Medical Centre Owner

General Practitioner, Dr B

A Report by the

Mental Health Commissioner

(Case 19HDC00458)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. A woman had a long history of substance addiction and mental illness. She was an enrolled patient with a medical centre. In 2017 the woman's general practitioner (GP) prescribed her medications used to treat depression. The woman's prescription stated that she should take one tablet of each medication per day, and authorised the pharmacy to dispense her fortnightly repeats of 14 tablets of each medication.

2. A few months later, the woman moved with her family to another region. Three months after the move, the woman telephoned the medical centre and requested a repeat of her prescription, which the GP granted. When the woman arrived, she asked to be dispensed a three-month quantity. The request was conveyed to the GP, who, without reviewing the woman personally, manually changed her prescription to allow the pharmacy to dispense 90 tablets of each medication.

Findings

3. The Mental Health Commissioner considered that the GP "gave the woman access to a quantity of medication that could be misused dangerously, which increased the risk of harm to the woman". The Mental Health Commissioner found that "the GP failed to provide services to the woman in a manner that minimised the potential harm to her", and so "breached Right 4(4) of the Code".

4. The Mental Health Commissioner also considered that "the GP's repeated failure to document important aspects of the services she provided to the woman was a clear departure from the standard described in *Good Medical Practice*", and therefore that she "failed to comply with professional standards and also breached Right 4(2) of the Code".

5. The Mental Health Commissioner found that the medical centre was not directly or vicariously liable for the GP's breaches.

Recommendations

6. The Mental Health Commissioner recommended that the GP reflect on her failings and report on her changes to practice, undertake further education on the subject of safe prescribing, and apologise to the woman's family.

7. The Mental Health Commissioner recommended that the medical centre investigate whether its general practitioners have been documenting their manual changes to prescriptions appropriately, and consider whether further policies concerning manual changes to prescriptions are necessary.

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Complaint and investigation

8. The Health and Disability Commissioner (HDC) received a complaint from Mr A about the services provided by Dr B, a general practitioner (GP), to his wife, Mrs A. The following issues were identified for investigation:

- *Whether the owner of the medical centre provided Mrs A with an appropriate standard of care between Month1[1]2017 and Month6 (inclusive).*
- *Whether Dr B provided Mrs A with an appropriate standard of care between Month1 2017 and Month6 (inclusive).*

9. This report is the opinion of Kevin Allan, Mental Health Commissioner, and is made in accordance with the power delegated to him by the Commissioner.

10. The parties directly involved in the investigation were:

Mr A	Complainant/Mrs A's husband
Dr B	Provider/GP
Provider/medical clinic	

11. Further information was received from Mrs A's daughter, the Accident Compensation Corporation, a pharmacy, and a district health board.

12. In-house expert advice was obtained from GP Dr David Maplesden (Appendix A).

Information gathered during investigation

Introduction

13. This report concerns the services provided by Dr B, a GP at the medical centre, to Mrs A between Month1 2017 and Month6.

14. At the time of these events, Mrs A was in her fifties and lived with her husband, Mr A, and their daughter. Mrs A had a long history of substance addiction and mental illness, including suicidal ideation.

15. Between 2012 and 2017, Mrs A was an enrolled patient at the medical centre in Town 1. During this time, medical centre staff documented a history of Mrs A presenting as struggling with a mental health condition, and self-reporting insomnia, abnormal weight loss, memory problems, anger problems, thoughts of self-harm, and marijuana dependency.

[1] Relevant months are referred to as Months 1–6 to protect privacy.

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16. In February 2012, a GP from the medical centre referred Mrs A to a specialist psychiatrist, (Mrs A had asked to discontinue taking risperidone [2], and fluoxetine [3], which she had been prescribed some years previously). The psychiatrist noted in her letter to the GP that Mrs A had suffered depression "on and off" over the past 15 years, and that until recently she had been using marijuana for the past 30 years. On that occasion, the psychiatrist advised Mrs A about how to discontinue her medication safely.

Month1 — initial prescription of mirtazapine and paroxetine

17. On 8 Month1, Mrs A was seen by Dr B, who recorded the following:

> "Deterioration on her memory skills
> Lost her balance the other night and hurt her right hip
> Spatial ability and balance
> Smoker: 1–2 packets a day
> Has had depression: feels suicidal
> Last menstrual period was March.
> Irritability and anger"

18. The medical centre recorded that Mrs A was prescribed:

> "Mirtazapine[4] 30mg Tab[5]SIGS: 1 tabs, Nocte for 2 weeks[6] QTY: 14[7]
> paroxetine[8] 20mg TabSIGS: 1 tabs, Mane[9] QTY: 14"

19. This meant that Dr B had prescribed Mrs A 14 30mg tablets of mirtazapine, and 14 20mg tablets of paroxetine, each to be taken one per day over the course of 14 days. Dr B told HDC that she prescribed paroxetine because "it has a better effect than fluoxetine for anxiety", and mirtazapine because it "is particularly useful when depression is accompanied with anxiety and disturbed sleep". She also told HDC that she instructed Mrs A to begin by consuming only half a tablet of mirtazapine per day, and to return to the medical centre for a review after two weeks.

20. Dr B did not document:

- Her rationale for prescribing mirtazapine and paroxetine to Mrs A;
- Any instruction that Mrs A begin by taking only half a 30mg tablet of mirtazapine per day; or

[2] An antipsychotic medication used to treat various mental health problems.
[3] A selective serotonin reuptake inhibitor (SSRI) medication used to treat various mental health problems, including depression.
[4] A medication used to treat depression.
[5] 30 milligram tablet.
[6] Take one tablet each night for two weeks.
[7] 14 tablets to be supplied.
[8] An SSRI medication used to treat various mental health problems, including depression and anxiety.
[9] Take one tablet each morning for two weeks.

