Dr C did not prescribe such treatment for Mrs A.

I accept that Mrs A did have periods when she was depressed and that she had been prescribed antidepressants when Dr C first saw her on 19 October 2000. I do not, however, accept that Mrs A experienced psychotic symptoms only when depressed.

I have considered the table of Mrs A's mood changes from 1981 to 2003 which Dr C provided during this investigation but, given the findings made above, I consider it very unlikely that Dr C had formed such a detailed impression of Mrs A's history when he changed her diagnosis on 19 October 2000. It is obvious also that in so far as the table covers events occurring after October 2000 it had no effect on Dr C's diagnostic process in October 2000. However, I do consider it relevant that when Mrs A was discharged from the city hospital in May 2001, her diagnosis had reverted to one of paranoid schizophrenia and to my knowledge she continues to be treated on this basis.

In my opinion, based on my expert advice, Dr C made an error in diagnosing Mrs A's illness as major affective disorder with involution melancholia or mood disorder with psychosis (melancholia). The appropriate diagnosis was either schizophrenia or schizoaffective disorder. He also made an error in failing to treat Mrs A's ongoing psychotic symptoms with an effective dose of antipsychotic medication.

Dr C therefore failed to provide services to Mrs A with reasonable care and skill and in compliance with relevant professional standards.

Possibility of bipolar illness

During my investigation Dr C suggested that he also considered bipolar disorder as a possible diagnosis.

The possibility that Mrs A had a bipolar illness is not mentioned anywhere in her notes (although Dr C thought that he had referred to it in a letter, which may have been misfiled). In addition, according to Dr K's notes, Dr C did not refer to it when he discussed Mrs A's diagnosis at their meeting in September 2001, nor is it mentioned in the letters from his barrister in response to my investigation. I therefore think it unlikely that Dr C did consider bipolar illness a possible diagnosis at the time he was treating Mrs A.

Even if Dr C did consider bipolar illness a possible diagnosis, he did not entertain it seriously enough to go on to diagnose Mrs A with such an illness or treat her on that basis.

Further, in Dr Plunkett's opinion, Mrs A's diagnosis was either schizophrenia or schizoaffective disorder. A diagnosis of bipolar disorder was not available because Mrs A continued to experience hallucinations, which do not occur in a bipolar disorder. Dr Plunkett commented:

"I am not aware of any convincing evidence ... that [Mrs A] had a diagnosis of bipolar disorder. Certainly, her prior doctor, [Dr G], did not record this as her diagnosis, and he had followed her up across a longer time period than [Dr C]. As above, bipolar disorder can only be diagnosed if the patient has a clear history of manic or hypomanic episodes, which I have seen no record of in [Mrs A's] case. A history of psychosis per se is insufficient to make a diagnosis of bipolar disorder, especially as there is evidence that the psychotic symptoms occurred at times when [Mrs A's] moods were stable. This points to a schizophrenic or schizoaffective disorder."

In my opinion, based on Dr Plunkett's advice, there is no evidence to support a diagnosis of bipolar disorder.

Comorbidity of schizophrenia and mood disorder

One of the factors that seems to have influenced Dr C's decision to change Mrs A's diagnosis was his belief that diagnoses of schizophrenia and mood disorder could not co-exist. When Dr K asked Dr C to justify his diagnosis, he maintained that a diagnosis of schizophrenia could not coexist with a diagnosis of depressive disorder.

Dr C appears to have based his belief on Exclusion Criterion D of the DSM IV definition of schizophrenia which requires that before schizophrenia is diagnosed:

"Schizoaffective Disorder and Mood Disorder with Psychotic Features have been ruled out because either:

- (2) no Major Depressive, Manic, or Mixed Episodes have occurred concurrently with the active-phase symptoms; or
- (3) if mood episodes have occurred during active-phase symptoms, their total duration has been brief relative to the duration of the active and residual phases."

In response to my provisional opinion, Dr C stated:

"To say that I hold the view that patients with schizophrenia cannot become depressed is quoting me wrongly. I said that a patient with schizophrenia who becomes depressed is a red light because of the caveat in DSM IV re-diagnosing depression and schizophrenia simultaneously, and because they tend to commit suicide."

Dr Plunkett reviewed Dr C's response and commented:

“I remain concerned that from [Dr C’s] initial discussion of the matter, he did seem to hold a belief at that time that depression could not occur in patients with schizophrenia, thus leading him to re-diagnose her and make major changes to her medication regime. The issue is not so much whether schizophrenia and major depression with psychotic features may lie at opposite ends of a spectrum, but whether a change from one diagnosis to the other was justified, and whether so marked a reduction of antipsychotic medication as a result of this diagnostic change was also justified. As stated in my prior reports, I do not agree that this was the case.”

With respect to the comorbidity of schizophrenia and depression, Dr Plunkett advised as follows:

“In saying that depression and schizophrenia could not ‘by convention’ be ‘co-morbid’, [Dr C] is probably referring to the DSM IV criteria for diagnosis of a Major Depression. The DSM IV states that a diagnosis of Major Depression should not be made if a Schizoaffective Disorder diagnosis in fact explains the episodes of depression better. It also states that a diagnosis of Major Depression cannot be made if the depressive episodes are superimposed on Schizophrenia. In fact, symptoms of depression are common (and widely documented in the literature) in schizophrenia and often do require treatment, even if they cannot ‘by convention’ according to the DSM IV be termed episodes of ‘Major Depression’. It is of concern to me that [Dr C] appears to have misinterpreted the DSM criteria in this matter such that rather than diagnosing a Schizoaffective Disorder, or Schizophrenia (in which depressive symptoms commonly do occur) he opted to re-diagnose [Mrs A] as having Major Depression and to taper off her antipsychotic medicine, effectively ignoring her long history of psychotic symptoms.

In my opinion, based on the clinical records available to me and, apparently, to Dr C when he made this re-diagnosis, ‘Major Depression with psychotic features’ was not an appropriate re-diagnosis based on [Mrs A’s] documented past history and symptoms. I think it far more likely that her diagnosis was that of Schizophrenia (paranoid type) with intermittent episodes of depressive symptoms, or a Schizoaffective Disorder.

... We have little evidence as to his reasoning, due to his poor documentation of this, but ... he appears to have held to the rigid and misguided view that patients with schizophrenia cannot also develop depression. This view is not upheld in the psychiatric literature, where management of depression in patients with schizophrenia is frequently discussed. [Dr C] appears to have based this re-diagnosis on a brief and inadequate cross-sectional assessment on 19 October, at which time [Mrs A] gave some history of intermittent depressive symptoms. In fact, [Dr C] records that although depressed the previous day she was not depressed on the 19th when he assessed her. Despite the fact that a true Major depression with psychotic features is a serious illness and does not fluctuate day to day in this fashion, he nevertheless altered her diagnosis to this.

In the lawyer’s letter of 11th November he appears to mainly be arguing that she had depressive symptoms and history, as the main justification. His reasoning is thus extremely unclear and does not appear to be based on a sound knowledge of important psychiatric syndromes or of basic DSM IV diagnostic criteria.”

On the basis of my expert advice, I consider that Dr C may have misinterpreted the DSM IV criteria for diagnosing schizophrenia in maintaining that schizophrenia and depression cannot coexist. Partly as a result of this, Dr C decided that Mrs A's longstanding diagnosis of schizophrenia was wrong.

In his response to my provisional opinion, Dr C stated that he did not hold the view that patients with schizophrenia cannot become depressed but regarded depression in a patient with schizophrenia as a "red light" because of the caveat in DSM IV re-diagnosing depression and schizophrenia simultaneously. However, the notes Dr K made in 2001 of Dr C's explanation of the change in diagnosis seem to me to indicate that Dr C did indeed hold the view that the two diagnoses could not co-exist. Dr C continued to maintain this argument in the initial responses to this investigation made through his barrister.

In my opinion the change in diagnosis amounted to a failure by Dr C to provide services to Mrs A with reasonable care and skill.

Summary of findings with respect to the change in diagnosis

In my opinion, when Dr C re-diagnosed Mrs A, he failed to provide services with reasonable care and skill and therefore breached Right 4(1) in the following respects:

- he did not conduct an adequate review of Mrs A's past clinical records before changing her diagnosis
- he failed to obtain sufficient information from Ms B before changing Mrs A's diagnosis
- he did not carry out an adequate assessment of Mrs A before changing her diagnosis
- his diagnosis of major affective disorder with involution melancholia or mood disorder with psychosis was incorrect and not one that a reasonable psychiatrist would make.

When Dr C re-diagnosed Mrs A, he also breached Right 4(2) by providing her with services that did not comply with relevant standards in the following respects:

- his diagnosis did not fit within recognised diagnostic systems (either DSM IV or ICD10) and included outdated terminology
- he appears to have misinterpreted the relevant DSM IV criteria.

Change in medication

Ms B complained that:

“... in October 2000 ... [Dr C] inappropriately prescribed [Mrs A] an anti-depressant (Cipramil) and advised a regime to wean her off the anti-psychotic (Risperdal) she had

been taking, on the basis of inadequate information and without adequately taking into account her almost 30 year history of paranoid schizophrenia.”

Having changed Mrs A’s diagnosis from paranoid schizophrenia, Dr C also changed her medication regime. Dr C decided to phase out the risperidone and nortriptyline and gradually introduce Cipramil.

According to Dr G’s letter, in August 2000 Mrs A was taking risperidone 8mg daily, nortriptyline 100mg daily and zopiclone 7.5–15mg nocte. The rural hospital’s computer record for 19 September 2000 also stated that Mrs A was taking 8mg risperidone and 100mg nortriptyline. Dr C, however, recorded in his letter of 19 October 2000 that Mrs A was taking risperidone up to 12mg daily.

In my view the weight of evidence suggests that Mrs A was taking 8mg risperidone when she saw Dr C on 19 October 2000. I have assumed this to be the case in considering whether Dr C treated Mrs A with reasonable skill and care when he altered her medication.

Appropriateness of questioning effectiveness of risperidone

During this investigation Dr C said that risperidone 12mg daily was a high dosage and its effectiveness was questionable as Mrs A continued to experience psychotic symptoms. Dr Plunkett confirmed that Dr C was correct to describe a dose of 12mg daily as high and described a dose of 8–10mg as higher than the usual adult treatment range. Dr Plunkett also agreed that it was appropriate for Dr C to question the effectiveness of risperidone in treating Mrs A’s psychotic symptoms. She stated:

“... [a dose of 12–13mg daily of risperidone] is a high dose. The usual treatment range in adults according to the ‘New Ethicals’ catalogue is about 4–6mg daily, and *New Ethicals* gives the upper limit as 16mg daily. Higher doses of about 8–10mg are however at times used in patients with more chronic and resistant psychotic illnesses, and it is possible that ... [Dr G] felt that her illness was of this type.

... I do not think that it would have been unreasonable for [Dr C] to be somewhat concerned a) that this was a relatively high dose and might have been causing [Mrs A] some extrapyramidal side effects and b) that if she nonetheless had psychotic symptoms on this dose then it appeared the risperidone was relatively ineffective for her resistant psychosis.”

I therefore accept that it was appropriate for Dr C to consider the possibility that risperidone was not an effective treatment for Mrs A’s psychotic symptoms and that another medication should be introduced to treat her symptoms.

Speed of reduction of risperidone

I have already concluded that it is most likely that on 19 October 2000 Mrs A was taking risperidone 8 mg daily. The rural hospital’s records indicate that by 2 November 2000 Mrs A was taking only 1mg risperidone daily.

Dr C described the reduction of Mrs A's risperidone from 8mg to 1mg daily between 19 October and 2 November 2000 (a period of 14 days) as gradual; however, Dr Plunkett described it as "an extremely rapid and sudden reduction". She advised that risperidone should be tapered off over a month:

"Risperidone is ... a new-generation or anti-psychotic drug. It is indicated for any mental disorder involving psychotic symptoms, including schizophrenia, schizoaffective disorder and major depression with psychotic features. The common dose range is 3 to 8 mgs daily but resistant longer-term psychotic illnesses sometimes require higher doses. ... Risperidone is relatively short-acting medication, and the blood levels would drop rapidly after a major dose change. It is usual to taper risperidone over at least one month when making a medication change. ...

For the risperidone [the reduction to 1mg] is virtually the same as cessation, as a 1mg dose would have been ineffective given [Mrs A's] chronic illness and prior much higher doses. In managing the appropriate tapering off of the prior medications, [Dr C] thus did not meet a reasonable standard of care, and by a too-rapid taper would have placed [Mrs A] at greater risk of relapse, especially as two medications were rapidly reduced simultaneously."

In my opinion, in reducing the risperidone to 1mg over 15 days Dr C did not provide treatment to Mrs A with reasonable skill and care. The risperidone should have been tapered off over at least a month. By allowing such a rapid tapering, Dr C placed Mrs A at greater risk of relapse.

Efficacy of 1mg dose of risperidone

Dr C has argued that Mrs A's psychotic symptoms were adequately treated by the reduced dose of 1 mg risperidone daily.

Dr Plunkett strongly disagreed that risperidone is therapeutic in a 1mg daily dose. She described 1mg as an "extremely low dose" which is "ineffective in a patient with a severe chronic psychotic illness". She stated that in Mrs A's case:

"[the reduction to risperidone 1mg daily] is virtually the same as cessation, as a 1mg dose would have been ineffective given her chronic illness and prior much higher doses."

In her additional advice, Dr Plunkett stated:

"... the issue is not really whether in some instances of the treatment of psychosis 1mg risperidone daily can be an effective dose, but whether this was likely to be the case for [Mrs A]. Studies over the past 10–15 years have indeed shown that lower antipsychotic doses can often be used effectively to treat patients with schizophrenia. The main message from these studies however is that this is the case in readily responsive patients, for example first-episode patient who do not have a long history of chronic illness. In patients, like [Mrs A], who do have a long history of a chronic, resistant psychotic illness an extremely low dose such as 1mg risperidone is very unlikely to be an effective antipsychotic dose. She had in fact been treated with a higher-than-average dose (8mg

daily) and would thus have become somewhat acclimatised to this higher dose. As above, the fact that moderate to high doses of risperidone across an extended period of time (from the past psychiatric records) had not fully controlled her symptoms indicates that her illness was resistant and hard to treat. A change to a different antipsychotic drug would thus have been more sensible, rather than the reduction to an ineffective dose of the existing (apparently already relatively ineffective) antipsychotic medication.”

Dr C referred me to a study which he said indicated that risperidone could be effective in reducing psychotic symptoms in a 1mg dose. The reference for the study is Bhana, N, Spencer, C M, “Risperidone: a review of its use in the management of the behavioural and psychological symptoms of dementia”, *Journal of Drugs and Aging*, (2000) 16(6): 451–471.

Dr Plunkett commented:

“... this study refers specifically to a very different patient population: elderly patients with a definite diagnosis of dementia and with associated psychosis, aggression or behavioural disturbance. Despite [Dr C’s] linkage of this ... to [Mrs A’s] later CT scan abnormalities detected after her psychiatric admission to [the city hospital], it is clear that at the time he initially assessed her he had not made any such diagnosis. Nor can [Mrs A] — a patient he later supported in making a trip [overseas] all by herself — reasonably be equated with elderly patients with significant dementia as in the Bhana study. I thus do not regard this study as providing useful guidance in her treatment.

[Mrs A] was however aged 62 and it is indeed true that lower medication doses are generally preferred in older patients. However, this would be particularly the case were she being treated for the first time, when it would be reasonable to exercise caution in commencing risperidone by gradually increasing her dose from 0.5mg daily to between 2–4mg daily. [Mrs A] however had been taking 8mg of risperidone daily so her ability to tolerate the medication was clearly established and was in fact quite robust. From the transcript ... [Dr C] felt she had some degree of a ‘mask face’ (possible bradykinesia) and ‘irritability’ — which he appears to have interpreted as definite akathisia, although in my view this is not certain. However, even these possible side-effects appear to have been only mild to moderate and she had tolerated them for some time. In my view it would have been reasonable to consider changing her antipsychotic medication to a new drug, or to reduce it to a more normal dose for adults (about 4mgs daily), while following her carefully across the subsequent three months to assess any benefit and ensure she did not relapse. Physically and functionally [Mrs A] does not appear to have been a frail, antipsychotic-naïve patient falling clearly into the ‘elderly’ category for whom very low doses like 1mg daily are appropriate. To place [Mrs A] in this category would indicate poor clinical judgment, were it in fact the basis for the treatment plan undertaken by [Dr C].”

On the basis of Dr Plunkett’s advice, it is clear that a 1mg dose of risperidone was unlikely to have been effective in treating Mrs A’s severe chronic psychotic illness. While it appears that lower doses of antipsychotics can be effective in treating readily responsive patients such as first episode patients, Mrs A had a long history of a chronic, resistant psychotic illness that had been treated over an extended period with a relatively high dose of risperidone. A dose

of 1mg was therefore unlikely to have been effective. In arguing that a 1mg dose of risperidone can be effective and promoting these studies in support of his arguments, Dr C seems to have overlooked Mrs A's particular characteristics as a patient who was not frail or demented and who was robustly tolerant of high doses of risperidone. Recognising that Mrs A's psychotic symptoms were not fully controlled by the risperidone, Dr C should have substituted another antipsychotic drug for risperidone. His failure to do so showed poor clinical judgment.

In my opinion, in reducing Mrs A's risperidone to 1mg daily, Dr C failed to provide services with reasonable skill and care.

Dr C's plan to replace risperidone with another antipsychotic

In response to my provisional opinion, Dr C stated that his intention was not simply to lower the dose of risperidone but to discontinue it altogether and replace it with another antipsychotic in the future, if that became necessary. Before introducing another antipsychotic, Dr C wanted first to see how Mrs A responded to citalopram.

Dr C stated that he did not add another antipsychotic immediately because Mrs A was completely free of psychotic symptoms when well. He also said justified his decision on the basis that DSM IV requires a deterioration for a diagnosis of paranoid schizophrenia and there had been no deterioration in Mrs A's case.

Dr Plunkett reviewed Dr C's response to the provisional opinion and advised me that "to risk an extended period of time off antipsychotic medication (or on so low a dose of risperidone as to effectively have ceased this) was very unwise".

In my opinion, regardless of Dr C's plan to introduce another antipsychotic to replace risperidone if that seemed warranted at a later stage, it was inappropriate for him to leave Mrs A with no effective antipsychotic medication for an extended period.

Extrapyramidal symptoms

During my investigation, Dr C suggested that another reason for changing Mrs A's medication was that she was suffering extrapyramidal symptoms from the risperidone. Yet Dr C did not mention extrapyramidal symptoms in his letter of 19 October 2000, nor did he raise them during discussions about Mrs A's treatment with Dr K in September 2001. Dr C's failure to point to extrapyramidal symptoms when initially called on to explain the changes he made to Mrs A's treatment leaves me doubtful that such symptoms did, in fact, influence the decisions he made in October 2000. Nonetheless, I have considered the issue of extrapyramidal symptoms on the basis that they *did* have a role in Dr C's handling of Mrs A's treatment. Dr C stated:

"Risperidone [in a dose of 8mg daily] gives patients extrapyramidal side effects which include restlessness, and a mask face — both of which [Mrs A] exhibited. It also carries a risk of tardive dyskinesia, which can cause disfigurement, which is [an] increased problem in more elderly patients."

Extrapyramidal symptoms associated with risperidone include tremor, rigidity, hypersalivation, bradykinesia, akathisia, and acute dystonia.

The only reference to Mrs A suffering from irritability appears in Dr G's letter, which stated that in June 2000 Mrs A was experiencing irritability with verbal aggression while taking risperidone 8mg daily and nortriptyline 100mg daily.

Dr Plunkett advised me:

“... it would not have been unreasonable for [Dr C] to be somewhat concerned a) that this was a relatively high dose and might have been causing [Mrs A] some extrapyramidal side-effects and b) that if she nonetheless had psychotic symptoms on this does then it appeared that the risperidone was relatively ineffective for her resistant psychosis. I do however think it was unreasonable and unwise for him to then reduce her risperidone dose down as low as 1mg daily across a relatively short timeframe. I do not believe this was an effective antipsychotic dose for [Mrs A].

... [Dr C] felt she had some degree of a ‘mask face’ (possible bradykinesia) and ‘irritability’ — which he appears to have interpreted as definite akathasia, although in my view this was not certain. However, even these possible side-effects appear to have been only mild to moderate and she had tolerated them for some time.”

In my opinion, while it was reasonable for [Dr C] to consider the possibility that the 8mg daily dose of risperidone might have been causing [Mrs A] extrapyramidal symptoms, this did not justify his decision to virtually eliminate her risperidone without replacing it with another antipsychotic.

Decision to phase out nortriptyline

At the consultation on 19 October 2000, Dr C also decided to reduce and then terminate her nortriptyline (100mg nocte) and simultaneously replace it with citalopram.

Dr Plunkett advised me:

“Nortriptyline is a tricyclic antidepressant. Tricyclics are ... indicated for mild to moderate Major Depression, but are traditionally preferred in severe psychotic depression. However, in psychotic depressions, as with SSRIs, they are given alongside an antipsychotic medication, not alone. Nortriptyline is a common and effective tricyclic and is relatively short-acting, leaving the body rapidly on cessation. After a major dose-reduction the blood levels would drop rapidly in a matter of days, before restabilising. Nortriptyline is also indicated in anxiety disorders. It interacts with some SSRIs so as to cause elevated tricyclic blood levels, but not with citalopram. The common dose range is 100 to 200mgs daily, for treatment of depression.”

Dr Plunkett's advice was that, as with risperidone, nortriptyline too should be tapered off over a month. She noted that because nortriptyline is a relatively short-acting medication it is advisable to taper it off over one month to avoid withdrawal effects that could cause distress or even relapse.

In my opinion the reduction of the nortriptyline over 15 days was too abrupt and exposed Mrs A to the risk of distressing withdrawal symptoms or relapse. Accordingly, Dr C did not use reasonable skill and care in relation to this aspect of Mrs A's treatment.

Risk of suicide

Dr C said that one of the reasons he decided to phase out Mrs A's nortriptyline and replace it with citalopram was the risk that she might commit suicide. When interviewed he said that he was aware that Mrs A had attempted suicide once, and possibly twice and he felt that suicide was "very much in the offing".

Dr C said that while he did not think the risk of Mrs A attempting suicide was high enough to justify hospitalising her, he could not ignore the risk. He therefore decided to replace the nortriptyline with citalopram, which he regarded as less dangerous in the hands of a potentially suicidal patient.

Ms B in her letter of complaint also said that Mrs A had been threatening suicide in the days before she saw Dr C for the first time, although there is no reference to such threats in the notes made by Ms F in the period preceding Mrs A's first consultation with Dr C on 19 October 2000 or in Ms H's notes of that consultation.

Dr C's barrister (in a letter to me dated 3 October 2003) noted:

"The medication [Mrs A] was taking was not only ineffective but dangerous: ... [nortriptyline is] cardio toxic and unsafe where there is a suicide risk."

However, the suggestion that Dr C decided to eliminate the nortriptyline and replace it with citalopram because he was concerned about the risk of suicide is inconsistent with the impression of Mrs A he recorded in the 19 October 2000 letter. In that letter, Dr C noted:

"She has at present no suicidal ideation ...

The family is well aware of her suicidal ideation at times but I don't think that is imminent effect, maybe more a cry for help."

I note also that Dr C did not offer the risk of suicide as an explanation for the changes he made to Mrs A's medication when he met with Dr K in September 2001. In fact, Dr C did not raise the risk of suicide until as late as October 2003 as part of his response to my investigation. In addition, the rural hospital notes for 19 October 2000 stated: "No safety concerns currently".

Dr Plunkett advised that nortriptyline is relatively toxic in overdose while citalopram is relatively safe:

"Citalopram's main advantage was its greater safety should [Mrs A] take an overdose. This is not an unreasonable basis to make a change for an out-patient, although [Dr C] does not appear to have been particularly worried initially about [Mrs A] being a major suicide risk."

I accept that there was some risk that Mrs A might commit suicide, although Dr C does not seem to have been unduly concerned about the risk when he made the decision to withdraw the nortriptyline and replace it with citalopram on 19 October 2000. I accept, also, that it was reasonable for Dr C to attempt to reduce the risk should Mrs A use her medication to attempt suicide by replacing her nortriptyline with the relatively less toxic citalopram. However, Dr C was required to balance the need to address the risk of suicide with the need to ensure that Mrs A's psychotic symptoms were addressed. The main issue throughout was the need to maintain adequate doses of antipsychotic alongside whichever antidepressant was used.

Introduction and tapering of citalopram

At the consultation on 19 October 2000 Dr C also decided to introduce gradually the antidepressant citalopram, also known by the brand name Cipramil. Mrs A was commenced on citalopram 10mg daily on 19 October 2000. In his letter to Dr E of 16 November 2000, Dr C stated that he was going to increase the dose to 40mg daily and this is the dose that Mrs A was taking by 5 December 2000.

Dr Plunkett advised me that 10mg daily is a normal starting dose for this medication which is not normally tapered much, if at all, on commencement. She said that an increase to 40mg daily over a six-week period is quite rapid but not unknown in treating a resistant depression.

In my view, the way in which Dr C introduced and tapered the citalopram was reasonable.

Efficacy of citalopram in treatment of psychotic symptoms

Dr Plunkett advised me as follows:

“[Citalopram]... is indicated particularly in mild to moderate Major Depression, and would generally be prescribed alone (without an antipsychotic drug) only in Major Depression without psychotic symptoms. It is well documented that Major Depression with psychotic symptoms requires treatment either with electro-convulsive therapy or with combined antidepressant and psychotic medication.

... [Dr C], in my opinion, misdiagnosed [Mrs A] as having major depression with psychosis. He then, in addition, proceeded with an inappropriate treatment regime for such a diagnosis. In major depression with psychotic symptoms combined treatment with antidepressant and antipsychotic medication is required, and [Dr C] in fact reduced and nearly ceased the antipsychotic risperidone. Use of citalopram in a major depression with psychosis is not unknown, but is not a common choice to treat such a condition, and is certainly not reported to have been used alone in this condition. To treat a Schizoaffective disorder or Schizophrenic disorder with depressive symptoms, the treatment of choice is increasingly to change antipsychotic medication to an atypical drug such as olanzapine, although concurrent antidepressants are often used as well. They are not used alone and without antipsychotic medications in these conditions, however.

... He appears to have felt that major depression with psychosis could be treated without antipsychotic medication, which is not a view traditionally held or based on evidence from the psychiatric literature. Alternatively, he possibly believed that a 1mg risperidone dose was adequate antipsychotic treatment — again, I do not concur with this view in

[Mrs A's] case. In the interview with [Dr K], he appears to be arguing that [Mrs A's] prior treatment was ineffective thus needed changing. He also in the lawyer's letter of 11 November 2002 for the first time stated that she suffered extrapyramidal symptoms (nowhere else documented). ... there is no sensible rationale for such a sudden change and [Dr C] has not recorded any management plan."

Dr C argued that citalopram was an effective treatment for psychotic symptoms and that this is well documented. Dr Plunkett's advice was clear:

"... I do not agree that [the use of citalopram in patients suffering from mood disorder with psychosis is well documented]. Any effective antidepressant can be used to treat a severe major depression with psychosis along with antipsychotic medication ... The treatment of choice of a psychotic bipolar disorder is antipsychotic medication and a mood stabilizer ± an antidepressant (in a depressed phase). Citalopram alone is not recommended as a treatment of 'mood disorder with psychosis' or of psychotic illnesses as such. Even in combination with an antipsychotic, the recommendation currently for treating a major depression with psychosis is to use a tricyclic antidepressant, rather than an SSRI antidepressant such as citalopram.

... [Citalopram] is an antidepressant not an antipsychotic agent. In severe depression with psychosis, the use of citalopram (or any depressant) by itself is in fact highly likely to worsen the illness, thus it is always given with effective antipsychotic medication if used in such conditions."

Dr Plunkett referred to guidelines for the treatment of major depression with psychosis in New Zealand (The Royal Australian and New Zealand College of Psychiatrists, *Australian and New Zealand Clinical Practice Guidelines for the Treatment of Depression* (2004)), Canada and the United States, none of which recommend citalopram in the treatment of treating major depression with psychosis.

In my view, Dr C did not treat Mrs A with reasonable skill and care when he prescribed citalopram. Mrs A was suffering from psychotic symptoms when Dr C made the change and had done so since the 1970s. I accept my expert advice that citalopram, as an antidepressant, is not an appropriate treatment for psychotic symptoms. Therefore, as well as citalopram, Mrs A required an antipsychotic medication to treat her psychotic symptoms. While Mrs A did continue to take risperidone (an antipsychotic) for the reasons set out above, I consider that the dosage of risperidone prescribed by Dr C (1mg daily) was so low that it was not effective in treating Mrs A's psychotic symptoms.

Essentially Dr C's decision to treat Mrs A with citalopram and risperidone 1mg daily left her psychotic symptoms untreated. His use of an antidepressant combined with an ineffective dose of antipsychotic medication was, in fact, highly likely to aggravate her illness. Even if Dr C's diagnosis of major depression with psychotic features had been correct, the medication regime he prescribed was inappropriate since such an illness requires combined treatment with an antidepressant and antipsychotic.

Evidence of effectiveness of citalopram combined with 1mg risperidone or alone

Dr C maintained that there is evidence in the literature that citalopram is effective in treating psychotic symptoms when combined with a reduced dose neuroleptic such as risperidone. He cited two studies:

- Kallionieme, H and Syvaelahti, E, “Citalopram, A Specific Inhibitor of Serotonin Reuptake in Treatment of Psychotic and Borderline Patients”, *Nordic Journal of Psychiatry* (1993) 47 (Supp 28): 390–393 (the Kallionieme study).
- Pollock, B G, Mulsant, B H, Rosen, J, et al, “Comparison of Citalopram, Perphenazine, and Placebo for the Acute Treatment of Psychosis and Behavioral Disturbances in Hospitalized, Demented Patients”, *Am J Psychiatry* (2002) 159(3): 460–465 (the Pollock study).

In Dr C’s view the Kallionieme study supported his view that the citalopram he prescribed for Mrs A along with risperidone 1mg daily would effectively treat her psychotic symptoms while the Pollock study established that citalopram acts effectively to reduce psychotic symptoms associated with depression.

Dr Plunkett disagreed that there is good evidence in the literature, or in the studies provided by Dr C, that citalopram on its own has any antipsychotic efficacy. Dr Plunkett advised me that the Kallionieme study and the Pollock study do not offer evidence to support Dr C’s view that the citalopram combined with risperidone 1mg daily would be effective or that citalopram alone reduces psychotic symptoms associated with depression.

With respect to the Kallionieme study, Dr Plunkett commented:

“The abstract makes it clear that citalopram was used in only 8 patients, 4 of whom appear to have been diagnosed with borderline personality disorder rather than psychosis. The exact diagnoses of the 4 ‘psychotic’ patients are not given. Little detail is provided eg the use of other medication is not clarified although concomitant use of neuroleptics (antipsychotics) is mentioned. Methodically the study appears from the abstract to be of poor quality, and the numbers are small. This study also reports that citalopram in the authors’ opinion helped with anxiety, impulsivity and aggression, not with core treatment of any ‘psychosis’ or ‘mood disorder’ as such.”

With respect to the Pollock study, Dr Plunkett advised:

“This study compares citalopram, perphenazine (a traditional antipsychotic) and placebo in treating psychosis and behavioural disturbance in hospitalized patients with dementia. It shows some benefit with citalopram and perphenazine. I do not however believe that the results can be generalized to treatment of ‘mood disorder with psychosis’ as this study looked at a completely different patient and diagnostic group. Some patients had psychosis (due to their dementia) and others did not. The addition of citalopram may actually have been treating underlying anxiety or an unrecognized mood disorder, not psychosis at all — the authors are cautious and do not actually claim that citalopram was working as an ‘antipsychotic’. This study does not confirm [Dr C’s] assertion that the use

of citalopram in patients suffering from mood disorder with psychosis is ‘well documented’.”

In my opinion, the studies put forward by Dr C do not support his contention that citalopram either on its own or with a low-dose antipsychotic is effective in treating psychotic symptoms.

Accordingly, in prescribing citalopram to treat Mrs A for the mood disorder with psychosis, which he had diagnosed on 19 October 2000, Dr C failed to provide services with reasonable care and skill. Whether Dr C’s diagnosis of mood disorder with psychosis was a provisional or working diagnosis as he has claimed or a categorical change in diagnosis is irrelevant, because Mrs A’s treatment was based on a diagnosis of mood disorder with psychosis from 19 October 2000 onwards.

Simultaneous change to both antipsychotic and antidepressant

In deciding to reduce Mrs A’s risperidone, phase out the nortriptyline and introduce citalopram, Dr C made changes to two medication groups — the antipsychotic group of which risperidone is a member, and the antidepressant group of which nortriptyline is a member.

Dr Plunkett advised me:

“It is unwise to alter more than one medication group simultaneously, unless there is a medical emergency requiring this. ...

There were no emergency reasons for altering several medications simultaneously. In the lawyer’s letter of 11th November [2003], [Dr C] states that [Mrs A] suffered marked extra-pyramidal symptoms on her risperidone (eg Parkinson’s disease-like effects and restlessness). However, he made no mention of these at all in the letter to the GP of 19th October 2000, nor are such severe side-effects mentioned in the referral letter from [Dr G]. I thus find this hard to credit as an ‘emergency’ justification. Despite this lack of an emergency cause of rapid drug changes, as well as tapering nortriptyline and commencing citalopram, [Dr C] also tapered the risperidone to an extremely low dose of 1mg daily (an ineffective dose in a patient with a severe chronic psychotic illness). It is usual to alter an antidepressant by reducing one while adding the other, but unwise to simultaneously reduce antipsychotic medication. Should symptoms recur (as they did), [Dr C] would be unsure which of the medication changes had caused this deterioration. In addition, there is always a risk of relapse of symptoms with any medication change, no matter how carefully managed. This risk increases considerably if any additional medications are simultaneously altered.”

In her additional advice, Dr Plunkett said that it might have been reasonable for Dr C to change Mrs A’s antipsychotic, risperidone, to another antipsychotic in view of Mrs A’s lack of response to relatively high doses of risperidone *or* to substitute the antidepressant citalopram for nortriptyline. It was, however, ill-advised to change both groups of medications simultaneously.

Given Dr Plunkett's advice, I consider that in deciding to reduce the risperidone significantly, phase out the nortriptyline and introduce the citalopram at the same time and in the absence of any emergency, Dr C did not use reasonable skill and care. It was unwise of Dr C to make more than one significant change to Mrs A's medication regime (the virtual phasing out of risperidone and cessation of nortriptyline and the introduction of citalopram) in the absence of an emergency. In my view, there was no emergency or crisis when Dr C saw Mrs A for the first time on 19 October 2000 and decided to change her diagnosis and medication.

In addition, while it may have been reasonable for Dr C to change Mrs A's antidepressant, nortriptyline, to citalopram, in the hope that she would experience an idiosyncratic improvement on citalopram and to reduce the risk if she took an overdose, this was only reasonable so long as her other medication was unchanged, which would have meant maintaining her risperidone at 8mg daily.