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- Details of any discussion with Mrs A about the expected risks of taking mirtazapine and paroxetine.

21. In response to the provisional opinion, Mr A told HDC that he does not recall Mrs A taking half a tablet of medication at any point.

22. On 22 Month1, Mrs A was seen again by Dr B. Dr B documented that after taking two weeks of her new medication, Mrs A reported "feeling slightly better". However, she also reported feeling "slightly [off] balance" and "totally flat", and enquired about counselling for her anger issues.

Month3 — last in-person review by Dr B

23. Mrs A was seen by Dr B on 17 Month3. According to the medical centre's records, this was Mrs A's last in-person review at the medical centre. Dr B recorded of this presentation:

> "Moving for good
> Moving next week.
>
> Memory problems.
>
> Having issues with forgetting task, and also feeling swaying
>
> Has been smoking weed today, she seemed happy today.
>
> Discussed about medications
> Also memory problems are likely due to weed use. Encourage to reduce/stop
> She said that [in her] new place she would not be able to smoke.
>
> Fingers crossed
> Wished her all the best.
> Repeated medications today
> Aware to find out a new doctor."

24. The medical centre recorded that Mrs A was prescribed 14 30mg tablets of mirtazapine and 14 20mg tablets of paroxetine, each to be taken one per day over the course of 14 days, with six repeats.

25. Later that month, Mrs A and her family moved to Town 2.

23 Month6 — telephone prescription

Mr A

26. Mr A told HDC that on 23 Month6, Mrs A drove to Town 1 to renew her prescriptions.

The medical centre

27. Around 1.15pm on 23 Month6, a medical assistant at the medical centre recorded:

> "RPT RX[10] — ACCEPTED
> Requested via: Phone

[10] Repeat prescription.

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Time: 1315
By: PT[11]
Has seen GP within last 6mth: yes
Actions: Processed
Meds in long term: Yes
Listed as below: Yes
Total no: 3
Aware of cost: Yes
Collect from: [the medical centre]
Rx prepared for signing by: [Dr B]
Sent to nurse to process at: [the medical centre]

Pt says she is doing well with the medication and denies any thought of self harm."

28. Later, a nurse at the medical centre recorded:

"Repeat RX[12] signed & returned to nurse.
Ready to collect, pt informed via phone call

Rx placed in folder at reception: yes"

29. The medical centre recorded that Mrs A was prescribed 14 30mg tablets of mirtazapine and 14 20mg tablets of paroxetine, each to be taken one per day over the course of 14 days.

Dispensing pharmacy

30. The pharmacy told HDC that on 23 Month6 it dispensed three months' quantity of medication to Mrs A on the basis of a prescription it received. The printed text of this prescription (which the pharmacy showed to HDC) said that Mrs A was to be dispensed 14 20mg tablets of paroxetine and 14 30mg tablets of mirtazapine, with six repeats. However, the prescription is marked with various handwritten notes. Next to the printed words "paroxetine" and "mirtazapine", the number "90" has been handwritten and circled. There is also a handwritten note saying "dispense 3 12 as moving". The prescription is inscribed with both Dr B's and Mrs A's signatures.

31. The pharmacy told HDC that the checking pharmacist "correctly interpreted" these handwritten notes as being "a case of 'certified exemption'[13] … thus 3 months of medication was dispensed and given to the patient". The pharmacy also showed HDC the labels of the medication dispensed to Mrs A. These labels show that the pharmacy dispensed 90 20mg tablets of paroxetine and 90 30mg tablets of mirtazapine to Mrs A. The pharmacy further told HDC that according to its records, it dispensed this medication to Mrs A at around 2.08pm.

[11] Patient.
[12] Prescription.
[13] An authorisation by the prescriber to the pharmacy to dispense a larger than prescribed quantity of the medication.

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32. The medical centre did not have any documentation of these handwritten notes. As mentioned above, its record of Mrs A's prescription on 23 Month6 said that she was prescribed only 14 tablets of mirtazapine and 14 tablets of paroxetine on that day.

Dr B

33. Dr B told HDC that she "did not see [Mrs A] in person on the 23rd of [Month6]", and that Mrs A originally requested a prescription over the phone. Dr B said that she signed a prescription instructing the pharmacy to dispense two weeks of Mrs A's medication to her, but "[w]hen [Mrs A] presented the script to the pharmacy she asked the pharmacist if she could have the full 3-months' supply of her medication as she had moved away from [Town 1]". Mrs A's request was conveyed to Dr B, who then "manually changed the paper script to authorise the release of the 3-month supply".

34. Regarding her reasons for instructing the pharmacist to dispense three months' worth of medication to Mrs A, Dr B explained to HDC:

> "[Mrs A's] request for 3 months of medication put me in a difficult position. It can take some time to find a new general practitioner when moving to a new town. Transfer of clinical notes can further delay continuation of care as general practitioners who don't know patients and have no patient background are understandably reluctant to continue prescribing. I felt that it was imperative that [Mrs A] had a continuous supply of medication in a time of uncertainty over access to medical care and prescriptions.
>
> In assessing her requests for 3 months of medication, I considered her long standing suicidal ideation [and] I believed that she seemed low risk at the time and that the risk management of potential suicide was reasonable.
>
> With the benefit of hindsight I should have only approved a 1-month supply and instructed the pharmacist to advise [Mrs A] to see a new GP in [Town 2]."

35. Dr B herself did not document any notes in respect of Mrs A on 23 Month6.

Further information — the medical centre

36. The medical centre told HDC:

- "[The medical centre] has around 40,000 patients cared for by approximately 30 General Practitioners. Individual practitioners hold responsibility for the wellbeing of their enrolled patients."
- "We have discussed this case at multiple peer review meetings, and at clinic educational meetings to re-emphasise the importance of caution during prescribing psychotropic medication, and the constant need for re-evaluating all risks at each repeat prescription."

Further information — Dr B

37. Dr B told HDC that she has undertaken the following:

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- She has "reflected at great length" and "discussed this case with trusted and experienced professional colleagues to gain better insight to [her] own decision making in this complex case".
- She has improved her documentation practices, including "more in-depth notes when it comes to mental health patients".
- She has stopped taking double bookings to give her more time with each patient, and now spends half an hour per day reviewing her notes.
- She now allocates 30 minutes for all mental health patients.
- She is "now much stricter with quantity dispensing of psychotropic medications and ha[s] declined every single request from patients that would rather have the full content of the script".

38. Dr B told HDC:

> "I am truly sorry … and I accept that my documentation was below standard in this particular case and I have taken steps to ensure this doesn't happen again …"

Responses to provisional opinion

39. Mr A and his daughter were given an opportunity to respond to the "Information gathered" section of the provisional opinion. Their responses have been incorporated into the report where appropriate.

40. Dr B and the medical centre were given an opportunity to respond to the relevant sections of the provisional opinion that pertained to them. Dr B advised that she accepted the provisional opinion.

41. The medical centre advised that it had no comments to make on the provisional opinion, restated its apology, and advised that it had taken on board the proposed recommendations.

Opinion: Dr B — breach

42. My role is to assess the quality of care provided to Mrs A in light of the information that was known at the time the care was provided and against the rights set out in the Code of Health and Disability Services Consumers' Rights (the Code).

Failure to minimise potential harm — breach

43. Mrs A had a long history of substance addiction and mental illness, which included suicidal ideation.

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44. On 23 Month6, Mrs A asked to be dispensed three months' quantity of mirtazapine and paroxetine. Dr B instructed the pharmacy to dispense 90 tablets of each medication to Mrs A, and the pharmacy dispensed those tablets.

45. My in-house medical advisor, Dr David Maplesden, advised that it was not safe or clinically appropriate to authorise the dispensing of a three-month supply of Mrs A's medication given the following risk factors for self-harm:

- Mrs A's history of depression.
- The potential for Mrs A to lose social supports because of her move to a different town.
- Mrs A's ongoing use of marijuana (a risk factor for suicide if used in excess).
- The fact that Mrs A had been taking the medication regimen for only a short period.

46. Dr Maplesden advised:

> "I do not think a brief assessment of the patient's mental health status by a practice nurse via telephone was sufficiently reassuring (taking into account [Mrs A's] past history) to make the decision that [Mrs A] could be safely dispensed a stat[14] three month supply of medication. However, the fact some assessment was undertaken (and the response from [Mrs A] in this regard) is a mitigating factor.
>
> …
>
> I am moderately critical that she chose to prescribe [Mrs A] a three month supply of [paroxetine and mirtazapine] with stat[15] dispensing without adequately establishing the safety of such prescribing."

47. Dr B told HDC that she was concerned that Mrs A would struggle to find a doctor nearer to her new home who would be willing to start prescribing her further mirtazapine and paroxetine tablets immediately. Dr B explained that she "felt that it was imperative that Mrs A had a continuous supply of medication in a time of uncertainty over access to medical care and prescriptions", and this was her rationale for instructing the pharmacy to dispense the quantity of medication requested.

48. Dr B also explained to HDC that although she considered Mrs A's "long standing suicidal ideation", she was reassured by Mrs A's improving clinical presentation at their appointments at the medical centre. Because Mrs A's mental health seemed to be improving, she assessed Mrs A as being "low risk".

49. I accept that Dr B was genuinely concerned about how Mrs A would obtain a continuous supply of medication, and that this concern was reasonable. However, I am of the view that neither Dr B's concern nor her assessment of Mrs A being "low risk" justified her decision to prescribe the quantity of mirtazapine and paroxetine that Mrs A requested,

[14] Immediate.
[15] Immediate.

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particularly without having seen her face to face to assess her risk adequately. Dr Maplesden advised:

> "By providing the three-month prescription without any discussion in this regard meant [Mrs A] could go without any clinical assessment of her mental health for a further three months which I do not feel was appropriate given her mental health history. A safer option available to [Dr B] was to prescribe a shorter supply of the medication (one month) with the instruction that [Mrs A] needed to register with a [Town 2] GP for review prior to getting further supplies."

50. I accept this advice. Given Mrs A's long history of mental health problems (including thoughts of self-harm), it was not appropriate for Dr B to prescribe her the quantity of medication she requested without first reviewing her (or arranging for another suitable doctor to review her) and establishing that she was safe to receive it. I acknowledge that Dr B has accepted, with the benefit of hindsight, that she should have approved only a one-month supply and instructed the pharmacist to advise Mrs A to see a new GP in Town 2.

51. Right 4(4) of the Code states that "[e]very consumer has the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer". By instructing the pharmacy to dispense 90 paroxetine and 90 mirtazapine tablets, Dr B gave Mrs A access to a quantity of medication that could be misused dangerously, which increased the risk of harm to Mrs A.

52. For these reasons, I consider that Dr B failed to provide services to Mrs A in a manner that minimised the potential harm to her, and I find that Dr B breached Right 4(4) of the Code.

Documentation — breach

53. The Medical Council of New Zealand publication *Good Medical Practice* states:

> "[Doctors] must keep clear and accurate patient records that report:
>
> - relevant clinical information
> - options discussed
> - decisions made and the reasons for them
> - information given to patients
> - the proposed management plan
> - any medication or other treatment prescribed."[16]

54. There were significant gaps in Dr B's clinical documentation. She did not document the following:

[16] Standard 5.