Plan to introduce mood stabiliser with antipsychotic

During my investigation Dr C said that his long term plan was to reduce Mrs A's risperidone and introduce what he variously described as a mood stabiliser with antipsychotic properties or an antipsychotic with mood stabilising properties such as olanzapine or clozapine. In Dr Plunkett's view, Dr C's references to mood stabilisers were probably references to:

“... the newer antipsychotic agents, the so-called atypicals. In New Zealand the available atypicals include risperidone, quetiapine, olanzapine and clozapine. The strongest evidence in the literature is for olanzapine as a mood stabilizing agent in bipolar disorder, although all the others have been tried. Olanzapine is listed as an option to use as a mood stabilizer in the acute treatment of manic and mixed affective episodes and (when used in combination with fluoxetine) as a treatment option for bipolar depression. The atypical antipsychotics are also first line treatment for schizophrenia and schizoaffective disorder, as in general their side-effects are better-tolerated than with the older, typical antipsychotics, and as they are often more effective. Treatment with an atypical antipsychotic other than risperidone would thus have been appropriate for [Mrs A] — especially as relatively high-dose risperidone treatment appeared not to be managing her symptoms. However, there is in my opinion no evidence ... that [Mrs A's] diagnosis was that of a bipolar disorder. Bipolar disorder can only be diagnosed if the patient has a clear history of manic or hypomanic episodes, which I have seen no record of in [Mrs A's] case. The atypical antipsychotic medications (especially olanzapine) appear to have some role in treating resistant depressions however so it is likely that this would have been worth trying both for chronic illness and her tendency to depressions.”

It would, therefore, have been reasonable for Dr C to have planned to introduce an atypical antipsychotic, other than risperidone, as a mood stabiliser. However, it was not reasonable for Dr C to leave Mrs A's psychotic symptoms untreated as he did when he reduced the risperidone below a therapeutic dose and introduced citalopram.

Management plan following re-diagnosis

There is no evidence that Dr C formulated a management plan to ensure that Mrs A responded positively to the significant changes in her medication initiated on 19 October 2000. Dr C's letter of 19 October 2000 states “I will see her again and follow up”, but does

not specify when. He does not specify plans for follow-up by a community mental health nurse and/or general practitioner or for family involvement in Mrs A's care.

Dr Plunkett advised me that a careful management plan with ongoing reassessment involving follow-up by the community mental health nurse and the client's caregivers should have been implemented to monitor the results of the change in medication and ensure that Mrs A's mental state did not deteriorate. There should also have been a relapse-prevention plan.

Dr Plunkett stated:

“Having made a significant rediagnosis which has implications regarding changes to treatment, there is a need to set in place a careful management plan with ongoing reassessments involving the follow-up team and (with the patient's permission) the patient's primary caregiver, to monitor the result of any treatment change and ensure that the patient's clinical state does not deteriorate. As medication changes can take 3 to 6 months to lead to clinical effects such as a relapse this plan needs to be in place for several months after any rediagnosis and treatment change. ...

Regarding the setting in place of a careful follow-up plan to monitor [Mrs A's] coping with these medication changes at least twice weekly, [Dr C] saw her again one week after the initial dose change, and then a fortnight after this. In addition, her community nurse [Ms H] visited her six days after the initial dose change, and then once weekly across the next two weeks. In most weeks [Mrs A] thus received two reviews, but often these were close together so that she was not seen for 5 to 6 days at a time, in the weeks after the major dose change. I am unsure if this was considered an adequate level of review by [Dr C] as he has written no management plan. I would regard it as inadequate in view of her chronic psychotic illness and the rapid near-cessation of her risperidone, together with a 75% drop in her nortriptyline dose. [Ms B] gives an account of her mother becoming more unwell quite rapidly after the initial large dose reductions, and does not appear to have been adequately supported and involved in the follow-up plan. In organising this aspect of her treatment plan I thus feel that [Dr C] has not met an adequate standard. In the lawyer's letter of 11th November, he appears to argue that he merely visited [the rural hospital] intermittently and saw whichever patients the nurses had scheduled for him, and that primary responsibility for organising patient care rested with the main community nurse. I entirely disagree with this abdication of clinical responsibility and find the argument specious. [Dr C] was the identified psychiatrist for [Mrs A] and as such, even as a psychiatrist visiting weekly, he had clear responsibility for overseeing her treatment plan on his regular contacts and for ensuring that this was safe and adequate. He was not responsible for every detail of practical implementation of the plan — that rested with the local clinic staff, but a responsible psychiatrist has a definite overarching role to establish, document and keep an eye on a management plan as treatment proceeds. [Dr C] failed to carry out that overseeing role.”

Dr Plunkett's advice is clear that:

- Dr C had a responsibility, as Mrs A's identified psychiatrist, to establish and document her treatment plan and ensure that it was safe and adequate, and monitor the plan as treatment proceeded;
- Dr C's monitoring and review of Mrs A was inadequate given her chronic psychotic illness and the rapid near-cessation of her risperidone and the 75% drop in her nortriptyline dose.

In my opinion, Dr C did not use reasonable skill and care in formulating a management plan for the change of Mrs A's medication. The change in medication was major and Mrs A's illness was chronic. Dr C had a duty to establish a plan that would ensure that her response to the change was adequately monitored. The monitoring that did occur, in the form of follow-up consultations with Dr C on 26 October and 16 November 2000, and visits by a community mental health nurse, was inadequate. Accordingly, Dr C breached Right 4(1) of the Code.

Summary of findings with respect to the change in medication

In my opinion, when Dr C reduced Mrs A's dose of risperidone, withdrew the nortriptyline and prescribed citalopram, he failed to provide services with reasonable care and skill and therefore breached Right 4(1) in the following respects:

- the risperidone dose was reduced too quickly and to a level that was not effective in treating Mrs A's psychotic symptoms
- he prescribed citalopram, which was inappropriate for treating Mrs A's psychotic symptoms unless combined with an antipsychotic (at a therapeutic dosage level)
- it was inappropriate to change Mrs A's antidepressant medication and her antipsychotic medication simultaneously
- Dr C did not establish and document a treatment plan for the change in Mrs A's medication.

Advice on Mrs A's trip overseas

Ms B complained that:

“From October 2000 to May 2001, [Dr C] did not provide [Mrs A] with information that a reasonable consumer in [Mrs A's] circumstances would expect to receive — in particular [Dr C] inappropriately recommended that [Mrs A] was well enough to travel [overseas], when she was not.”

At the 16 November 2000 consultation Ms B informed Dr C of plans for Mrs A to visit another of her daughters overseas in early December for six weeks. Ms B asked Dr C whether he thought the trip was advisable. Dr C felt that Mrs A was well enough to make the trip. Mrs A travelled overseas on 7 December 2000. While there she became acutely ill and

on 16 January 2001 Ms B had to borrow money to fly to an overseas country to bring her mother home. Mrs A arrived back in New Zealand on 18 January 2001 extremely unwell and in crisis.

Dr C felt that Mrs A was not sufficiently unwell to be prevented from travelling and that he could have done nothing to stop her going overseas, even if he had considered the trip unwise. He said that he could only do his best to ensure Mrs A and her daughters were aware of the need for her to continue taking her medication, and who to contact if they experienced any difficulties.

Dr Plunkett advised me that in her opinion Mrs A's trip overseas was contraindicated, or at least extremely unwise, so soon after major medication changes. She stated:

“Even if there had not been any signs or reports of deterioration there would have been a risk that the stress and excitement of an overseas trip would further destabilize matters, together with even mild jetlag affecting sleep. In fact, [Ms B] did forcefully express her concerns about her mother's mental state, but these were ignored a mere two weeks before the trip was due. ... A further matter to consider is that after a marked reduction in medication there can be an initial, relatively brief 'window' of improvement, due to rapid fading of side effects such as sedation. However, this is often then followed by a subsequent deterioration in mental state and then relapse, as more time passes without effective treatment. This may have occurred in [Mrs A], and [Dr C] should have been aware of this common pattern and anticipated it by using caution when supporting an overseas trip during a time when she was still vulnerable to deterioration.”

In my opinion Dr C should have advised against Mrs A's trip overseas. Dr C had instituted a major change to Mrs A's medication less than a month before Ms B sought his advice on the trip. Ms B described Mrs A as still hearing voices, increasingly paranoid and sleeping poorly. Mrs A could not, therefore, be said to have stabilised on the new medication.

These factors should have caused Dr C to advise against the trip. I accept that Dr C may not have been able to prevent Mrs A going overseas if she was determined to go. I accept also that, for a number of reasons, Ms B may have wanted her mother to go overseas. However, Ms B was clearly concerned about the wisdom of her mother going overseas. She sought advice from Dr C and in my view would have tried to ensure that her mother followed his advice, had he advised that Mrs A should not go.

While it appears that Dr C was motivated in part by the stress that caring for Mrs A placed on Ms B, he showed poor judgement in failing to advise against the trip. I do not accept that the disappointment Mrs A and her family might have felt if Dr C advised against the holiday outweighed the many factors that should have prompted him to counsel against the trip. In asking for his advice, Ms B was entitled to expect that Dr C would exercise his judgement with reasonable care and skill.

I am concerned that even now (almost four years later) Dr C attributes Mrs A's deterioration almost entirely to her failure to continue her medication. He does not appear to appreciate the significance of the substantial changes he had made in Mrs A's medication and the

limited time allowed for stabilization and the consequences of his failure to provide adequate medication for her antipsychotic symptoms. Nor does he appear to have factored in the other stresses Mrs A would experience in travelling overseas.

I do not accept that Mrs A's deterioration while overseas can be attributed solely to her failure to take all her medication as Dr C suggests. Having concluded that the information available before the trip should have caused Dr C to advise against it, it is not necessary for me to determine the cause of Mrs A's deterioration.

In my opinion, Dr C's failure to advise against Mrs A's trip overseas amounts to a failure to provide services with reasonable care and skill, in breach of Right 4(1) of the Code.

Failure to provide Mrs A with letter outlining history to take overseas

I am also of the view (on the basis of Dr Plunkett's advice) that Dr C ought to have written a letter for Mrs A to take with her overseas outlining her history, diagnosis and current treatment plan. The letter should also have noted that Mrs A's diagnosis and medication had only recently been changed. Such a letter may have enabled Mrs A's daughter to obtain treatment overseas more easily.

While Dr C says that he advised Mrs A to contact him or her GP if she became and unwell and provided her with his mobile telephone number, a letter would have short circuited the need for clinicians overseas to contact him and enabled decisions about her treatment to be made more quickly.

Services provided on Mrs A's return from overseas

The complaint is that:

“In January 2001 when [Mrs A] returned in crisis from [overseas] [Dr C] did not arrange for her admission or alternatively arrange adequate support to allow her principal caregiver, [Ms B], to care for her at home.”

Mrs A arrived back from overseas with Ms B on 18 January 2001. Ms B believed that when she arrived back, Mrs A would be admitted to hospital compulsorily under the Mental Health (Compulsory Assessment and Treatment) Act 1992. What happened, however, was that Dr C decided that Mrs A should be cared for at home by Ms B who would be assisted by a respite caregiver for 70 hours a week.

Dr Plunkett advised me that Dr C should have had Mrs A admitted to hospital compulsorily. Dr C contested this advice, saying:

- “1. It is very cruel to take somebody to hospital against the wishes of their family, because if they do not want to take the patient one has to resort to the police to take the patient to hospital, and that I did not want to do.
2. Using the Act does not create a bed. I knew that the ward was full.

3. [Mrs A], Dr Plunkett will no doubt agree, was not easily certifiable under the second limb of the Act.”

I have not formed a view whether Mrs A should have been admitted to hospital when she returned from overseas. I accept that there may have been a shortage of inpatient beds and that invoking the compulsory assessment and treatment provisions of the Mental Health (Compulsory Assessment and Treatment) Act 1992 would not have created a bed.

My consideration of this aspect of Mrs A’s treatment is not therefore focussed on the issues of admission to hospital and compulsory assessment and treatment. Instead, I have focussed on the adequacy of the arrangements Dr C made for Mrs A’s care once he had decided that she would not be admitted.

Mrs A was very unwell and her family was under stress with her primary caregiver, Ms B, expressing doubts as to her ability to manage her mother at home. Dr C’s response was for Mrs A to be provided with respite care in her home.

Dr Plunkett advised that in these circumstances:

“[Dr C’s] part in this [respite] plan was to ensure appropriate medication, which in my view he failed to do, and to set out a clear management plan for daily visits and respite care and maintain an overview of the plan, checking that this was being followed. Given [Mrs A’s] unwell state he should have checked on this by telephone from [the city hospital] at least weekly, but appears not to have done so (at least nothing of this sort is documented).”

In my opinion, Dr C did not provide services with reasonable skill and care in treating Mrs A on her return from overseas. Dr C did not establish a clear plan for Mrs A’s care (which ought to have included respite care and daily CMHN visits). In addition, it appears that he did not check Mrs A’s progress in the weeks following her return home.

Prescription of clozapine

Ms B complained that:

“In February 2001 [Dr C] inappropriately prescribed [Mrs A] the anti-psychotic clozapine (Clozaril).”

Standards applicable to prescription of clozapine

Dr Plunkett described the standards applicable to a decision to prescribe clozapine as follows:

- “a. The patient should have a treatment-resistant long-term psychotic illness, generally schizophrenia or a schizoaffective disorder, or should be unable to take alternative antipsychotic medications due to side-effects or medical complications.
- b. Treatment-resistance is usually defined as: the patient needs to have tried three different anti-psychotic medications from at least two different therapeutic groups,

when given at adequate therapeutic doses for adequate duration (usually, a minimum of six weeks each) in the past.

- c. The possible benefits and risks of clozapine use need to be carefully explained to the patient and their caregivers, and should also be given in the form of a written information sheet. Informed consent must be obtained for all voluntary patients.
- d. The patient needs to be physically examined and screened medically via blood testing, history, an electrocardiogram (ECG) and any other investigations indicated, to ensure that there are no medical conditions present which would mean clozapine prescription was contraindicated, eg a history of suppression of white blood cell production, significant cardiac disease, epilepsy etc.”

Further standards against which a clinician’s decision to prescribe clozapine can be judged include:

- the Novartis Data Sheet for clozapine (the data sheet) current in February 2001
- the *Guide to the Clinical Use of Novel (Atypical) Antipsychotic Drugs in New Zealand* (the Guide).

Both the Novartis Data Sheet and the Guide outline the conditions for which clozapine is indicated, the contraindications and risks associated with clozapine, and the monitoring regime that must be established.

Clozapine indicated for schizophrenia or schizoaffective disorders only

Dr C changed Mrs A’s diagnosis from paranoid schizophrenia to mood disorder with psychosis (melancholia) or depression with psychotic features in October 2000. When interviewed in April 2004, Dr C continued to claim that diagnosis was correct and that he prescribed Mrs A clozapine to treat that condition.

Dr Plunkett advised that for clozapine to be prescribed:

“The patient should have a treatment-resistant long-term psychotic illness, generally schizophrenia or a schizoaffective disorder, or should be unable to take alternative antipsychotic medications due to side-effects or medical complications. ...

... clozapine is not indicated for [m]ajor depression with psychotic features.”

The data sheet for clozapine also states that clozapine is indicated for treatment resistant schizophrenia, stating:

“Treatment with Clozaril is indicated in patients with treatment resistant schizophrenia only ie patients with schizophrenia who are non-responsive to or intolerant of classical neuroleptics.”

The Guide also states that clozapine is indicated for treatment-resistant schizophrenia.

With respect to diagnosis, Dr Plunkett advised:

“[Mrs A’s] initial diagnosis was appropriate for use of clozapine, but regarding [Dr C’s] rediagnosis, clozapine is not indicated for Major (sic) depression with psychotic features. It must be assumed that he had revised the diagnosis back to schizophrenia or schizoaffective disorder, but there is no clinical note or GP letter which clarifies this. In a ‘to whom it may concern’ letter of unclear purpose dated 23rd March 2001, [Dr C] discusses his reasons for prescribing clozapine, but fails to mention her diagnosis at all. It is thus difficult to know whether he met this standard in terms of a rational reason for clozapine prescription based on a revision of her diagnosis.”

The Novartis Data Sheet for clozapine also supports Dr Plunkett’s advice that clozapine is not indicated for major depression.

“Treatment with Clozaril is indicated in patients with treatment-resistant schizophrenia only, i.e. patients with schizophrenia who are non-responsive to or intolerant of classical neuroleptics.”

It is clear from the evidence that clozapine is indicated for treatment-resistant schizophrenia and schizoaffective disorders only. Clozapine is not indicated for depressive illnesses.

Throughout my investigation Dr C has maintained that his diagnosis of major depression with psychotic features was correct and that he did not deviate from that diagnosis when he prescribed clozapine for Mrs A in February 2001. When interviewed, Dr C also rejected Dr Plunkett’s suggestion that he must have reverted to a diagnosis of schizophrenia when he decided to trial Mrs A on clozapine.

I must therefore conclude that in deciding to prescribe clozapine to treat an illness he had diagnosed as mood disorder with psychosis (melancholia) or depression with psychotic features, Dr C’s prescription of clozapine was contrary to accepted standards including the Novartis data sheet, and *A Guide to the Clinical Use of Novel (Atypical) Antipsychotic Drugs in New Zealand*. Accordingly, Dr C did not provide services to Mrs A that complied with relevant standards.

Treatment resistance

Even if the matter is approached on the basis that Dr C *had* reverted to a diagnosis of paranoid schizophrenia when he prescribed her clozapine, his decision to prescribe clozapine was flawed since it is a further requirement for prescription of clozapine that the client’s schizophrenia is treatment-resistant. Mrs A’s condition was not treatment resistant as she had been stable while on thiothixene and risperidone.