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- Her rationale for prescribing mirtazapine and paroxetine to Mrs A.
- Any instruction that Mrs A begin by taking only half a 30mg tablet of mirtazapine per day.
- Details of any discussion with Mrs A about the expected risks of taking mirtazapine and paroxetine.
- Her manual amendment to the dispensing instructions on 23 Month6.

55. Dr Maplesden advised:

> "[T]here were mild to moderate deficiencies in clinical documentation in relation to the rationale for immediate initiation of augmented therapy, actual dose of mirtazapine to be taken, discussion of side effects and follow-up arrangements."

56. He also advised that he was critical of Dr B for not "recording the change in dispensing instructions in the clinical record" after she made the handwritten amendments to the prescription slip.

57. I accept this advice. Dr B's repeated failure to document important aspects of the services she provided to Mrs A was a clear departure from the standard described in *Good Medical Practice*. Clinical records allow a provider to verify when and what occurred during a consultation. They also allow care to be provided in an appropriate fashion, in light of past treatment, including if a new provider becomes involved.

58. Right 4(2) of the Code states that "[e]very consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards". The "clear and accurate patient records" standard in *Good Medical Practice* was a professional standard. Accordingly, I find that Dr B failed to comply with professional standards and also breached Right 4(2) of the Code.

Opinion: Medical centre owner — no breach

59. As a healthcare provider, the medical centre is responsible for providing services in accordance with the Code. In this case, I consider that the error that occurred was an individual error, and did not indicate broader systems or organisational issues at the medical centre.

60. In addition to direct liability for a breach of the Code, under Section 72(2) of the Health and Disability Commissioner Act 1994 (the Act), an employing authority is vicariously liable for any acts or omissions of its employees. A defence is available to the employing authority under Section 72(5) if it can prove that it took such steps as were reasonably practicable to prevent the acts or omissions.

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61. In Month6, Dr B was an employee of the medical centre. As set out above, I have found that Dr B breached Right 4(4) of the Code by failing to provide services to Mrs A in a manner that minimised the potential harm to her.

62. I note that Dr B was an experienced GP. In my view, the errors that occurred were the result of Dr B's individual, clinical decision-making. The medical centre was entitled to rely on Dr B, a fully qualified, experienced GP, to provide an appropriate standard of care in accordance with her professional obligations.

63. I further note that the medical centre's ability to monitor Dr B's decisions would have been considerably encumbered by Dr B's omission to document key details of the events in question. Accordingly, I am satisfied that the medical centre took reasonably practicable steps to prevent Dr B from instructing the pharmacy to dispense three months' quantity of medication, and that the medical centre is not vicariously liable for Dr B's breach of the Code.

Recommendations

64. I recommend that Dr B:

a) Provide a written apology to Mrs A's family. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Mrs A's family.

b) Reflect on her failings in this case and provide a written report to HDC on her reflections and the changes to her practice she has instigated as a result of this case, within three months of the date of this report. Dr B's report should include:

   i. An explanation of the changes she has made to her documentation practices, and an evaluation of the effectiveness of those changes.
   ii. An explanation of the changes she has made to her work time-tabling (allocating half an hour to "catch up time" each day and allocating 30-minute appointments for mental health patients), and an evaluation of the effectiveness of those changes.
   iii. An explanation of her new practice of being stricter when prescribing large quantities of psychotropic medications, and an evaluation of the effectiveness of that new practice.

c) Undertake further education on the subject of safe prescribing — preferably safe prescribing of psychotropic medications — within three months of the date of this report, and report back to HDC on what she has learned from that education within four months of the date of this report.

65. I recommend that the medical centre:

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a) Investigate whether its general practitioners have been documenting their manual changes to prescriptions appropriately, and provide HDC with the outcome of that investigation within three months of the date of this report.

b) Consider whether further policies concerning manual changes to prescriptions, or documentation of manual changes to prescriptions, are required, and report to HDC on the outcome of its consideration within three months of the date of this report.

Follow-up actions

66. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Medical Council of New Zealand, the Australian Medical Council, the Royal New Zealand College of General Practitioners, and the Royal Australian College of General Practitioners, and they will be advised of Dr B's name.

67. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the district health board and the Director of Mental Health, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

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Appendix A: In-house advice to the Commissioner

The following in-house clinical advice was obtained from Dr David Maplesden, a general practitioner:

"1. Thank you for providing this file for advice. To the best of my knowledge I have no conflict of interest in providing this advice. I have reviewed the available information: complaint from [Mr A]; response from [the medical centre's medical director]; … response from [the pharmacy] and copies of prescriptions and dispensing labels; response from [Dr B]; selected [medical centre] clinical notes. **Additional responses were received from [the medical centre] on 13 August 2019 and [Dr B] on 10 September 2019. Comments in relation to this information are recorded in bold in the relevant sections below.**

2. [Mrs A] (aged [in her fifties]) … had a many year history of anxiety, depression and substance addiction (marijuana, methamphetamine, nicotine) …

3. … Historical mental health reports reviewed were:

(i) Letter from … the psychiatrist who had reviewed [Mrs A] [in] 2012 following referral by [a GP]. Current medications at that time were risperidone 2mg nocte and fluoxetine 20mg daily which [Mrs A] wanted to stop. Past history of recurrent depression and substance abuse noted together with previous treatments including medication and CBT. Mental health examination was unremarkable and [Mrs A] claimed to have been *free of anxiety and depression for years and wants to wean off medication.* Recommendations were provided for a withdrawal regime with review in one month (no further correspondence from the psychiatrist on file).

(ii) …

6. In her response to HDC dated 22 April 2019 [Dr B] reiterates her impression that [Mrs A] was *making good progress regarding her mental health* at the time of the last consultation with her in [Month3]. She recalls signing a repeat prescription in [Month6] when she was no longer residing in [Town 1]: *I was prepared to sign her script for a total of three months based on [the medical centre's] policy regarding psychotropic medications, my knowledge of her history and the progress she made based on our last interaction.*

7. An issue has been raised regarding [Dr B's] admission that she made retrospective additions to [Mrs A's] clinical notes. I have been provided with a notes audit for the consultation of 17 [Month3]. This refers to an update to the notes on 14 March 2018 by [Dr B]. However, when the audit trail is opened, this refers to the original notes being written at 1259 hrs on 17 [Month3] as: *Moving for good Moving next week. Memory problems. Having issues with forgetting task, and also feeling swaying.* The audit then notes an addition to the entry on 17 [Month3] at 1446 hrs by [Dr B] as: *Has been smoking weed today, she seemed happy today. Discussed about medications.*

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Also memory problems are likely due to weed use. Encourage to reduce/stop. She said that new place would not be able to smoke. Fingers crossed. Wished her all the best. Repeated medications today. Aware to find a new doctor. In her response to HDC, [Dr B] states that … *I immediately realised that my notes were not thorough and did not reflect well enough what was discussed and shared during her consultations which were much longer than usual. I remember being upset about my lack of documentation and without deleting any existing notes, added a few lines which in hindsight was a mistake and one I feel very bad about.*

Comment: I would regard a significantly retrospective change to a consultation note, without identifying the date and intention of the change, as a departure from accepted practice. The degree of departure depends to some extent on the nature and intent of the alteration. In this case I am unable to confirm what change was made. My interpretation of the audit provided is that two hours after the original entry made by [Dr B] on 17 [Month3] she added to the consultation note — essentially elaborating on the previous content. I would not regard this situation as representing a departure from accepted practice. It is not uncommon for GPs to complete consultation notes at the end of a consulting session or consulting day and I would not regard this as a significantly retrospective entry. The addition appeared to be completion of an initially scant consultation note. The audit shows [Dr B] did access the consultation note on 14 March 2018 and some change must have been made on this date for the 'Last updated' comment to appear. However, if there were any changes made on this date it does not appear they were saved … Consequently, I am unable to confirm the nature of any significantly retrospective note [Dr B] made in relation to [Mrs A's] file and I am therefore unable to quantify any departure from accepted practice in this regard. However, it is appropriate [Dr B] has reflected on her apparent decision to add to her notes retrospectively without identifying the addition as retrospective.

Addendum 23 October 2019: [Dr B] is unable to recall the extent or nature of any retrospective changes made to her clinical notes. She agrees with my interpretation of the clinical audit records. I am therefore unable to confirm that any retrospective entry was made to [Mrs A's] clinical file other than the details added two hours after the initial consultation on 17 [Month3] with that action being consistent with accepted and common practice.

8. Clinical notes review and comments

Consultation notes have been reviewed from [2016]. The form in which they have been provided is somewhat unusual in that prescriptions provided are recorded separately to the consultation notes. However, I assume the contemporaneous record is available in its entirety (including prescriptions, outbox and inbox entries) to someone viewing it on the PMS.

9. Prescribing records show [Mrs A] was prescribed quetiapine from June 2016 to July 2017 at a dose of 25–75 mg daily. She was seen by [a doctor] on [three occasions in] 2016 with a variety of physical and psychological issues. Notes for the [third]

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consultation include: *feels like she is falling apart, exploring her mental health issues … does not want to get involved in Mental Health system again … stopped meds as not sure if feeling worse, quetiapine helps … Examination: alert, tearful, voices strong desire to help daughter, no tosh* [thoughts of self harm] *… Impression: depression w bipolar traits. Plan: OK to increase quetiapine to 3 a day, she has not had sustained benefit with SSRIs. Strongly encouraged to journal, be her own advocate, take meds …*

10. [In] 2016 [Mrs A] was reviewed by [another doctor] as she required *a letter addressing the courts that she is mentally unwell. She has recent thoughts of self harm. But she prefers not to talk to our counselors.* No other mental health assessment recorded. Impression was *Anxiety with depression, PTSD.* Prescriptions provided for quetiapine and omeprazole and requested letter apparently supplied.

…

11. [In] 2017 [Mrs A] was reviewed by [a doctor] who noted she was *tired, not sleeping well.* Repeat prescription for quetiapine provided. [In] 2017 [Mrs A] was reviewed by [another doctor] — *would like to increase quetiapine dose and get a repeat … has been decreased to one a day in [month]* [this not evident from available notes]. *Was there times daily [in] 2016. She has not been coping and has been unable to sleep properly, so has been taking three a day and run out of tablets.* Further quetiapine prescribed.

12. Repeat prescription for quetiapine provided [in] 2017 ([doctor], no face-to-face consult recorded) and again [in] 2017 ([doctor] — consult for repeats and other physical issues).

13. Next GP consultation was with [Dr B] on 8 [Month1]. Clinical notes are: *Deterioration in her memory skills, lost her balance the other night and hurt her right hip, special ability and balance. Smoker: 1–2 packets a day. Has had depression, feels suicidal. Last menstrual period was march. Irritability and anger.* Wt 64.4. From the prescribing records it is apparent [Mrs A] was prescribed a supply of paroxetine 20mg mane and mirtazapine 30mg nocte with two-weekly dispensing (total duration of supply provided not able to be confirmed from the clinical records supplied). There is no documented follow-up plan or reference to discussion regarding the prescribed medication.

Comments:

(i) Clinical documentation is moderately deficient. There is no reference to exploration of severity of [Mrs A's] psychological distress, or provoking/protective factors for suicide[1]. There is no working diagnosis. There is no reference to clinical rationale for immediate prescribing of augmented/combination antidepressant therapy (as opposed to monotherapy) or discussion of the potential risks associated with the

[1] BPAC. Suicide prevention: what can primary care do to make a difference? 2017. https://bpac.org.nz/2017/suicide.aspx Accessed 22 May 2019

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prescribed therapy (including serotonin syndrome potential although not extreme[2] and potential for increased suicidality in the first few weeks of therapy). There is no follow-up plan documented. If the clinical documentation accurately reflects the extent of the assessment/communication undertaken (and it may not) I would be moderately critical of the assessment standard.