Dr Plunkett acknowledged that the diagnosis of treatment-resistance is not straightforward, as what is considered treatment-resistance may vary from clinician to clinician:

“The diagnosis of treatment-resistance is not straightforward, as clinicians vary as to what level of residual symptoms can be called ‘a failure to respond’ Some would define treatment-resistance as the continuation of any, even low-grade symptoms, while others

would see only more serious and distressing symptoms or a clear relapse as indicating treatment-resistance.”

In Dr Plunkett’s view, however, Mrs A did not meet the usual criteria for treatment resistance:

“She had a history of having been relatively stable, with a moderate response of her psychotic symptoms to treatment, on her medication prior to transferring to [Dr C’s] care. ... Past medications on which she appears to have done reasonably well appear to be thiothixene and risperidone, in that she was stable on this prior to moving to [a rural township]. In my opinion, the records indicate that [Mrs A] had had reasonable responses to antipsychotic medications, but that her mental state at times worsened due to psycho-social stressors related to moving accommodation and difficulties with her family. It is likely that the adjustment to living in a new environment within her daughter’s family was more responsible for any worsening of her symptoms at the time of the initial assessment in October, rather than resistance to the risperidone prescribed. After altering her diagnosis, [Dr C] in fact nearly ceased the risperidone, rapidly lowering this to 1 mg from 8 mgs daily. After this and other medication changes as above, she relapsed, with a return of psychotic symptoms. The records indicate that [Mrs A’s] mental state fluctuated after her return from [overseas], with intermittent worsening of the psychotic symptoms. [Dr C] did not trial any other antipsychotic medications, nor did he reinstate the prior full dose of risperidone 8 mgs daily so as to treat these symptoms. Instead, he eventually prescribed clozapine in March 2001.”

Dr Plunkett did not agree that treatment resistance justified Dr C’s decision to commence clozapine:

“... given the risks and difficulties attendant on clozapine use in a far-flung rural area and in an older patient, ... there were [no] grounds to start a medically risky drug on the basis of mild chronic symptoms despite which [Mrs A] had previously managed a reasonable quality of life when stable on appropriate prior medication.”

The data sheet clearly states that clozapine is indicated *only* for schizophrenia that is treatment resistant.

Side effects of other antipsychotics

The emergence of intolerable side effects while using other antipsychotics is a further indicator for use of clozapine.

Dr Plunkett advised that treatment with clozapine is also indicated if a patient is “*unable to take alternative antipsychotic medications due to side-effects or medical complications*”. There is nothing in Mrs A’s patient records to indicate that she had unacceptable side effects when taking either risperidone or thiothixene.

During the investigation, Dr C stated that Mrs A’s irritability and inability to settle were extra-pyramidal side effects from risperidone. In a note dated 2 June 2000, Dr G does refer to Mrs A’s irritability but records “side effect — says nil from risperidone or thiothixene”.

I note also that Dr C does not appear to have suggested that he phased out Mrs A's risperidone because she had unacceptable side effects when he discussed Ms B's complaint with Dr K in September 2001. I would have expected him to have raised the side effects then if they had influenced his decision to withdraw the risperidone.

Dr Plunkett, however, advised that it may have been reasonable for Dr C in October 2000 to have considered substituting another antipsychotic for risperidone on the basis that the risperidone was causing mild to moderate extrapyramidal side effects. Following that advice, I accept that it was reasonable for Dr C to consider the possibility that risperidone had in the past caused Mrs A extrapyramidal side effects as one of the factors in his decision-making process.

Difficulty of monitoring commencement on clozapine in community

Patients must be closely monitored during the commencement phase of clozapine. Daily blood pressure, temperature and pulse readings and regular blood testing are required. In deciding to commence Mrs A on clozapine in the community, Dr C should have taken into account the difficulty of achieving such close monitoring for Mrs A given that she lived in an isolated rural community.

Dr Plunkett advised that Dr C's decision to commence Mrs A on clozapine in the community was unwise, given the risks and difficulties associated with monitoring her response. I am therefore of the view that Dr C did not provide services with reasonable care and skill.

Assessment prior to commencement of clozapine

Dr Plunkett advised me that before clozapine is commenced:

“The patient needs to be physically examined and screened medically via blood testing, history, an electrocardiogram (ECG) and any other investigations indicated, to ensure that there are no medical conditions present which would mean clozapine prescription was contraindicated, e.g. a history of suppression of white blood cell production, significant cardiac disease, epilepsy, etc.”

In Dr Plunkett's opinion full blood counts were done correctly both before the trial commenced and thereafter in so far as blood samples were taken and sent for testing. However, it is not clear whether Dr C routinely checked the results or had arranged for someone else to check them.

There is no evidence that Dr C either performed, or arranged for Mrs A's GP to perform, a physical examination. Nor is there any evidence that Dr C arranged for Mrs A to have an ECG before she was started on clozapine. Dr Plunkett advised that an ECG is required prior to the trial and at the end of the first two weeks to screen for myocarditis, and thereafter only if cardiac symptoms develop.

Further, Dr Plunkett noted:

“The manufacturers provide a special form to document all the prescreening history-taking and tests, to assist doctors with the process. This has been left entirely blank and

uncompleted, apart from a tick noting that [Mrs A] was not pregnant. This is a poor standard of medical screening as part of the decision to prescribe clozapine.”

In my view, Dr C’s failure either to examine Mrs A himself, or arrange for Mrs A’s general practitioner to conduct a physical examination, breached Mrs A’s right to have services provided with reasonable skill and care. Without a physical examination, Dr C could not be satisfied that Mrs A was a suitable candidate for treatment with clozapine. In addition, the omission of a physical examination meant that there was no baseline against which to monitor Mrs A’s physical response to clozapine.

Prescribing issues

Dr C recorded two versions of his prescription for the commencement of clozapine. One version is recorded in his letter of 23 March 2001 as follows:

“... I have started her off on Clozaril, starting off with a low dose and increasing it gradually, while phasing [out] the risperidone that she was on, having stopped Cipramil previous to that.

At present we are increasing the dose to 100mgs a day, again increasing it to 200mgs a day in five days time and again to 300mgs a day in another five days time.”

The other version is recorded in Mrs A’s medication chart as:

“Clozaril regime as documented in her notes. Increase Clozaril to 100mg nocte, then 200mg nocte, then 300mg nocte with 5 day intervals between dose increases.”

Ms D recorded a third version of the regime as follows:

“Start on Clozaril 25mg and reduce risperidone to 4mg for three days. Increase Clozaril to 50mg and reduce risperidone to 2mg for one week. Dosage of Clozaril will be increased to 100–200mgs depending on response.”

Dr Plunkett described Dr C’s charting as:

“imprecise ... as no starting dose is specified, nor is it clear when the dose is to be increased to 100mgs nocte. ... his practical prescribing of clozapine was at a very poor standard.”

In my opinion, Dr C’s lack of precision is very concerning. The prescription created the possibility for confusion on the part of Ms D and Mrs A’s family. It also created the risk of misunderstanding by other health professionals involved in Mrs A’s treatment. Dr C was responsible for ensuring that his prescription of the regime for commencing Mrs A on clozapine was clear and recorded accurately. Dr C’s failure to do so amounts to a breach of Mrs A’s right to have services provided with reasonable care.

Summary of findings with respect to decision to prescribe clozapine

In my opinion, Dr C did not provide services complying with relevant professional standards when he decided to prescribe clozapine for Mrs A and therefore breached Right 4(2) in the following respects:

- Dr C's diagnosis of major depression with psychotic features meant that clozapine was not indicated
- Mrs A's condition was not treatment resistant as she had been relatively stable on thiothixene and risperidone prior to her care being transferred to Dr C
- The side effects Mrs A experienced while taking thiothixene and risperidone were not significant enough to warrant changing medications on which she had been relatively stable
- Dr C's prescriptions were imprecise and unclear.

In addition, Dr C did not provide services with reasonable care and skill and therefore breached Right 4(1) in relation to:

- his failure to give appropriate weight to the risks of introducing clozapine in a rural setting
- the lack of a proper assessment before commencement of clozapine.

Monitoring of clozapine

Mrs A complained that:

“In February 2001 ... [Dr C] did not ensure adequate monitoring of [Mrs A's] clozapine and did not take appropriate steps in a timely fashion when Mrs A became increasingly unwell.”

Monitoring introduction of clozapine

While *A Guide to the Clinical Use of Novel (Atypical) Antipsychotic Drugs in New Zealand* endorses the initiation of clozapine in the community, it does so on the provision that an adequate level of monitoring and supervision is available. It also stipulates that dose titration in the community should be done slowly and patients' physical condition closely monitored for at least the first two weeks of treatment, including daily monitoring of blood pressure, pulse and temperature.

Dr Plunkett noted that Mrs A's pulse was not monitored at all during her first three weeks on clozapine. She also indicated that Mrs A's blood pressure should have been taken both standing and lying as any lowering of blood pressure is generally orthostatic (posture-related). This was particularly important as Mrs A began to complain of dizziness and on one occasion reported blacking out.

Dr Plunkett advised that when a patient is commenced on clozapine the following monitoring is required:

“Weekly blood testing for the first 18 weeks of a clozapine trial:

- i A full blood count especially to check white cells is mandatory prior to the trial and weekly in the first 18 months of the trial. ...
- ii Liver function tests, electrolytes and renal function are checked prior to commencement and thereafter each month in the first 18 weeks.
- iii Serum clozapine levels are needed between weeks two to four so as to determine whether the serum level is adequate or a larger dose is needed; Once the desired serum level is achieved, these are done occasionally, to check that the serum level remains stabilized and appropriate.

Daily physical recordings for the first three weeks of a clozapine trial

All patients need daily pulse, blood pressure and temperature recordings taken for the first three weeks. This is often logistically difficult to manage in out-patient clozapine trials, and is one reason these are generally not attempted in isolated areas. As any lowering of blood pressure is generally orthostatic (posture-related) blood pressure should be checked both lying and standing so as to detect this symptom.

An ECG (electrocardiogram) is required prior to the trial, at the end of the first two weeks to screen for myocarditis, and thereafter only if cardiac symptoms develop, eg palpitations, chest pain or a marked tachycardia (rapid heart rate)

General monitoring eg for side effects and to ensure that the dosage regime is understood:

Daily visits are required for an out-patient clozapine trial, to support the patient and caregivers, ensure the rather complex dosage titration is understood and organised, and to monitor the person’s mental state and for any side-effects. Continuing explanation of the treatment programme and of possible side effects is carried out at these visits, and weekly blood tests are ensured so that weekly clozapine supplies can be delivered. (The supply of clozapine weekly from any pharmacy is dependant on an adequate white cell count from the latest blood test taken that week.)”

The records indicate that a full blood count was done before Mrs A began taking the clozapine. This requirement for the commencement of clozapine was therefore met.

Full blood counts were done on 17 and 24 April 2001. It is not clear who reviewed the blood tests. Blood testing should have occurred weekly.

Blood pressure and temperature recordings were taken most days during the first three weeks of the trial. However, blood pressure should have been taken both lying and standing so as to check postural drops in pressure, which can cause falls.

In addition, Mrs A’s pulse rate was not recorded at all until she was admitted to the rural hospital on 29 March 2001 in week four of the trial. Dr Plunkett said:

“The pulse [is] an important recording as clozapine can cause tachycardia initially, and to monitor for myocarditis.”

There is no record of Mrs A having an ECG either before or during the trial. Dr Plunkett advised me that this was not adequate and Dr C should have arranged ECGs with Mrs A’s general practitioner.

With respect to general monitoring for side effects and to ensure the dosage regime was understood, there was no written plan.

A table setting out the monitoring that was undertaken appears below.

Date	Action	Blood Testing
15 February 2001	Decision to commence Clozapine.	
5 March 2001	Clozapine commenced.	
6 March 2001		Blood sample received by a pathology laboratory.
7 March 2001	Blood pressure and temperature taken twice.	Blood test results reported by a pathology laboratory
8 March 2001	Blood pressure and temperature taken twice.	
9 March 2001	Blood pressure and temperature taken twice.	
10 March 2001	Blood pressure and temperature taken twice.	
11 March 2001	Blood pressure and temperature taken twice.	
12 March 2001	Blood pressure and temperature taken twice.	
13 March 2001	Blood pressure and temperature taken twice.	Blood sample received by a pathology laboratory.
14 March 2001	Blood pressure and temperature taken twice.	Blood test results reported by a pathology laboratory
15 March 2001	Blood pressure and temperature taken once.	
16 March 2001	No blood pressure or temperature results recorded.	
17 March 2001	Blood pressure and temperature taken once.	
18 March 2001	Blood pressure and temperature taken once.	
19 March 2001	Blood pressure and temperature taken once.	Blood sample taken to test clozapine levels.
20 March 2001	Blood pressure and temperature taken once.	

21 March 2001	No blood pressure or temperature results recorded. The pathology laboratory reports results of testing on blood sample received 20 March 2001.	Clozapine level reported as 300 nmol/L.
22 March 2001	Blood pressure and temperature taken once.	Dr C sees Mrs A for first time after commencement of clozapine.
23 March 2001	Blood pressure and temperature taken once.	
24 March 2001	Blood pressure and temperature taken once.	
25 March 2001	Blood pressure and temperature taken once	
26 March 2001	Blood pressure and temperature taken once.	
27 March 2001	Blood pressure and temperature taken once.	
28 March 2001	Blood pressure and temperature taken once.	
3 April 2001		Blood sample taken for clozapine levels. Reported on 5 April as 1590 nmol/L.
10 April 2001		Blood sample taken for clozapine levels. Reported on 12 April as 1430 nmol/L.
14 April 2001	Clozaril reduced to 200mg nocte.	
24 April 2001		Blood sample taken for clozapine levels. Reported on 27 April as 660nmol/L.

In response to my provisional opinion, Dr C stated:

“I prescribed Clozaril according to the Clozaril regime, on the prescription sheet. The Clozaril registration sheet contains all the required safety checks requested and it falls on the nurse to make the arrangements with the GPs to do them. The fact that the results are not in her file is a reflection on the filing system, not on me or the nurse.

There was ongoing monitoring of [Mrs A] whilst on Clozapine. For example, on 3 April 2001 her blood level was measured at 1590 nmol/L. Whilst this is not a high level (levels up to 2000 nmol/L are acceptable) the dose was reduced because she reported feeling dizzy. It is eschewing of the facts to say we waited until the patient reported dizziness. If the patient did not report it as asked, how would we know it? We then reduced the dose.

[Ms B] had said that there are no records of her mother's pulse having been checked other than by herself. It was taken on every occasion that blood pressure was recorded. Without taking the pulse, blood pressure cannot be taken. It is sometimes also automatically indicated. A fast pulse or disrhythmic pulse would be noted by the nurse taking the blood pressure."

Dr Plunkett did not agree that the monitoring arrangements should be delegated to nursing staff. She stated:

"[The monitoring requires] medical overview and direct contact with the GP by [Dr C] was needed. In the event, these medical safety checks do not appear to have been properly arranged with the GP or with nursing staff (eg regarding pulse and ECG recordings).

[Dr C] also states that [Mrs A's] pulse was taken 'on every occasion that blood pressure was recorded. Without taking the pulse, blood pressure cannot be recorded.' This is not necessarily correct. Some modern digital devices do record pulse as well as blood pressure, and if such a device were used, recordings of the pulse should have been placed in [Mrs A's hospital case notes] — which they were not. Older models of sphygmomanometer do not automatically register pulse, and a nurse taking blood pressure would not automatically count the pulse while listening through a stethoscope so as to record blood pressure — taking an accurate pulse requires digital palpation of the pulse while timing with a watch. It appears that [Mrs A's] daughter did not witness this occurring. Again, it was [Dr C's] responsibility to ensure that nursing staff knew which recordings to take, took such recordings, and that they recorded these in the files, so that he could check the recordings regularly."

I share Dr Plunkett's view that it was Dr C's responsibility to ensure that arrangements were in place for Mrs A to be monitored by a GP. While it might fall to a nurse to make the practical arrangements, responsibility for ensuring the arrangements were made rested with Dr C as Mrs A's consultant.

In addition, while it is clear that some monitoring did take place, for instance the blood tests that led to a reduction in the clozapine dose referred to by Dr C, the monitoring was not regular and consistent.

I do not accept Dr C's statement that Mrs A's pulse was taken on every occasion on which her blood pressure was recorded. There is no record of Mrs A's pulse in her patient record and Ms B does not recall her mother's pulse being taken. Dr Plunkett has also advised me that blood pressures can (contrary to Dr C's belief) be taken without also taking a patient's pulse.

In my opinion, the monitoring of Mrs A's response to clozapine was inadequate. As Mrs A's psychiatrist, Dr C was responsible for overseeing the way in which she responded to clozapine and is accountable for any shortcomings in the monitoring. In failing to ensure Mrs A was monitored appropriately, Dr C failed to meet the standards set out in the data sheet and *A Guide to the Clinical Use of Novel (Atypical) Antipsychotic Drugs in New*

Zealand and therefore breached Mrs A's right to services that complied with relevant professional standards.

Titration of clozapine dose

Dr Plunkett advised:

"... [Dr C] prescribed the clozapine titration in a highly unusual manner. His initial charting of clozapine on the prescription sheet is merely as 'Clozaril regime' as documented in her notes. Increase Clozaril to 100mgs nocte, then 200mgs nocte then 300mgs nocte then 400mgs nocte with 5 day intervals between dose increase. This is imprecise charting as no starting dose is specified, nor is it clear when the dose is to be increased to 100mgs nocte. ... [The imprecise charting and [Ms D's] reference to clozapine as clopixon and clozapine cause] me serious concern, as [Dr C] delegated documentation of the exact drug regime prescribed to the nurse [Ms D], who appears so unfamiliar with clozapine that she repeatedly recorded it using an incorrect name. There must have been a more accurate prescription used at the local pharmacy to actually obtain the clozapine supply, but [the rural hospital] records are seriously inaccurate and show an extremely poor standard regarding the most basic prescribing principles, for which [Dr C] is responsible as only psychiatrists are registered so as to prescribe clozapine medication.

It thus appears that [Mrs A] probably commenced 25mgs clozapine on 5th March then increased this to 50mgs on about 8th March, after which it was increased to 100mgs on 22nd March and then up to 400mgs daily via weekly increments of 100mgs.

For a 62 year old woman this is an extremely rapid and coarse dose titration, and at variance with the much more gradual regime recommended by the manufacturing company and adhered to in all other mental health services where I have worked. I would expect even a young fit patient to experience distressing side effects on such a regime, and far more so in an older person. [Ms B] describes her mother's physical health as having gone 'down hill dramatically' with vomiting, diarrhoea and incontinence and worsening of her psychotic symptoms. ...

The correct dose is partly determined by serum levels of clozapine. These were done regularly from 21st March. By 28th March the level was just below 100nmol/L which is very close to the level aimed at to treat resistant psychosis. If the initial planned titration was followed as laid out by [Dr C] (there are no records of this, but also none to indicate that the plan deviated) then [Mrs A's] clozapine was again increased by 100mgs even after this quite good serum level in a 62 year old woman, and by the next test on 5th April the serum level had risen to 1590 nmol/L. A young person might tolerate this, but as the level of toxicity is 1000nmol/L and [Mrs A] was not young, she is highly likely to have experienced significant side-effects as well. At his next review on 14th April [Dr C] reduced the dose by half to 200mgs daily, probably partly as he was concerned by this high serum level of clozapine. Again, there are no clinical notes and also no evidence that the significance of these levels was recognized by the clinic nurses and conveyed to [Dr C] by phone, so dose adjustments only occurred belatedly, at his weekly visits. This demonstrates a poor standard in the overall management of the clozapine prescription and treatment plan by [Dr C].

In summary, [Dr C's] decision to prescribe clozapine was inappropriate, as above, and his practical prescribing of clozapine was at a very poor standard and led to significant side effects."

Based on Dr Plunkett's advice, I consider that Dr C did not manage Mrs A's commencement on clozapine, prescribe the regime for her commencement on the drug or titrate her dosage with reasonable skill and care or consistently in compliance with relevant professional standards. In my view, he failed by a significant margin, to act with reasonable care and skill.

In addition, it is clear that Dr C's failure to manage the introduction of clozapine appropriately had serious consequences for the well being of Mrs A and her family. Mrs A's psychotic symptoms worsened and her physical health was affected with vomiting, diarrhoea and incontinence, an increasingly high degree of sedation and a loss of ability to function. Mrs A's family, who had cared for Mrs A without major difficulty for many years, found it more and more difficult to manage her at home. Dr C must accept responsibility for these consequences.

In my view, Dr C breached Right 4(1) of the Code in this regard.

Informed consent

Informed consent to clozapine

Ms B complained that Dr C did not provide her or Mrs A with information that a reasonable consumer in Mrs A's condition would expect to receive. In particular, when Dr C prescribed clozapine for Mrs A, he did not provide her with adequate information about clozapine, and did not inform her about the side effects and warnings associated with clozapine.

Dr C did not make a note of the consultation on 15 February 2001 at which he decided to trial clozapine. It is difficult therefore to determine what information Dr C gave to Mrs A and her daughter though it would seem likely that there was some discussion of the reasons for the change. Ms D's note of the consultation on 15 February 2001 records:

"Discussion about change in medication with visiting psychiatrist [Dr C]. To commence on Clozaril. ...Daily observation of neuroleptic [symptoms] during this period. Observe for signs of muscle rigidity, increased temperature and excessive sweating. ... Homevisit [Mrs A] to discuss change."

Ms B says that Dr C did not provide any information about clozapine. He simply reassured her that when he worked overseas they used clozapine often and that it would work. She got the impression from Dr C that clozapine was some kind of miracle drug. Ms B says that before Mrs A was started on clozapine, she herself obtained some written information about the drug from Novartis, the manufacturer of clozapine.

When interviewed Dr C said that he did not provide information about clozapine to Ms B because she did not want to speak to him at that stage and left the room. Instead, Dr C stated

that he asked the community mental health nurse (Ms D) to tell Ms B about clozapine. He said:

“... [Ms B] didn’t want to talk to me so I didn’t provide any information to her, but I told the nurse to go through quite a strict protocol about the introduction of Clozaril. First of all the, the blood tests and things that have to be done and that has to be discussed with the family because [Ms B] is the one that has to bring the patient in. So it’s unfair of [Ms B] to say that we didn’t tell her anything about the Clozaril. I might not have told her anything about the Clozaril but the nurse certainly did.”

In my opinion, the evidence suggests that Dr C did not provide Mrs A and her daughter with adequate information prior to Mrs A’s commencement on clozapine.

In a letter dated 11 November 2002 provided via his barrister, Dr C stated “... it is inconceivable that the testing and monitoring regime would not have prompted the patient or her daughter to ask questions”. This suggests that he did not provide information proactively but expected Mrs A or her daughter to ask for it. Dr Plunkett describes this as:

“ ... an extraordinary statement as it appears to indicate that rather than providing proper information at the start of the process, [Dr C] expected the patient and family to take the initiative to ask questions based on the monitoring regime set in place, so as to obtain information. This contravenes all normal standards of the provision of adequate information as part of an informed consent process.”

I share Dr Plunkett’s rejection of Dr C’s suggestion that he had no obligation to provide Mrs A and Ms B with information but could expect them to take the initiative to obtain information themselves. Dr C had an obligation to provide information about clozapine, regardless of the steps Ms B might take to inform herself.

In addition, the fact that Mrs A’s daughter found it necessary to seek information from the manufacturer of clozapine suggests that she did not feel adequately informed about the drug.

Further, Ms D had never before cared for a client undergoing a trial on clozapine, whether in a community or hospital setting, let alone in a remote area. She had recently arrived in the area from another part of the country where she had worked in the community. According to Ms D, in the area she previously worked patients were always started on clozapine as inpatients in hospital. She therefore had no experience in commencing clients on clozapine and is therefore unlikely to have been able to provide Mrs A and her daughter with adequate information about the drug.

Dr Plunkett advised:

“The potential benefits [of clozapine] need to be explained as well as the risk and side-effects, with practicalities of follow-up, monitoring and the titration of doses. It is usual to inform patients about any side-effects which occur more frequently — for example the listed side effects in 17(b) [of Dr Plunkett’s advice] which occur at least a 10% frequency. In addition, it is necessary to discuss rare but potentially very serious side-effects. The

main warnings discussed are agranulocytosis (suppression of white blood cell production), but also the possible risk of seizures, cardiac symptoms, abdominal pain or gastrointestinal symptoms, visual side-effects and symptoms of raised blood sugar. ... It is difficult for patients and families to retain all these details, so written information must be provided and a clear plan to call the clinic or to see their GP if symptoms occur needs to be arranged, including weekend and after-hours back-up. The treating psychiatrist has considerable initial responsibility to convey this information and to ensure that a written version is provided. This task cannot be delegated to nursing staff as it forms a key part of a proper informed consent process. ... [The decision-making] process and the provision of information, was not adequately carried out by [Dr C].”

As an additional indication of the standards applicable to the provision of information, the Novartis data sheet for clozapine current in February/March 2001 advises doctors to discuss the following issues with patients for whom they prescribe clozapine:

“Patients who are to receive CLOZARIL (clozapine) should be warned about the significant risk of developing agranulocytosis. They should be informed that weekly blood tests are required for the first 6 months, if acceptable WBC [white blood cell counts] (WBC greater than or equal to 1000/mm³, ANC ≥ 1500mm³) have been maintained during the first 6 months of continuous therapy, then WBC counts can be monitored every other week in order to monitor for the occurrence of agranulocytosis, and that CLOZARIL (clozapine) tablets will be made available only through a special program designed to ensure the required blood monitoring. Patients should be advised to report immediately the appearance of lethargy, weakness, fever, sore throat, malaise, mucous membrane ulceration or other possible signs of infection. Particular attention should be paid to any flu-like complaints or other symptoms that might suggest infection.

Patients should be informed of the significant risk of seizure during CLOZARIL (clozapine) treatment, and they should be advised to avoid driving and any other potentially hazardous activity while taking CLOZARIL (clozapine).

Patient should be advised of the risk of orthostatic hypotension, especially during the period of initial dose titration.”

The Guide also emphasises the need for patients to be fully informed about the possible benefits and risks associated with clozapine as well as the rigorous monitoring regime.

Dr Plunkett advised:

“As ever, due to the paucity of clinical records it is extremely difficult to know whether a true informed consent process was carried out with [Mrs A] and her daughter but overall I doubt this. Her community nurse [Ms D] noted in the [database] records that a discussion about starting clozapine occurred at an appointment with the details of drug doses to be altered and that there would be ‘daily monitoring’ for a number of symptoms, some of them highly unlikely to occur on clozapine. ...

[Dr C] was primarily responsible for carrying out the informed consent process and in ensuring written information was provided, especially as it was unlikely that a rural outreach clinic would often commence clozapine de novo in out-patients so the clinic staff [was] unlikely to have been experienced in this process. In my opinion a reasonable standard was not met as regards informed consent, in the prescribing decision.”

Dr Plunkett advised that although Dr C may have had little option but to delegate to Ms D the responsibility for providing Mrs A with information about clozapine, he should have overseen the process:

“[Dr C] appears to have had few options in the matter if as he states [Ms B] thereafter refused to meet with him to discuss her mother’s treatment. As I have made clear, in my opinion the whole plan to commence clozapine for [Mrs A] as an outpatient in a far-flung rural community was unwise. This was obviously further complicated by [Dr C’s] poor relationship with the primary caregiver, [Ms B]. It was unfortunate that the provision of information had to be delegated, and it appears that Dr C did not oversee this to the degree required — ie he did not ensure that [Ms B] and [Mrs A] received detailed written as well as verbal information about clozapine treatment, before this was commenced.”

Before commencing treatment with clozapine, Dr C was obliged to ensure that Mrs A:

- had the information that a reasonable consumer, in her circumstances would expect to receive, including an explanation of her condition and the treatment options available including an assessment of the expected risks, side effects and benefits of each option, as required by Right 6(1);
- before making a choice or giving consent, had the information that a reasonable consumer, in her circumstances, would have needed to make an informed choice or give informed consent, as required by Right 6(2);
- made an informed choice and gave informed consent before treatment with clozapine began, as required by Right 7(1).

In my opinion, Dr C failed to discharge his obligations under Rights 6(1) and (2) and 7(1). A consumer in Mrs A’s circumstances was entitled to an explanation of the potential benefits of clozapine as well as the risks and side effects, particularly the very serious condition of agranulocytosis but also the possibility of seizures, cardiac symptoms, abdominal pain or gastrointestinal symptoms, visual side effects and the symptoms of raised blood sugar levels.

Mrs A should also have been given an explanation of the requirements for monitoring, including the need for an initial ECG and blood tests to check white blood cell count, daily checking of blood pressure, temperature and pulse during the initial weeks and monthly checking of white blood cell counts and clozapine levels. She should have been told about the process for introducing clozapine and titrating the dose.

I accept that the difficulties in the relationship between Dr C and Ms B may have meant that Dr C could not provide this information personally, however he should have taken active

steps to ensure that Mrs A was provided with adequate information by Ms D. He does not appear to have done so. Instead, he appears to have relied, without checking, on Ms D relaying the information.

Recordkeeping

My investigations of the services Dr C provided to Mrs A raises questions about his recordkeeping.

The maintenance of accurate and complete records of treatment is a fundamental and essential part of providing medical services to a client. A failure to maintain accurate and complete records exposes the patient to the risk that other providers involved in a patient's care will lack full information about a patient's history, treatment plans and medications. Poor recordkeeping magnifies the likelihood of error.

In my opinion, Dr C did not maintain accurate and complete records of the treatment he provided to Mrs A and in this way failed to provide Mrs A with services of an appropriate standard. In addition, Dr C's failure to maintain adequate records left the community mental health nurses involved in Mrs A's care without proper direction as to her diagnosis and the plan for her treatment.

Dr C saw Mrs A on the following six occasions and made notes as follows:

19 October 2000	Notes in form of letter dated 19 October 2000 to Dr E
26 October 2000	No notes made
16 November 2000	Notes in form of letter dated 16 November 2000 to Dr E
18 January 2001	No notes
15 February 2001	No notes
22 March 2001	Notes in form of letter dated 23 March 2001 "to whom it may concern".

On three occasions — 26 October 2000, 18 January 2001 and 15 February 2001 (a critical consultation at which it was decided to trial clozapine) — Dr C made no record at all of his consultations with Mrs A. When Dr C did document his consultations, he did so in letter form. Dr C did not sign the letter dated 19 October 2000 and during an interview said that he did not review the letter before it was placed on Mrs A's file.

Dr C himself has admitted that his documentation in client notes was inadequate. On 7 August 2001 in an email to Dr K, Clinical Director and Director of Area Mental Health Services at the DHB, Dr C said:

"As far as the second charge [of poor record keeping] is concerned: Yes, I am guilty. Sometimes, I hope very seldom, do I not dictate a note, but it does happen. I doubt that I could have left out 40 files, but if it is so I will gladly make any amends you require."

Dr K described the absence of clinical notes as “totally unacceptable. I could find only two items of correspondence from him but even they fell well short of acceptable standards.” She describes the obligation to keep adequate records as a “fundamental and core requirement of medical practice”.

It is concerning that although Dr K discussed with Dr C on 3 September 2001 the need for proper documentation in clinical records, and Dr C agreed to improve his performance in this area, Dr K’s random audit of patient files at another mental health service on 23 October 2001 found that there were still “serious deficiencies in your notes which put patients at risk”.

In the course of this investigation, Dr C said that his notes were in the form of correspondence. In the case of the rural hospital clinic, Dr C would dictate notes onto a tape and give the tape to the typist, who typed up the notes and either gave them to him for signing or emailed them to him to check. Dr C could not explain how it came about that he did not sign the letter of 19 October 2000.

Dr C said that he did not make notes in the computer system. He also said that if he had done home visits and was not returning to the clinic at the end of the day, he would ask the nurse accompanying him to make the clinical notes of those home visits.

Dr Plunkett was also critical of Dr C’s recordkeeping. With respect to Dr C’s decision to change Mrs A’s diagnosis to major depression with psychotic features in October 2000, Dr Plunkett commented:

“We have little evidence of his reasoning, due to his poor documentation of this ...”

Dr Plunkett noted that “when a rediagnosis is made, there needs to be careful documentation of this with the reasons for the rediagnosis being recorded fully so as to explain the change.” She advised:

“Regarding careful documentation, [Dr C] clearly did not meet a reasonable standard. He made no clinical notes of the consultation [on 19 October 2000] in the file, and a remedial process was later implemented by [the DHB] regarding recurrent deficits in his clinical documentation. The brief typed letter to [Dr E] states brief details of history and mental state, and then the rediagnosis and planned treatment change, but gives no actual explanation as to the reasoning for this, so as to explain the changes. In my opinion [Dr C] did not meet a reasonable standard in terms of documenting the reasoning for the rediagnosis.”

“... there is no documentation of a management plan regarding the involvement of her family, frequency of community nurse reviews or of psychiatrist reviews, or of a relapse prevention plan.”

Dr C also created difficulties when he failed to check his letter of 19 October 2000 and so left uncorrected substantial errors in the terms he used to describe Mrs A’s diagnosis. Dr C’s

failure to ensure that this letter was corrected before it was filed has resulted in uncertainty as to the diagnosis he assigned to Mrs A.

The Medical Council of New Zealand's *Guidelines for the Maintenance and Retention of Patient Records* state:

“Introduction

Records form an integral part of any medical practice: they help to ensure good care for patients and also become critical for any future dispute or investigation.

1 Maintaining patient records

- (a) Records must be legible and should contain all information that is relevant to the patient's care.
- (b) Information should be accurate and updated at each consultation. Patient records are essential to guide future management, and invaluable in the uncommon occasions when the outcome is unsatisfactory.”

In my view, Dr C's documentation of his treatment failed to meet the legal, professional, and ethical requirements of a medical practitioner and he therefore breached Right 4(2) of the Code. Dr C made significant changes in Mrs A's diagnosis and medication on several occasions but failed to record his decisions and the reasons for them accurately. He also failed to record details of the management plan including family involvement, community nursing support, psychiatrist review and relapse prevention. He relied excessively on nursing staff to keep records of his consultations.

Even when Dr C did record his consultations with Mrs A, in letters, he did not record sufficient information to make his treatment decisions transparent and comprehensible. Dr C also failed to check the letter of 19 October 2000 before it was filed. In failing to keep adequate records, Dr C exposed Mrs A to the risk that that the community mental health nurses who were charged with treating Mrs A might misunderstand his instructions. Dr C created a situation where there was a significant risk of Mrs A suffering serious harm.

Opinion: No Breach — Dr C

Taking account of family concerns

Ms B complained that:

“... in October 2000 ... [Dr C] did not adequately take into account concerns expressed by [Mrs A’s] daughter and primary caregiver, [Ms B], about [Mrs A’s] mental health and the new medication she had been prescribed.”

Dr Plunkett stated:

“... whatever the level of distress of a concerned relative, it is the responsibility of the psychiatrist as a trained professional to listen carefully to the concerns and to respond to these appropriately. ...

... a psychiatrist should take careful note of reports from family members, especially the primary caregiver, regarding a patient’s symptoms. Family commonly do see symptoms that patients keep hidden from health professionals during brief reviews. If a relative expressed strong concerns that a patient was deteriorating after a medication change, an urgent clinical review should be arranged. As far as I can see this did not occur, in the two weeks prior to [Mrs A’s] overseas trip. When travel of this sort is planned, there is even more reason to ensure that a careful reassessment occurs.”