(ii) The prescribing, from the outset, of a combination of antidepressants would not be consistent with accepted practice in primary care. Using relevant NZ guidance[3], the initial prescribing of an SSRI (paroxetine in this case) as monotherapy would be consistent with accepted practice if [Mrs A] had been assessed as suffering from moderate to severe depression. In terms of combining antidepressants, the guidance states: *Combinations of antidepressants may be prescribed to patients with depression who have not responded to monotherapy; regimens are often initiated or overseen by a psychiatrist. When combining antidepressants, treatment choice is generally guided by pharmacological knowledge, clinical experience and the limited amount of available evidence. Some experts recommend the use of low-dose TCAs, e.g. nortriptyline 10–25 mg, in combination with citalopram or sertraline, if the patient's response has been suboptimal. Mirtazapine is sometimes used in combination with a SSRI, venlafaxine or a TCA, and lithium is sometimes prescribed with TCAs, SSRIs or other antidepressants. Patients taking combinations of antidepressants should be monitored closely for adverse effects, particularly in the first weeks of treatment.* While [Mrs A] had apparently not had sustained improvement with some SSRIs in the distant past, it is not apparent she had previously used paroxetine. Accepted practice would be to trial the different SSRI initially and monitor response, with consideration of a change in SSRI or a different type of antidepressant as monotherapy before considering combination therapy. If combination therapy with mirtazapine was to be considered, accepted practice would be to begin with a low dose because of the increased risk of adverse drug effects (including serotonin syndrome) with combination therapy. [Dr B] commenced [Mrs A] on 30mg mirtazepine at night which is double the starting dose recommended by the manufacturer for monotherapy[4]. I believe [Dr B's] prescribing on 8 [Month1] departed from accepted management of depression in primary care to a moderate degree.

(iii) Although not evident from the clinical notes, follow-up for [Mrs A] had been scheduled for review two weeks hence which was consistent with accepted practice, as was provision of a very limited supply of medication initially (important particularly noting [Mrs A's] suicidal ideation).

(iv) Addendum 23 October 2019. [Dr B] described her rationale for initiating augmented antidepressant therapy rather than a trial of monotherapy as follows:

[2] https://nzf.org.nz/ Accessed 21 May 2019
[3] BPAC. The role of medicines in the management of depression in primary care. 2017. https://bpac.org.nz/2017/depression.aspx Accessed 21 May 2019
[4] https://www.medsafe.govt.nz/profs/datasheet/a/ApoMirtazapinetab.pdf Accessed 22 May 2019

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- **[Mrs A] had previously required augmented antidepressant therapy (fluoxetine (SSRI) + quetiapine (atypical antipsychotic)) and there was some specialist oversight of this treatment (psychiatrist).**
- **[Mrs A] had responded well to the augmented therapy over several years but had not had similar stability on SSRI monotherapy.**
- **[Dr B] felt the SSRI paroxetine would be more effective than [fluoxetine] for the anxiety component of [Mrs A's] mental health issues, and that the sedating effects of mirtazapine would assist [Mrs A's] chronic insomnia, with both drugs having antidepressant properties.**
- **Although not documented, mirtazapine was actually commenced at 15mg daily with [Mrs A] being instructed to halve the 30mg tablet (only tablet strengths available in New Zealand being 30mg and 45mg).**
- **[Dr B] states it is her usual practice to discuss risks of the therapy prescribed, including potential for serotonin syndrome, and she would have done this with [Mrs A].**

I remain of the opinion that it is not accepted practice to initiate augmented antidepressant therapy in primary care without trialling monotherapy initially (as per the previously cited guidance) and I note in this case a different SSRI which [Mrs A] had not previously used was initiated ie lack of response to the new SSRI could not be assumed. However, I acknowledge [Mrs A's] prior use of augmented therapy (although it is not possible to establish who initiated the therapy — the psychiatrist was involved only in advising how best to withdraw from the therapy). This therapy had proved successful over several years but some adverse effects eventually led [Mrs A] to request its withdrawal. The clinical rationale for using the combination of paroxetine and mirtazapine appears reasonable if augmented therapy is to be used, and [Dr B] has clarified the starting dose of mirtazapine used (which is consistent with accepted practice) and that there was discussion with [Mrs A] regarding potential adverse effects of the combination. I believe there were mild to moderate deficiencies in clinical documentation in relation to the rationale for immediate initiation of augmented therapy, actual dose of mirtazapine to be taken, discussion of side effects and follow-up arrangements. However, taking into account the additional information provided by [Dr B] I withdraw my previous moderate criticism of her prescribing but recommend she review the cited guidance on role of medicines in management of depression.

14. [Dr B] reviewed [Mrs A] on 22 [Month1]. Notes include: *2 weeks of new medications, feeling slightly better, slightly balance but also concerned about being totally flat … Also went back to smoking cigarettes but not weed since mid-June. Discussed about this as well. Anger is an issue as well and she struggles with this, she asked me if there is counselling for this so referred to SW* [presumably social worker] *for this.* Prescribing records show [Mrs A] was issued prescriptions for omeprazole, zinc and acyclovir (regular medications). The SW attempted to contact [Mrs A] on 23 [Month1] (message left) and on 28 [Month1]. An appointment was made to discuss referral for anger management counselling but [Mrs A] declined the support.