The RANZCP *Summary of guidelines for the treatment of depression* also states that an effective treatment plan must include treatment alliances with family and friends of a patient. Ms B was her mother’s primary caregiver and had played a pivotal part in caring for her for many years.

Clearly Dr C should have taken into account Ms B’s concerns in relation to her mother’s instability and the effect of the change in medications. Even though the 16 November 2000 consultation seems to have been difficult for all involved, Dr C, as the medical professional charged with Mrs A’s care, was required to manage the conflict with Ms B in ways that would optimise Mrs A’s treatment. Dr C’s failure to develop a cooperative relationship with Ms B and to manage conflict with her effectively had a negative impact on Mrs A’s treatment.

When interviewed Dr C indicated that he had listened to Ms B’s views and agreed that it was important to do so. While he does not appear to have acted on Ms B’s views I am not convinced that it follows that he did not adequately consider them. I consider that Dr C’s behaviour in this respect does not amount of a breach of Right 4(1) of the Code. However, I draw to Dr C’s attention my expert’s comments on this matter and the need to maintain an appropriate relationship with the primary caregivers of patients.

Opinion: Breach — The rural hospital

Management of Mrs A on her return from overseas

The complaint is that the rural hospital did not provide services of an appropriate standard to Mrs A when she returned in crisis from her overseas trip in January 2001, in that the rural hospital did not arrange for her admission or alternatively provide Mrs A or her principal caregiver, Ms B, with adequate and appropriate psychiatric community support.

In my opinion, the rural hospital failed to provide services to Mrs A with reasonable skill and care when she returned from overseas in crisis in January 2001. In particular, the rural hospital community mental health nurses (CMHNs) failed to complete a comprehensive assessment of Mrs A on her return from overseas, plan and evaluate interventions, and document nursing interventions. In addition, a nursing management plan that accurately reflected the outcomes of ongoing nursing assessments and collaboration with Mrs A and her family was not maintained.

In coming to this view I am mindful of the difficulties faced by the rural hospital and its CMHNs given Dr C's poor diagnostic decisions and failure to plan Mrs A's management adequately, the breakdown in communications between Dr C and Ms B, and the lack of inpatient beds at times when Mrs A's condition may have justified her admission coupled with the family's resistance to her admission. I have made allowance for these difficulties in forming my conclusions.

Relevant standard — Standards of Practice for Mental Health Nursing in New Zealand

Mr Woods advised that the standard against which best practice for mental health nurses (including those working in the community) is specified is the Australian and New Zealand College of Mental Health Nurses' Standards of Practice for Mental Health Nursing in New Zealand (1995) (the Standards of Practice).

Standard III of the Standards of Practice requires that "the Mental Health Nurse provides nursing care that reflects contemporary nursing practice and is consistent with the therapeutic plan". Standard III also requires the CMHN to "facilitate the process of comprehensive nursing assessment" and "document assessment outcomes, nursing management plan, strategies for care and outcomes".

No comprehensive nursing assessment

In relation to the nursing services provided to Mrs A, Mr Woods advised:

"... It [was] hard to identify a therapeutic plan. I was unable to find a comprehensive nursing assessment subsequent to [Mrs A's] referral from [the CMHC] early in September 2000. Assessment and planning appears limited to the letter from [Dr C] to the [general practitioner] [Dr E] [19/10/2000] and the nursing notes that record [Dr C's] initial assessment [26/10/2000]. Mostly these relate to a change of diagnosis [to major affective disorder] and medication.

The nursing assessment documented around the time of [Mrs A's] return from [overseas] was completed before staff back in [the rural hospital] saw her. It was completed as a result of discussion with daughter [Ms B] via telephone. I refer to [Ms H's] clinical note of 15/01/01 and [Ms D's] Clinical Assessment Form of the same date. Four days after [Mrs A's] return a Respite Clinical Assessment and Treatment Care Plan was completed by [Ms D], which noted a return to the original diagnosis of schizophrenia.

While the notes show a high degree of concern on the part of nursing staff prior to the client's return, subsequent crisis assessment was not fully done. Intervention planning was limited to daily review by the CMHN, increased Community Support Worker [CSW] input, and an increase in medication. Nursing evaluation of this ongoing plan of respite care does not appear in the notes. Nursing visits are alluded to in [Ms B's] account of the care received after her mother returned from [overseas], however these are not documented for the period between 18/01/2001 and 30/01/2001."

Mr Woods also noted that the Standards of Practice require that the nursing management plan "accurately reflects the outcomes of ongoing nursing assessment, collaboration with the consumer, family or whanau and consultation with other members of the mental health team". This standard was not met.

I endorse Mr Woods' view that:

"[The rural hospital's] response to the situation should have been based on a comprehensive assessment by the multidisciplinary team. Given the level of concern expressed by [the family] it seems remiss that a comprehensive assessment was not done, which could have outlined [Mrs A's] mental state, risk factors, and the family's coping ability. ... Assessment was limited to [Ms D's] reportage of the psychiatric consultation."

Response to Mrs A's return from overseas

"The Clinical Assessment done by [Ms D] for the purposes of crisis respite [dated 23/01/01] notes an increase in the [passive-like] 'negative' symptoms of schizophrenia and an increase in auditory hallucinations. Other nursing notes at that time state that the voices [Mrs A] was hearing were of a persecutory nature and that she believed members of her family were being harmed. Suicidality did not appear to be a concern, though impulsivity was present. It is also noted that along with non-compliance there had been a change in the diagnosis and the medication prescribed, which may have contributed to the deterioration. Given this picture and the family's situation, admission was indicated."

However, Mr Woods noted:

"[Ms B's] account indicates that clinical opinion was that her mother would be better managed in the home, with assistance from a respite caregiver present overnight, for some nights. The interview with [Dr C] is at variance with this indicating his preference was for hospital admission, however there were no beds at [the city hospital].

... [Mrs A] was refusing both admission and respite placement, and it is debatable whether she would have met the requirements for admission under the Mental Health Act [MHA] 1992. Notes indicate family would have also been reluctant to support formal admission.

Usual practice for informal admissions to hospital by community teams requires the community consultant to request this via a written assessment of the client, as only doctors have admission rights. If admission was not possible due to the lack of a bed, then the CMHN would have to explore other options eg respite, in consultation with the team. Nursing intervention using powers as a Duly Authorised Officer [DAO] to arrange an assessment under [Mental Health (Compulsory Assessment and Treatment) Act 1992] would be most uncommon and unfeasible without the cooperation of the psychiatrist, in this case [Dr C].”

Mr Woods advised:

“In the absence of admission, prudent crisis care would have included daily or twice-daily nursing visits, as well as experienced respite staff in the home, to manage the client successfully. The notes do not show this level of care being provided. ...

Standard II of the [Standards] requires that the ‘Mental Health Nurse establishes partnerships as the basis for a therapeutic relationship with consumers’ (p.8). Consumer and family satisfaction with this process is one of the performance criteria for the standard. Standard III sees that the nurse should be able to ‘Collaborate with consumer, family or whanau, and other colleagues to develop a nursing plan for care’ (p.9) [ANZCMHN, 1995]. These competencies were insufficiently met.”

The rural hospital disputed that Mrs A was in crisis when she returned from overseas, saying that she was not, to its knowledge, “acutely ill or in any degree [needing] to be admitted under section 8 of the Mental Health [Compulsory Assessment and Treatment] Act 1992”. Yet Dr C said that Mrs A was sufficiently ill that he wished to admit her to hospital. He did not do so because Mrs A’s family was opposed to her being admitted and there were no beds available. In my view, Mrs A was in crisis at this time.

I accept that it was Dr C’s, not the rural hospital’s, responsibility to decide whether Mrs A would be admitted and that the rural hospital was to some extent saddled with the consequences of Dr C’s decision that Mrs A not pursue admission given the shortage of inpatient beds in the area.

However, the question whether Mrs A was in crisis, and whether she should have been admitted, is somewhat irrelevant. Whatever Mrs A’s state, and whatever the background circumstances, the rural hospital’s obligation to Mrs A as a patient was to assess her comprehensively, and to plan, evaluate and document its nursing interventions. It was also obliged to maintain a nursing management plan reflecting its ongoing assessments of Mrs A.

In my opinion, based on Mr Woods' advice, the rural hospital did not assess Mrs A adequately or plan her care appropriately when she returned from overseas on 18 January 2001.

Duration of respite care

Ms B complained that the rural hospital promised her 70 hours of respite care. The rural hospital stated that it was not contracted to provide respite care and therefore could not, and did not, promise to provide 70 hours of respite care. The DHB was contracted to provide respite care services but did not have the capacity to provide them to Mrs A. The rural hospital therefore decided to provide a respite care worker to give Ms B some relief. There is no record in Mrs A's patient record that 70 hours respite care were promised. The Respite Service Treatment Care Plan completed by Ms D on 23 January 2001 records a plan to have a respite care worker in Mrs A's home over the next four days.

I am unable to reconcile the conflict in the evidence as to what promises were made about the duration of the respite care and therefore cannot form an opinion as to whether there was a breach of the Code by the rural hospital in relation to this issue.

Standard of care provided by respite caregiver

I accept that the rural hospital did not have a contract to provide respite care and I commend it for seeking to address Mrs A's needs for respite care even though it did not receive funding for this service. However when the rural hospital decided to place a respite worker in Mrs A's home, it assumed responsibility for ensuring that the respite care worker discharged the responsibility of caring for Mrs A adequately even though it had no contract to provide this service.

Ms B complained that Ms I knitted, did not supervise Mrs A's medications, had her pre-school children with her while on duty and did not intervene when Mrs A went out on to the road saying she wanted to kill herself. The rural hospital responded:

“[Ms B's] description of the behaviour of the respite worker was not validated during our investigations into the original complaint in June 2001.

... [The rural hospital] found a creative and safe solution that most health organisations would not have considered: [the rural hospital] provided respite care in the home without having funding for this service. [The rural hospital] ensured that the respite care was safe by supporting the trained respite care worker with daily supervision from the [CMHN]. Respite care work involves long and tedious hours for the worker. The fact that the respite care worker knitted during this time is understandable and in no way undermined her ability to undertake her responsibilities.”

The rural hospital also stated that Ms I was not accompanied by her children while on duty but only during a visit when she was not on duty. From the information provided by the rural hospital it would also appear that the incident involving Mrs A walking out on the road took place during Ms I's visit when she was off-duty.

It is difficult for me to resolve the conflicts in the evidence on these issues. Although the rural hospital stated that its own investigation into Ms B's complaint about Ms I did not validate her concerns, the rural hospital did not expressly contest Mrs A's recollections and did not provide details of the findings of its investigation.

It is clear that Ms B's expectations of the respite caregiver were not met particularly with respect to supervision of her mother's medications and ensuring her safety. It seems likely that Ms B's accounts of her son's telephone call requesting help with Mrs A's medication (at a time when Ms I was caring for Mrs A) and of her mother going out on to the road to kill herself and Ms I taking no preventative steps, are true. However the fact that Ms I was not on duty at the time of the second incident may go some way towards explaining her inaction. It also calls into question the extent to which the rural hospital can be held responsible for Ms I's acts or omissions.

I consider that the respite care service provided by Ms I on the rural hospital's behalf was suboptimal in some respects. There are however mitigating factors: two of Ms B's concerns relate to events that occurred when Ms I was off duty; there are evidential conflicts; the rural hospital has developed a policy on the provision of respite care as a result of Ms B's complaint; and the rural hospital was attempting to fill a gap in the services that would have otherwise been unavailable. Taking these factors into account I do not consider there is a breach of the Code in relation to the standard of care provided by the respite caregiver. However I emphasise the fact that the rural hospital was not contracted to provide a service did not reduce the obligation to ensure that it was provided appropriately.

Daily visits by CMHN

With respect to the plan for daily visits by a CMHN, the rural hospital stated in its response to the provisional opinion:

“On 22nd January 2001, [Ms D] noted in the patient's medical record that the home visits over the weekend and 20th and 21st had been done and the patient's condition was recorded. The care plan was reviewed and respite care in the home was arranged — respite care plan was made in consultation with the family. The medication regime was reviewed, and daily [CPMH] home visits were to be continued.

Another medical entry was made later in the same day after the second visit by the CPN. Again the care plan was reviewed. Daily visits and observations are recorded in the patient's notes. Clinical assessments and observations were noted where appropriate in the medical record.”

The rural hospital also stated that “the respite worker was supported by daily nurse visits that were clearly documented”. In addition, the Respite Service Treatment Care Plan specified that there would be daily visits by a CMHN to monitor Mrs A's mental state. My further review of Mrs A's patient records, however, should identify any records of visits by a CMHN between 18 January 2001 and 7 February 2001.

In summary

In light of Mr Woods' and Dr Plunkett's advice, I believe that aspects of the care the rural hospital provided to Mrs A on her return from overseas were inadequate and that the rural hospital therefore breached Right 4(1) of the Code.

Breach — The rural hospital

Commencement and monitoring of clozapine

The complaint is that the rural hospital did not provide services of an appropriate standard when, from February 2001 to May 2001, while Mrs A was prescribed the antipsychotic clozapine, it did not adequately monitor her medication.

In my opinion, the rural hospital did not monitor Mrs A's commencement on clozapine with reasonable skill and care.

Mr Woods advised:

“A CMHN could be expected to monitor and record physical signs and symptoms, to ensure that the client had blood tests done, and that they were receiving and taking the medication as prescribed. The initial dose of clozapine is small.”

Mr Woods criticised the rural hospital for failing to appreciate the significance of Mrs A's unsteadiness and falling blood pressure in the weeks following her commencement on clozapine and to report it to Dr C:

“Blood pressure problems and light-headedness had been noticed prior to starting clozapine ... The notes do not show this being brought to the attention of [Dr C], though his letter of 23/03/01 ... mentions hypotension as a possible side effect. The monitoring and clinical observations show that her blood pressure was down as a result of starting clozapine. Over the three week period of monitoring the systolic and diastolic levels dropped from around 135/80 to 120/70. This hypotension and resulting unsteadiness of gait should have been seen as significant, given that [Mrs A] [was] three weeks into the new regime, when the full dose had yet to be reached. Other factors that should have indicated concern were that her unsteadiness was not limited to getting out of bed in the morning, but occurred ‘walking around the house during the day’ ... and [Mrs A's] age.”

In response to my provisional opinion, the rural hospital noted that Mrs A's blood pressure was stable until 26 March 2001 when it dropped. It said that it was the drop in Mrs A's blood pressure and her unsteadiness at this stage that led to arrangements being made for Mrs A to be admitted to the rural hospital for closer observation. The rural hospital felt that a breach finding in respect of this aspect of Mrs A's care was harsh. The rural hospital also said that Mr Woods had misread the reading of 120/70 and that it was in fact 120/79.

My examination of Mrs A's patient records indicates that she was admitted to the rural hospital for respite care, not because of concerns about her blood pressure. On 24 March 2001 Ms D visited Mrs A in her capacity as a Duty Authorised Officer (DAO) under the Mental Health (Compulsory Assessment and Treatment) Act 1992 and noted a plan to organise crisis respite. On 25 March 2001 Ms D noted that Mrs A continued to be challenging to manage at home without increased support and was to be seen on 26 March 2001 to be reviewed for crisis respite. Mrs A's blood pressure is recorded as dropping to 120/82 on 26 March 2001.

By 29 March 2001 Ms B had advised Ms D that crisis respite was needed because Mrs A's mental state had deteriorated significantly and she required increased supervision. Ms D completed a DAO/Crisis Intervention Record of Clinical Contact in which she noted that crisis respite funding was to be requested on 29 March 2001. This form contains the only reference to blood pressure, noting daily blood pressure and temperature readings as a component of the intervention plan but still not noting any concern about falling blood pressure.

In my view, the primary reason for Mrs A's admission to the rural hospital for respite care was that her mental state was deteriorating and she was becoming increasingly difficult to manage at home. Mrs A's falling blood pressure and unsteadiness were not factors in the decision to admit her for respite, or, if they were factors, were not major factors.

I have therefore formed the view that the rural hospital did not provide services of an appropriate standard when it failed to respond to Mrs A's hypotension and unsteadiness after first noting them between 26 and 28 March 2001. This amounts to a failure to use reasonable skill and care, in breach of Right 4(1) of the Code.

Training of CMHNs responsible for commencing clozapine in community

In my opinion, the rural hospital had a responsibility to ensure that CMHNs employed by it, who were required to manage trials of clozapine in the community were adequately trained and supported. The rural hospital did not discharge this responsibility adequately and therefore failed to treat Mrs A with reasonable skill and care.

Mr Woods advised:

“The training required of a Registered Comprehensive Nurse should be sufficient for a nurse subsequently specializing in community mental health to understand the effects of clozapine, possible adverse effects, and to monitor its use. However the protocol around the drug is sufficiently medically complex that many CMHNs might need to review their knowledge of haematology and the pharmacology of atypical antipsychotics. The [Auckland District Health Board] has provided a specific policy around use of the drug, which requires the collaborative effort of nursing and medical staff in seeing the drug is safely used [ADHB, 2003]. The drug companies themselves take an active role in providing information [at least in the larger centers] with presentations aimed at medical and nursing staff outlining the use of products. It is not clear whether this level of resource was available to [Ms D]. It appears she was being required to oversee the

implementation of a complex change in treatment, with little medical or psychiatric support, in an isolated rural area.”

The rural hospital advised that Ms D had considerable experience with the application of clozapine and was fully aware of the protocols. It pointed to Ms D’s note of a discussion about Mrs A’s commencement on clozapine on 15 February 2001 as an indication that Ms D was fully aware of the clinical monitoring required for a clozapine trial. The rural hospital did not provide any evidence that it had provided Ms D with training or taken any steps to satisfy itself that she had the necessary training and experience to safely commence Mrs A on clozapine in the community.

When interviewed, Ms D was clear that she had always worked in the community and had recently moved from an area where clozapine was always introduced in an inpatient setting. She had never commenced a client on clozapine before, in an inpatient setting or in the community.

Aspects of Ms D’s involvement in the commencement of clozapine suggest that she was not familiar with the protocol for introducing clozapine or experienced in its introduction. Those aspects include:

- the confusion between clozapine, clopixon and cloxapine in her notes;
- her reference in her note of 15 February 2001 to the need to observe for neuroleptic symptomatology after the commencement of clozapine when (according to Dr Plunkett such symptomatology is rare and less likely to be a problem than sedation, dizziness, salivation and racing heart), suggesting that she was unfamiliar with the likely side effects of clozapine;
- her failure to record, and possibly to measure, Mrs A’s pulse when tachycardia is known to occur in about 25% of patients in the initial two to three weeks of treatment;
- her failure to note and respond to the drop in Mrs A’s blood pressure recorded on 26 March 2001.

I do not, therefore, accept the rural hospital’s submissions that Ms D had considerable experience in the introduction of clozapine and was fully aware of the protocols. I do, however, accept that Ms D was part of an integrated multi-disciplinary clinical team which had the support of the Medical Director, Dr E, and that she had access to resources and information.

In my view, the rural hospital had an obligation to Mrs A to ensure that Ms D, as an employee, had the requisite training and experience to commence Mrs A on clozapine safely, and to provide any training required. Given the number and seriousness of clozapine’s side effects and the complexity of the introductory regime and monitoring, a responsible employer would ensure that employees required to undertake this process had the necessary training and experience. In addition, Ms D was a new employee of the rural hospital, a factor which heightened the need to ensure she was trained and experienced. In my view, the rural

hospital in this respect failed to provide services of an appropriate standard to Mrs A, in breach of Right 4(1) of the Code.

Documentation

In my opinion, the rural hospital's documentation of Mrs A's treatment did not comply with professional standards and therefore breached Right 4(2). The rural hospital failed to document adequately its assessment and management plan when Mrs A was first referred by the CMHC and her diagnosis changed by Dr C, when she returned from her overseas trip, and when it was decided to introduce clozapine.

Mr Woods advised:

“Competency VIII of nursing skills listed under Standard III of [the Standard] requires the mental health nurse to be able to ‘Document assessment outcomes, nursing management plan, strategies for care and outcome’. Competency XII in the same section says the nurse should be able to ‘Evaluate and document the effectiveness of planned interventions in consultation with the consumer, and in collaboration with the multidisciplinary team’. ... the nursing notes and the DAO/Crisis intervention reports completed by D only partially meet the standard. It does not appear that all client/family interactions were recorded in the clinical notes. There was no documentation outlining an ongoing plan of care. A ‘Comprehensive Mental Health Assessment’ and associated ‘Risk and Relapse Assessment’ form are included in the notes, but are only partially completed and are dated 15/06/2001 [the progress notes] — nine months after the initial referral and after the period that relates to the complaint.

... Where they do appear, the nursing notes made on clinical contacts do seem of an appropriate standard. The deficiencies relate primarily to the lack of support documentation and planning.”

Ms D did prepare a treatment care plan for the respite care provided by the rural hospital in January 2001 as well as a treatment plan dated 23 April 2001, a comprehensive mental health assessment dated 28 July 2001 and an undated relapse plan. However no similar plans or assessments appear to have been completed at any earlier stage. In my view, according with Mr Woods' advice, comprehensive assessments should have been undertaken and plans put in place when Mrs A first came under the rural hospital's care and updated regularly thereafter to take account of the changes in her mental state and treatment regime.

In response to my provisional opinion, the rural hospital questioned whether information supplied by it in connection with this investigation (particularly a file of information provided on 18 October 2002) had been lost by my office. My checks have indicated that the information provided by the rural hospital on 18 October 2002 has not been lost and I have considered it as part of my investigation.

In my opinion, based on Mr Woods' advice, the rural hospital failed to provide Mrs A with services that complied with professional standards for community mental health nurses when its CMHNs did not adequately record their assessments and plans for Mrs A's management at

key junctures such as Mrs A's referral from the CMHC, her return from overseas and her commencement on clozapine. This failure amounts to a breach of Right 4(2) of the Code.

No Breach — The rural hospital

Lack of clozapine policy/protocol

In my opinion, the risks associated with the use of clozapine and the complexities of monitoring clients for side effects suggest that the rural hospital would have benefited from a localised policy or protocol setting out the expectations and requirements of medical and nursing staff when commencing a client on clozapine in the community. The policy or protocol could have followed one adopted by another District Health Board but tailored to fit the rural hospital's rural setting.

In response to my provisional opinion, the rural hospital submitted that it would be dangerous to create its own protocol for monitoring patients taking clozapine when there is already a nationally prescribed and very detailed protocol.

I accept that providers should not adapt national protocols on essential elements such as administration of a drug and monitoring its side effects. However, a localised protocol may be helpful to address variations in practice and procedure dictated by factors such as the location and size of a particular service, its relationship with other providers and services and the resources available to it. While I appreciate that Ms D had the benefit of working in a team and access to a Medical Director, I think a localised protocol may have offset some of the inevitable disadvantages associated with working with a consultant psychiatrist who was physically present at the service only one day a week. Such a protocol may also have helped Ms D, as a new employee of the rural hospital, to deal with any practical issues peculiar to practice in the area. While I do not consider that the absence of a localised clozapine protocol amounts to a breach of the Code, I recommend that the rural hospital consider the need for a policy or protocol to address issues and requirements particular to its community.

Conclusion

This is a tragic case. Although Mrs A had a lengthy history of sometimes severe mental illness, her family had been able to care for her confidently and successfully in the community. Mrs A had experienced some periods of crisis, yet her illness had for the most part been relatively well controlled on medication. Mrs A was terrified of being hospitalised and her daughters had been able to keep their promise that their mother would never have to return to hospital.

Between October 2000 and April 2001, Mrs A's mental health deteriorated dramatically.

Ms B described the effect of this period eloquently:

“Mum always spent time in [the psychiatric unit] and they always committed her there. Memories for Mum and memories for me are horrible. They drugged her to the eyeballs and she used to plead with us to take her home. Mum had a break-down when I was 14yrs old, my sister was 13 yrs old. We spent 4 days of forcing Mum down on the floor and holding her down and making her take her pills as she had stopped taking them. I swore she would never go back to [the psychiatric unit] again. She never had. Mum’s biggest fear as a result of past with [the psychiatric unit] is being taken away and locked up forever. Mum will sit and agree with any Nurse or doctor as she is in fear of them. I have nursed Mum back into well being for 18 yrs. I have always been confident looking after her needs and administering all medications as needed. Always hiding it when appropriate so as not to kill herself with it. Have always taken Mum to doctors, Hospitals, Nurses etc when needed and always been interested and informed of what is going on. For the first time in 18 years I feel as though I am being kept in the dark and made to feel like it’s me with a problem not Mum.”

In my view, Mrs A’s deterioration was largely a result of Dr C’s management of her treatment. Her physical health and ability to function were also affected and her family were adversely affected by the stress of taking care of her at home. Ultimately Mrs A needed to be admitted to hospital for five weeks. The suffering she and her family endured could and should have been avoided.

Actions taken

The rural hospital advised me that it has developed a policy on the provision of respite care.

Dr C has provided a written apology to Mrs A and her family

Recommendations

I recommend that Dr C take the following actions:

- review his diagnostic, prescribing and patient management skills
- ensure that he meets regularly with a clinical supervisor.

I recommend that the rural hospital take the following actions:

- provide a written apology to Mrs A and her family;
 - review its mental health services in light of this report.
-

Proposed follow-up actions

- This matter will be referred to the Director of Proceedings in accordance with section 45 of the Health and Disability Commissioner Act 1994 for the purpose of deciding whether any proceedings should be taken in relation to Dr C.
- A copy of my final report will be sent to Dr C's current employer and to the DHB, the Medical Council of New Zealand, and the Royal Australian and New Zealand College of Psychiatrists.
- A copy of my final report, with details identifying the parties removed, will be sent to the Australian and New Zealand College of Mental Health Nurses, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes, upon completion of the Director of Proceedings processes.

Addendum

The Director of Proceedings issued proceedings before the Health Practitioners Disciplinary Tribunal and, at a hearing on 12 April 2006, a charge of professional misconduct was upheld. The Tribunal considered that Dr C's failure to document his care of Mrs A amounted to malpractice: "The Tribunal regards note-taking as an important part of a medical practitioner's role. It should show a doctor's observations, history, the thinking about diagnosis and a plan. It is not just window dressing or of minor importance to a doctor's clinical skill. It is an important discipline necessary for the proper clinical management of the patient." The Tribunal also considered that Dr C's failures in the management and control of risperidone and Clozaril amounted to malpractice. Dr C was censured and ordered to pay a fine of \$2,000 plus 30% of the costs of the hearing and prosecution. The Tribunal also ordered that, for a period of 18 months, a Medical Council approved supervisor oversee Dr C's note-taking, recording of clinical records, and prescribing practices, particularly relating to cases in which a decision was made to change the diagnosis, and the reasons for the consequences of this decision.

Appendix 1

The following submissions in response to the provisional opinion were received.

Dr C

“Thank you for the opportunity to respond to your provisional opinion. There are a number of matters to which I wish to respond. These are factual and medical matters.

I appeal that the breach finding is not reasonable. I do accept it is reasonable to be critical of some aspects of my care, such as the lack of notes in my own hand but I request that the referral to the Director of Proceedings for consideration of disciplinary proceedings be stayed. There are significant contextual issues in this case that I believe have not properly been taken into account. I also take issue with a large proportion of Dr Plunkett’s advice.

Change in diagnosis from schizophrenia to major depression with psychotic features

Please take into consideration that I was requested to see [Mrs A] because she was, in the opinion of her daughter not well: she was having anger outbursts which were distressing to the family.

During these outbursts she cried, missed her long dead husband and believed without reason, that her children were going to take her to a mental health hospital, long since closed. During these times she was markedly agitated, depressed, irritable, and would have anger outbursts, even at [Ms B’s] children. She was unable to sleep without medication and would not eat.

I felt that the status quo was unacceptable and I wanted to have a good look at other options as far as treatment goes.

Preamble

I was aware that [Mrs A] was diagnosed as a paranoid schizophrenic 30 years ago, but, different aspects of an illness can come to the fore over time, as the DSM-4 indicates. What made me look at a mood disorder was:

- (1) Paranoid schizophrenia and mood disorder lie on a spectrum (DSM-4 TR Guidebook Page 173)
- (2) The diagnostic criteria have changed since 1970 (DSM-4 TR Guidebook Page 173)
- (3) An approach from the side of depression offered more therapeutic options,
- (4) The medication she was on was only partially effective.
- (5) The medication (nortriptylline), which she was taking was dangerous in an overdose and she had a history of suicide. Her daughter [Ms B] was worried about this aspect as well.

- (6) She had been diagnosed as suffering from major depression in the past
- (7) The symptoms she exhibited was indicative of a mood disorder (major depression with psychosis (involuntal) melancholia, in partial remission; It was documented that she had suffered from major depression previously.

I elected to address the depression more aggressively and with a safer medication. Since the risperidone she was taking was not effective I also decided to reduce the risperidone slowly and to replace it (in time) with something else, if still needed. (Clozaril would be the gold standard since [Mrs A] qualified for the criteria set by the RANZ College of Psychiatrists, if she remained psychotic).

The DSM-4 clearly states that the diagnosis between schizophrenia and mood disorder with psychosis lies on a scale with schizophrenia at one end and mood disorder with psychotic features at the other. I quote from the latest DSM-4 TR Guidebook: (Page 173 Para 4): *'This situation reflects the ongoing debate about the degree to which Schizophrenia and Psychotic Mood Disorders are qualitatively distinct conditions versus being different aspects of the same condition'*.

As [Mrs A] has been treated for 30 years for the one condition without much success, I felt she might benefit from the wider spectrum of treatments that the diagnosis of a Mood Disorder with Psychosis offers. (Major affective disorder with melancholia in partial remission), i.e. major depression in only partial remission i.e. better but not completely under control, which is what I diagnosed.

With regard to [Mrs A's] historical records, and my knowledge of these at the time I saw her, the Provisional Opinion concedes that I might have had the notes, but concludes that I would not have had the time to read them! It is unclear how she arrives at this finding. It is well documented that the nurse [Ms F] requested the notes long before I saw [Mrs A] — and a letter from [the CMHC] to me is dated 20 August 2000, long before I saw her. Therefore I must have read it. As far as I remember I initially saw [Mrs A] at home and since I have had the notes I would have read them either before or after seeing her. It is debatable what is best practice: to read old notes before seeing a patient or afterwards (it gives you chance to form your own impressions). Since she concedes that I had the old notes, she will no doubt on reflection agree that I probably read them. I can remember reading the notes because I remember thinking that it was good on the part of the nurse to get them so soon.

Time spent:

It is not correct that I only spent 20 minutes, as [Ms B] has stated. I need at least 40 to 50 minutes time to build rapport and gain a patient's trust to obtain get an intimate history: to the extent that [Mrs A] would tell me about missing her late husband, and her fears of going back to the asylum. (for example).

I acknowledge that I may not personally have obtained a significant amount of information from [Mrs A's] daughter. Prior to my consultation with [Mrs A], [Ms F] had met with both [Mrs A] and her daughter and as recorded in her note of 9 October, she had

‘a lengthy talk about her mother's illness’ with [Ms B]. We worked as a team, and the information gathered by [Ms F] was conveyed to me. While it is useful to obtain information from family members about one's patients, it is not necessarily useful to undertake that process in the presence of the patient. I did not consider it would have been in this case, since it is unpleasant for a patient to hear how much of a burden they are. Especially not in light of the Nurse's comment of ‘a lot of expressed emotion there’, the second time she saw [Ms B].

The diagnostic terms used

Dr Plunkett founds her allegation that I do not know the main diagnostic terms, on a draft letter, where the typist probably could not hear clearly, what I dictated. The diagnosis ‘Major affective disorder with involuntional melancholia in partial remission’ is a current diagnostic term with the proviso that the word involuntional is not often used. I wanted to use it in this case because I wanted to illustrate her involvement with her late husband, as part of her symptomatology. I therefore also put it in brackets. This thus indicates that I am well aware of the change in the diagnostic system. I am indeed surprised that Dr Plunkett did not recognize the typing mistake, and raised the question that I might have been using a foreign language or diagnostic system.

At page 73 of the provisional report Dr Plunkett is quoted as acknowledging that to diagnose [Mrs A] correctly she would need to assess her directly. Since this has not happened and since [Mrs A's] symptoms varied over the years, as is expected by the DSM-4, Dr. Plunkett should have seen [Mrs A] for a valid opinion, as she suggests.

A fundamental point must be made: that this is a complex case, with a many add-on complicating circumstances.

There are many indications from [Mrs A's] presentation and her medical records that would urge one to look closely at the diagnosis of one of the mood disorders (major depression or ‘major affective disorder’ with melancholia or depression with psychosis, terms, used for the same condition, however you wish to describe it, all being ways to do so.) And this leads the authors to conclude: There is an on-going debate ‘about the degree to which Schizophrenia and Psychotic Mood Disorders are qualitatively distinct conditions versus being different aspects of the same dimension.’ DSM -4 Guidebook P173 Para 4

Dr Plunkett's suggestion of a schizo-affective disorder is one way of attacking a diagnosis of schizophrenia or depression. While I agree with her to that end, I refer you to page 173 of the DSM-IV Guidebook (copy **attached**). ‘The decision in DSM-IV was to restrict the diagnosis of schizo-affective disorder to a given (single) episode. This was intended to increase the reliability of the diagnosis but can result in a somewhat strange situation of an individual sequentially presenting with fairly similar symptom patterns that are nonetheless labelled as episodes of Schizoaffective Disorder, episode of Schizophreniform Disorder or as **psychotic mood episodes.**’ (And Dr Plunkett says there are not such terms in the DSM-4!)

To say that I hold the view that patients with schizophrenia cannot become depressed is quoting me wrongly. I said that a patient with schizophrenia who becomes depressed is a red light because of

- the caveat in DSM-4 re diagnosing depression and schizophrenia simultaneously, and
- because of the risk of suicide and
- because reviewing the diagnosis of schizophrenia opens up additional treatment options.

The difficulties attached to the diagnosis that Dr Plunkett suggested, Schizo-affective disorder, is referred to above. It is inter alia supposed to be a diagnosis restricted to a single episode. It however often offers an easy way out ... 'just call it both.'

Page 110 Para 1: Therefore I dictated in 'partial remission'. That is one of the specifiers of mood disorder. The typist however typed it less clearly.

I therefore request that the conclusion of the Provisional Opinion be revisited.

P 111 to Page 123 Summary of findings:

Use and discontinuation of risperidone:

I did not only want to lower the dose of the risperidone, I wanted to discontinue it altogether and replace it with another antipsychotic, in time to come, if needed. Risperidone should not just be stopped. It needs to be phased out, which is the way I changed her dose, aiming to reduce it to only one milligram a day before going on to something else. First, however, I wanted to see how she reacts on the citalopram, of which the dose could be increased with safety, and which offered, as such, another approach. The reason why I did not add on other antipsychotic was because she was completely free from psychotic symptoms when well, and because DSM-4 states that for the diagnosis of paranoid schizophrenia, deterioration is required, of which she had none: The diagnosis of paranoid schizophrenia requires deterioration — refer DSM-IV Guidebook, p176. I do not consider that a person having had schizophrenia for 30 years will present as very ill one day and very well the next, as Mrs A frequently was.