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Comment: There is no reference in [Dr B's] notes to specific review of [Mrs A's] previously expressed suicidal ideation but a slight improvement in her general wellbeing is noted. There were no apparent adverse effects from the medications. There is no scheduled GP follow-up noted but this may have been dependent on involvement with the SW following the internal referral. While the content of the consultation might have been more extensively documented in relation to [Mrs A's] current mental health status, I think overall management on this occasion was satisfactory taking into account the SW referral. I remain of the view that it was inappropriate to have initiated combination antidepressant therapy, and to use 30mg [of mirtazapine] as a starting dose as part of the combination, without trialing monotherapy initially.

15. [Dr B] reviewed [Mrs A] on 12 Month2. It is not clear if this was a scheduled review of her response to treatment or an opportunistic appointment. There is reference to some gynaecological issues but in relation to mental health [Dr B] has recorded: *Sleeping is much better. On mirtazapine and paroxetine. Anger management is much better … more positives than negatives. However had pot on Friday …* There was no prescription provided and no record of planned follow-up.

Comment: It appears [Mrs A's] overall mental health was improving with the current medication regime. Best practice would have been to specifically document [Mrs A's] current status in relation to her previously expressed suicidal intent and to document a follow-up plan.

16. The next review by [Dr B] was 17 [Month3] (see s7). Clinical record was: *Moving for good Moving next week. Memory problems. Having issues with forgetting task, and also feeling swaying. Has been smoking weed today, she seemed happy today. Discussed about medications. Also memory problems are likely due to weed use. Encourage to reduce/stop. She said that new place would not be able to smoke. Fingers crossed. Wished her all the best. Repeated medications today. Aware to find a new doctor.* Prescriptions were provided for mirtazapine, paroxetine, zinc and acyclovir. I am unable to confirm from the available records the dispensing instructions on this occasion noting instructions on the 23 [Month6] script were altered manually by [Dr B] (see below). The instructions, if not altered manually on this occasion, were for two weekly dispensing of mirtazapine and paroxetine (doses unchanged since initiation) with a total supply of three months available.

Comment: [Mrs A] was about to shift to a different area of the country ([Town 2]). She admitted to ongoing use of marijuana (a risk factor for suicide if in excess). It is unclear whether she had a good social support network in the [new region] but loss of social supports (if she had such a network in [Town 1]) was another potential risk factor for suicide, as was the history of … depression (see Appendix 1). [Mrs A's] mental health appeared to have improved on her medication regime which she had been taking for just over two months and there is no reference to her voicing ongoing suicidal ideation since the medications were commenced. Under the circumstances, I think it was important to encourage [Mrs A] to enroll with a local GP practice as soon as she

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was able and to send relevant health information to that GP in a timely manner. There was apparently some communication on this issue. It was reasonable to continue her current regime in the meantime. From a practical perspective, if [Mrs A] needed some of her antidepressants before leaving [Town 1] the two-weekly dispensing might prove problematic as it was not possible for her to travel from [Town 2] to [Town 1] every two weeks to collect her medication. On the other hand, I do not believe it was safe or appropriate to issue a three-month stat dispensing prescription given the relatively short period of stability since starting the medication and ongoing potential risk factors for suicide. As stated, I am unable to confirm the dispensing instructions on this occasion. If [Mrs A] was able to have the prescription issued by [Dr B] dispensed from a [Town 2] pharmacy (and assuming a three-month supply of medication was available from the prescription issued on 8 [Month1] this should have been the case), I think continued dispensing of the medications at two-weekly intervals was appropriate with a decision whether or not to extend the interval to be made following face-to-face review by her new GP within the three month period covered by the prescription.

17. On 23 Month6 [Mrs A] evidently contacted [the medical centre] by telephone and requested a repeat of her regular medications (paroxetine, mirtazapine and omeprazole). Along with the request template, [the practice nurse] has documented *Pt says she is doing well with the medication and denies any thoughts of self harm.* There was no reference to [Mrs A] having found a new GP or having requested transfer of notes since the consultation of [Month3]. There is no reference to [Mrs A] requesting a change in dispensing arrangements from that previously provided (which has been assumed to be two-weekly dispensing). [Mrs A] was evidently in [Town 1] as she wanted to collect the prescription in person that day. Based on the information available, it appears [Dr B] was instructed that [Mrs A] required a repeat prescription that day. The prescriptions were generated by the practice nurse as repeats of the last prescription (which stated two-weekly dispensing of mirtazapine and paroxetine) and left for [Dr B] to sign. [Dr B] manually altered the prescription to enable three months' supply to be dispensed at once and [Mrs A] took the prescription to a [Town 1] pharmacy and obtained the three month supply. There is no reference in the clinical notes to the change in dispensing instructions or the reasons for this although [Dr B] has elaborated on this in her response (see s6).

Comment: Under some circumstances, provision of three-month stat dispensing of antidepressants might be appropriate eg a patient who has exhibited long-term stable mental health on the medication and is not felt to be at increased risk of self harm. MCNZ recommendations regarding repeat prescribing are outlined in Appendix 2. I feel it was inappropriate to prescribe [Mrs A] a three-month stat supply of mirtazapine and paroxetine on 23 [Month6] for the following reasons:

(i) [Mrs A] had been taking the medication regime for just over two months at the time of most recent medical review and in the three months since that review she was subject to factors that might increase her risk of self harm as discussed above. I do not think a brief assessment of the patient's mental health status by a practice nurse via

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telephone was sufficiently reassuring (taking into account [Mrs A's] past history) to make the decision that [Mrs A] could be safely dispensed a stat three month supply of medication. However, the fact some assessment was undertaken (and the response from [Mrs A] in this regard) is a mitigating factor, and I acknowledge that had a face-to-face assessment been undertaken, it might also have been reassuring for [Dr B] that [Mrs A] was mentally well.

(ii) It is not apparent [Mrs A] specifically requested a stat three month supply of medication. It was important [Mrs A] register with a GP in [Town 2] and she had shown no inclination to do this in the three months since her shift. By providing the three-month prescription without any discussion in this regard meant [Mrs A] could go without any clinical assessment of her mental health for a further three months which I do not feel was appropriate given her mental health history. A safer option available to [Dr B] was to prescribe a shorter supply of the medication (one month) with the instruction that [Mrs A] needed to register with a [Town 2] GP for review prior to getting further supplies.

(iii) Any change in dispensing instructions should be evident from the clinical record and [Dr B] failed to change the prescribing instructions in the PMS prescribing module and/or to make a consultation note that the dispensing instructions had been changed and the reasons for this.

… I am moderately critical that [Dr B] chose to prescribe [Mrs A] a three month supply of paroxetine and mirtazapine with stat dispensing without adequately establishing the safety of such prescribing and without recording the change in dispensing instructions in the clinical record. Taking into account these comments and those relating to the initial prescribing of the combination antidepressant regime it might be appropriate to consider a MCNZ review of [Dr B's] competency.

(iv) Addendum 23 October 2019. [Dr B] commented further on her rationale for the three-month stat prescribing of medication to [Mrs A] on 23 [Month6]:

- **[Dr B] did not review [Mrs A] face-to-face on 23 [Month6]. However, she felt that given how well [Mrs A] had responded to her new medication regime at the time of previous review on 17 [Month3] and the knowledge she had a very supportive partner, together with the documented report following practice nurse enquiry that [Mrs A] was doing well with no thoughts of self harm, it was reasonable to provide a repeat prescription.**
- **Providing the repeat prescription was consistent with [the medical centre's] repeat prescribing guidelines.**
- **The prescription was printed as two-weekly dispensing but [Dr B] received a call from the local pharmacist stating [Mrs A] was requesting a three-month stat prescription as it was not practical for her to travel from [Town 2] to [Town 1] to collect her repeats.**
- **[Dr B] states she wanted to ensure *a continuous supply of medication in a time of uncertainty over access to medical care and prescriptions.* She therefore**

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authorized the three-month stat dispensing but failed to record this in the clinical notes.

- **[Dr B] states that, on reflection, she could have prescribed [Mrs A] a one-month supply of medication which would have been a sufficient time for her to find a local GP.**

I remain of the view that it was clinically inappropriate to prescribe [Mrs A] a three-month supply of her antidepressant medication with stat dispensing and without face-to-face review for the reasons described in my initial advice above. I remain moderately critical of this aspect of [Mrs A's] care. However, given I have reconsidered the appropriateness of the initial prescribing of her antidepressant regime, I withdraw the recommendation that referral to the MCNZ for competency review might be considered.

18. …

19. Addendum 23 October 2019

(i) [Dr B] has noted changes in practice she has implemented since this complaint and these actions seem appropriate.

(ii) I have reviewed the [medical centre's] guidance on repeat prescribing and this appears largely consistent with similar policies I have reviewed from other practices in regard to the repeat prescribing process. I think it should be emphasized within the policy that the information contained in the policy Appendices 1 & 2 is for general guidance only, and the individual prescriber must always be satisfied that the prescription they are signing is appropriate for that patient. There is much variability in factors such as requirement for monitoring before prescribing (eg recommended frequency of checking electrolytes in patients on diuretics will vary depending on the patient's co-morbidities and co-prescribing; recommended monitoring of patients on lithium requires more than 'annual serology'). Some monitoring scenarios are more critical than others (eg warfarin, DMARDs) and it is not possible to cover all scenarios in a simple Appendix.

Appendix 1.

A 2017 BPAC editorial on suicide prevention[5] included a mnemonic for suicide risk factors with the rider: … *although bearing in mind that most people with these characteristics will not die by suicide and cumulative risk is more important than individual risk factors.*

[5] https://bpac.org.nz/2017/docs/suicide.pdf Accessed 16 May 2019

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SAD PERSONS acronym: risk factors for self-harm and suicide
S: Sex – male
A: Age – <19 or >45 years
D: Depression
P: Previous attempt
E: Excess alcohol or substance use
R: Rational thinking loss
S: Social supports lacking
O: Organised plan
N: No spouse
S: Sickness

Appendix 2

From MCNZ statement 'Good prescribing practice. 2016' www.mcnz.org.nz

Repeat prescriptions

33. It is important that any system for issuing a repeat of an earlier prescription issued to a patient takes full account of the obligations to prescribe responsibly and safely and that the doctor who signs the prescription takes responsibility for it. Before signing a repeat prescription, you must be satisfied that secure procedures are in place to ensure that:

- *The patient is issued with the correct prescription.*
- *Each prescription is regularly reviewed so that it is not issued for a medicine that is no longer required.*
- *The correct dose is prescribed for medicines where the dose varies during the course of the treatment.*
- *You have appropriate information available (which may include access to the patient's clinical records) so that you can review the appropriateness of the repeat prescription.*
- *Any subsidy conditions that have changed since the last prescription (such as a change to subsidised medicines or a change to the patient's Dispensing Frequency requirements) are amended by you on the prescription.*
- *You review all relevant information before completing the prescription, and ensure that the patient record is maintained and updated.*
- *Repeat prescriptions should include details about the number of the repeats allowed within a given time frame and, for the patient's benefit, clear instructions relating to the dosage including quantity, frequency and route.*

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34. Patients receiving repeat prescriptions should be assessed in person on a regular basis to ensure that the prescription remains appropriate, adverse effects are monitored, and the patient is taking or using their medicines as intended. Patients who need a further examination or assessment should not receive repeat prescriptions without being seen by a doctor. This is particularly important in the case of medicines with potentially serious adverse effects. It is at the doctor's discretion whether a patient is given a repeat prescription. Decisions not to issue a repeat prescription should be explained to the patient and documented accordingly."

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