Dr. Plunkett's advice is good advice but:

- A. [Mrs A] was reported by her daughter to be suicidal at times, and the nortriptylline 100mg a day was (1) not working very and (2) lethal in an overdose. So I clearly had to change it and prescribe something safer. Citalopram was a safer choice and held the hope to be more effective in a higher dose *because all the antidepressants recommended by Dr. Plunkett are, like nortriptylline, fatal in an overdose.* (Today we have an alternative but during the year 2000 we had none).
- B. Citalopram can be used as an alternative to nortriptylline in major depression (and she initially responded well to it), especially when used in a higher dose, such as I prescribed before she left for [her overseas trip]. The dose can be increased even a

little more, which is one of the reasons I wanted them to call me if she should become unwell [while overseas].

Before going [overseas]

Since she had a history of having used two anti-psychotics when I saw her the first time and was alleged to be still not well by her daughter, I thought that if she does not respond, she might do well with clozapine, (Clozaril), the gold standard in this sort of case, sometime in the future. I did not however want to introduce another antipsychotic then, as she was much better than what she was.

Other options, like some of the so called 'newer antipsychotics' could be looked at if her condition should deteriorate while she was [overseas], which was the reason why I requested the family, or the GP of the family, should contact us should her condition deteriorate.

Page 125 'Advice on trip overseas'

My clear recollection prior to [Mrs A] going [overseas] was that [Ms B] was happy for her mother to go. Although she did express worries, those were not that she did not want her to go.

[Ms B] was under psycho-social stress, which affected [Mrs A] as well.

I reiterate that my clear instructions were that myself or [Dr E] was to be contacted, if [Mrs A] became unwell. In addition to my usual contact numbers I provided my private mobile telephone number.

As for the question of whether [Mrs A] took her medication with her, it was my clear expectation that she would of course do so.

There has been some dispute regarding whether or not [Mrs A] took her medication with her. [Ms B] told the nurse that she had left them behind. That she had found them at her house after [Mrs A] became ill.

She was supposed to have been taking a number of medications with her which should not be stopped suddenly. These types of medication would make anybody very ill if discontinued in an uncontrolled manner, namely: clonazepam; citalopram 40mg /day; nortriptylline 25mg/day and risperidone 1mg /day. Reducing one medication **may** make her ill. Discontinuing all her medication **will** make her ill. Dr Plunkett appears to believe that the reduction in risperidone was the major problem, and that is probably not right. [Mrs A] ceased taking **all** of her medication. That in my view was the main cause of her relapse. Stopping clonazepam, nortriptylline and citalopram was bound to make her ill. The Provisional Opinion chooses to focus on the risperidone dose reduction, but I wish to focus her attention on the above as well.

- My instruction to [Mrs A] was to retain 1mg of risperidone and I postulate that [Mrs A's] relapse would not have been so bad, if at all, had she carried on taking it, in conjunction with her other medication.

- I request that the stopping of the other medication be considered before putting the blame on me for reducing one. (Dr.Plunkett does not mention the danger of stopping **all** the medication, **at all**).
- [Mrs A] should not have stopped her medication without medical advice and also not without involving me.

Furthermore:

- logic dictates that they would and should have let me know when she became ill and.....
- not only 3 days before her return.

The fact that [Ms B] confessed to the nurse that her mother had not taken her medication with her [overseas] means she had stopped all when she left.

This inconsistency raises my suspicions that she was actually well until shortly before her return, while [Ms B] said she became grossly unwell soon after her leaving.

In addition, the Provisional Opinion also chooses to ignore the question: Why did they not call me when she started to become ill?

The nurse provided [Mrs A] with a letter to take [overseas]. I instructed [Mrs A's] family to let me know if anything went wrong and gave them my mobile number. I undertook to make myself available to allay some of [Ms B's] fears. Also, if she became ill I could ring the doctor [overseas] to achieve maximum input.

Monitoring of Clozapine

I prescribed Clozaril according to the Clozaril regime, on the prescription sheet. The Clozaril regime requires a registration sheet which contains all the required safety checks, and it falls on to the nurse to make the arrangements with the GPs to do them. The fact that the results are not in her file is a reflection on the filing system, not on the nurse. Without the safety checks required being in place the Clozaril would not have been issued by the pharmacist.

There was ongoing monitoring of [Mrs A] whilst on Clozapine. For example, on 3 April 2001 her blood level was measured at 1590nmol/L. Whilst this is not a high level, (levels up to 2000nmol/L are acceptable) the dose was reduced because she reported feeling dizzy.

[Ms B] has said that there are no records of her mother's pulse having being checked other than by herself. Fact is it was taken on every occasion that blood pressure was recorded. Without taking the pulse, blood pressure cannot be taken. It is sometimes also automatically indicated on an electronic device.

A fast pulse or disrhythmic pulse would be noted by the nurse taking the blood pressure who would then seek assistance or advice. For [Ms B] to say the nurse did not take the

pulse indicates that [Ms B] did not understand what the nurse was doing. It is also utilized to make the nurse look inefficient.

The pharmacist may only release the medication if satisfied that the mandatory blood tests have been performed. [Mrs A] was advised to contact her doctor as soon as possible should she experience any adverse symptoms. However, barring blood abnormalities for which [Mrs A] was monitored with blood tests, most of the warnings that Dr Plunkett has listed are not unique to Clozaril, and would have been present, even more noticeable with risperidone at the high dose she was on i.e. extrapyramidal effects.

In terms of monitoring in the community: The publication to which Dr Plunkett refers: 'Use of Novel Antipsychotic Drugs in New Zealand' endorses the initiation of Clozapine in the community.

I wanted to admit [Mrs A] to the hospital the day she returned from [overseas] and often afterwards. But a bed could not be found and so I had to resort to everything I could do to get her better.

Dr Plunkett suggests that I should have utilized the Mental Health Act but I am not in agreement because:

- It is very cruel to take somebody to hospital against the wishes of the family, because, if they do not want to take the patient to the hospital one has to resort to the police to take the patient to hospital, and that I did not want to do.
- Using the act does not create a bed. I knew the ward was full.
- [Mrs A], Dr Plunkett will no doubt agree, was not readily certifiable under the second limb of the act.

Informed consent

With regard to commencing [Mrs A] on Clozapine: Ms B was not willing to talk with me. For this reason I asked [Ms D] to explain the Clozapine regime. I dispute that side effects and warnings associated with the drug were not discussed. [Ms B] was her mother's legal guardian and if she was not willing to consent, she could have stopped the process any time.

Record keeping

As above, I accept criticism in relation to my record keeping.

I wish to thank the nurses for their efforts and wish to exonerate them from any blame.

Concluding comments

I regret that I have been instrumental in causing any distress to [Mrs A] and her family, and have no hesitation in offering my apology to them. I have enclosed a separate letter of apology."

The Rural Hospital

September 13, 2004

“ ...

Management of [Mrs A] on her return from [overseas]

‘They were apparently promised up to 70 hours weekly home care with respite workers’
... This comment appears central to Dr Felicity Plunkett’s response in relation to [the rural hospital]. At no stage was [the family] promised this level of respite care by [the rural hospital]. The important fact is that [the rural hospital] did not have a contract to provide respite care services. On page 52, Dr Plunkett is in error in her statement — *‘Apparently Mrs A refused to go into the local respite facility ([the rural hospital])’* — what facility is she referring to? Mental health respite care services are provided by [the DHB] completely outside of [the rural hospital’s] domain.

[The DHB] did not have capacity to provide the respite care support and additionally the family did not want [Mrs A] to go to [the city hospital].

[The rural hospital] takes strong exception to Dr Plunkett’s comments.

‘... This was however clearly difficult in such a far flung rural area and the main respite worker assigned was untrained and was reported to do little but knit and have meal breaks.’

This comment indicates prejudice about the quality of health services in a so called ‘far flung’ rural community. [The rural township] is not ‘far flung’ to the people who reside here. The use of the term is offensive and reveals the urban centric view of the advisor. In fact very few health providers would have taken the initiative to provide respite care at home without receiving funding to do so. I suspect that only rurally based health providers would take such a step on behalf of their patients. It would have been somebody else’s problem in an urban setting. This is the irony here.

The respite worker that was assigned was not a ‘main’ respite worker, but was the most appropriate person to undertake the work (and was certainly not untrained by 2001 standards). The respite worker was supported by daily nurse visits that were clearly documented.

... the report states:

[Mrs A’s] mental state had deteriorated enough to warrant admission to hospital ...

The view that [Mrs A] returned from [overseas] ‘in crisis’ is not supported by the documented clinical assessments. As far as [the rural hospital] was aware, [Mrs A] was not acutely ill or in any degree needed to be admitted under Section 8 of the Mental Health Act on her return from [overseas]. This would surely be the requirement to define her condition as needing ‘crisis’ respite care. Home based respite care was put in place to

provide relief for the patient's daughter. [Ms B's] description of the behaviour of the respite worker was not validated during our investigations into the original complaint in June 2001. Dr Plunkett's opinion seems only to be informed by [Ms B's] statement. The investigation by HDC did not question [the rural hospital] about these allegations and has consequently assumed in the absence of information that the allegations are true. In fact the allegations remain completely untested by the investigation.

'[The rural hospital] did not arrange for her admission ...'

[The rural hospital] used its best endeavors to find options for admission into a hospital respite facility, because the family sought respite care. The family however did not wish for [Mrs A] to go to a hospital. Ensuring an admission to a respite care facility was outside [the rural hospital's] control.

'... or alternatively provide [Mrs A] or her principal caregiver, [Ms B], with adequate and appropriate psychiatric support'

[The rural hospital] arranged an urgent psychiatrist review on the day that [Mrs A] returned from [overseas]. A care plan was immediately prepared and documented following the clinical assessment (clinical note from [Ms D] 18/1/02): Medications reviewed and re-prescribed. Commence respiridone 1 mg, increasing to 6 mg daily, utilise clonazepam 0.5 mg x 3 prn. Increase support to family with CSW, Daily review by CPN.

On 22nd January 2001, [Ms D] noted in the patient's medical record that the home visits over the weekend and 20th and 21st had been done and the patient's condition was recorded. The care plan was reviewed and respite care in the home was arranged — a respite care plan was made in consultation with the family. The medication regime was reviewed, and daily [CPN] home visits were to be continued.

Another medical entry was made later in the same day after the second visit by the CPN. Again the care plan was reviewed. Daily visits and observations are recorded in the patient's notes. Clinical assessments and observations were noted where appropriate in the medical record.

The provisional opinion of HDC alleges:

'the promised allocation of 70 hours a week respite was not provided'

[The rural hospital] was not responsible to provide respite care and it could not and did not make this promise. No commitments of this nature were made.

'the respite caregiver did not supervise [Mrs A] or support [Ms B] adequately'

Adequate respite care was provided, despite [the rural hospital] not having a contract to do so. This is because it was assessed that [Ms B] was in need of support to care for her mother and respite care in the home was the only option.

The respite worker had received specific training in respite care through [the DHB] mental health services training programme. This training programme was specifically provided for the purpose of training non-clinical staff to learn the skills to undertake respite care work in the home.

Referring to Mr Woods' comment quoted on page 147 that there is 'no role for the second level nurse in Mental Health': this is a judgment of a care plan made in early 2001 from the viewpoint of 2004. With the benefit of this foresight, would the HDC have judged it as reasonable care and skill for [the rural hospital] to have not provided respite care in the home? Would not providing any care have protected [the rural hospital] from the alleged breach of the code?

'the planned daily visits to [Mrs A] by a CMHN [CPN] did not take place'

The patient's medical record is clear evidence that the CPN ([Ms D]) visited daily in accord with the care plan.

Monitoring of Clozapine Trial

The blood pressure was monitored daily by the CPN (Community Psychiatric Nurse) — [Ms D]. There is sufficient evidence in the information provided to confirm this. This evidence alone confirms that the nurse was sufficiently aware of the requirement to daily monitor the blood pressure of the patient. On the day that [Ms B] apparently did the BP (26th March 2001), [Mrs A] was not at home because she was 'away with her group' and missed the planned appointment time.

A detailed monitoring record was kept by [Ms D] during the period that [Mrs A] was on Clozapine. It is acknowledged that the pulse was not recorded as it should have been.

... the report states:

'Mr Woods criticised [the rural hospital] for failing to appreciate the significance of [Mrs A's] unsteadiness and falling blood pressure in the weeks following her commencement on clozapine and to report it to [Dr C]'

On examination of the patient medical records from 14th March to 29th March 2001, [Ms D] consistently reported a stable BP of around 135/85 until the 26th March when the BP which was recorded at 120/79. (Note: [the rural hospital] disputes the BP 120/70 referred to on page 148 — the BP appears to have been misread by Mr Woods). This was the first day that the recorded BP had dropped. The BP was however recorded as stable. Arrangements were made with [the rural hospital] for [Mrs A] to be admitted for closer observation. It is highly likely that [Dr C] was consulted about this. The arrangements would have been made in consultation with the duty GP at [the rural hospital]. Closer monitoring in the following two days prior to admission was arranged. The patient record over the following days records careful monitoring of the patient to ascertain whether she was suffering hypotension.

The conclusion that this represents a breach of the Code by [the rural hospital] is extremely harsh. The BP dropped only slightly twelve days after commencement of Clozapine. The BP was consistently recorded as stable throughout the trial. The BP level was consistently within a normal range for the age of the patient. [Ms D] would have consulted with a GP (evidenced by the hospital arrangements) when the BP dropped slightly as a precautionary measure. The patient's medical record clearly shows that the movement in BP was taken seriously by [Ms D].

Failure to ensure that CMHNs responsible for commencing clozapine in community were trained

... Mr Woods states in reference to information on Clozapine:

'It is not clear whether this resource was available to [Ms D]. It appears she was being required to oversee the implementation of a complex change in treatment, with little or no psychiatric support, in an isolated rural area'

The words 'it is not clear' and 'it appears' are key features of this statement. Despite this uncertainty, the HDC concluded that [the rural hospital] is in breach of the Code.

This conclusion is drawn solely from the presumption that an isolated rural area does not have access to information or support. At [the rural hospital], the mental health team is supported by an integrated multi-disciplinary clinical team. In this regard, the mental health services are managed and fully supported by the Medical Director, [Dr E]. Thus, in many aspects the mental health team at [the rural hospital] enjoys a level of support that is not experienced by many urban mental health services. All our clinical staff have access to the latest information and have regular in-service training and staff development.

[Ms D] made the following record in the patient's medical record prior to the commencement of clozapine on 15th February 2001:

'Discussion about change in medication with visiting psychiatrist [Dr C], to commence on Clozaril.... Dosage of Clozaril will be increased to 100–200 mgs depending on response ... Daily observation for neuroleptic symptomology during this period. Observe for signs of muscle rigidity, increased temperature and excessive sweating'

These are clearly notes made by a clinician who was fully aware of the clinical monitoring required with a Clozapine trial. [Ms D] had had considerable experience with the application of Clozapine and was fully aware of the protocols. If the HDC had interviewed [Ms D], this would have been evident.

There is no evidence presented by HDC that [the rural hospital] failed to ensure the adequate training of the CMHN. In fact the evidence points to the contrary.

Lack of Clozapine policy / protocol

... the report discusses the information provided by [Dr E] about the national protocol that is adopted by [the rural hospital]. The key issue here is whether or not a health organisation should create its own protocol when there is a nationally prescribed and very detailed procedure for monitoring patients taking clozapine. Would it not be dangerous for [the rural hospital] to create its own protocol? The evidence of this case shows that our clinical staff were fully aware of and adhered to the requirement of the national protocol.

Documentation

The conclusions drawn by HDC appear to be made in the absence of the key documentation that [the rural hospital] supplied in October 2001 which appears to have been subsequently lost by HDC. Detailed patient records were kept by [Ms D]. [The rural hospital] does suffer from one aspect of rural isolation, which is unfortunately outside its control. Access to broadband is not available — which severely restricts full utilisation of [the DHB's database] system. This may have been a factor in some of the earlier information and communication issues. [The rural hospital] continues to take every opportunity to improve communication systems when the technology is available.

[The rural hospital] recommends that the HDC reserves judgment in regard to this alleged breach until it reviews what documents it actually has on file.

Conclusion

'This is a tragic case'

From [the rural hospital's] point of view, [Mrs A] did not suffer any harm from the services that were provided by [the rural hospital].

Recommendations

The service provided by [the rural hospital] clinicians was of a very high quality. In responding to the "catch 22" situation placed upon the service by the family of [Mrs A] (i.e. a demand for respite care, but not in a hospital), [the rural hospital] staff found a creative and safe solution that most health organisations would not have considered: [the rural hospital] provided respite care in the home without having funding for this service. [The rural hospital] ensured that the respite care was safe by supporting the trained respite care worker with daily supervision from the CPN. Respite care work involves long and often tedious hours for the worker. The fact that the respite care worker knitted during this time is understandable and in no way undermined her ability to undertake her responsibilities. On a day off, the respite care worker visited [Mrs A] to check how she was doing. She had her children with her. In hindsight, this act of kindness may have been unwise. [Ms B] appears to have taken strong exception to this visit and this event triggered complaints about the worker to [the rural hospital] staff.

- Acknowledgments of the perceived hurt to [Ms B] were made by [the rural hospital] staff at family meeting in July 2001. This meeting was arranged to support the healing process for the family following the original complaint to [the rural hospital] in June 2001.
- [The rural hospital] considers that it is unsafe and inappropriate for a health organisation to adopt a different protocol on the administration and monitoring of clozapine than the national protocol.
- [The rural hospital] is committed to safe clinical practice. Ensuring that staff have the highest standards of training to undertake their work is always paramount. The recommendation to ensure CMHNs have adequate training in the administration and monitoring of clozapine is fully acknowledged.
- [The rural hospital] has developed a policy on the provision of respite care as a result of the original complaint.
- [The rural hospital] is committed to the staff development and training of all its staff. In the case in question, adequate training (by 2001 standards) had been provided. The recommendation is received.”