District Health Board

Psychiatrist, Dr C

Registered Midwife, RM D

A Report by the

Deputy Health and Disability Commissioner

(Case 19HDC00773)

Health and Disability Commissioner

Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns a woman who became pregnant whilst taking Epilim (sodium valproate), which places the fetus at high risk of developing serious birth defects, and can affect the way in which the child develops as it grows. The report reinforces the significance of the informed consent process, and highlights in the context of fetal anticonvulsant syndrome, the importance of prescribing clinicians sharing with women clear information about the risks and benefits of taking Epilim when there is a possibility that they may become pregnant whilst taking the medication.

2. The woman became pregnant whilst taking 1200mg of Epilim per day for treatment of a mood disorder. Her complaint arose because of the lack of information she received from the health professionals involved in her care at the district health board (the DHB) before and during her pregnancy.

3. The complaint has provided an opportunity to share information about Epilim and other teratogenic medications with the wider community — most importantly, its specific risks to pregnant women. The Deputy Commissioner has committed to ensure that this happens as a result of the woman's experience.

4. The complaint also offers an opportunity for the Government agencies involved in safe prescribing practices to review the adequacy of the current safeguards for mitigating the risk of fetal abnormalities in babies who are exposed to certain drugs while in the womb.

Findings

5. The Deputy Commissioner found the following:

- The practice of psychiatrists using a letter to the client's GP rather than recording detailed clinical notes, and not having in place a policy or procedure relating to the prescribing of Epilim to women of childbearing age, were systemic factors at the DHB that contributed to the lack of information provided to the woman.
- The locum psychiatrist, who initially prescribed Epilim to the woman, did not provide her with information that a reasonable consumer in her circumstances would expect to receive at a critical point in her care. This included an explanation of the options available other than Epilim, and the specific risks of Epilim in relation to pregnancy. The locum psychiatrist was found in breach of Rights 6(1)(b) and 7(1) of the Code.
- Discussions between the second psychiatrist, who prescribed Epilim to the woman, and the woman about the risks of Epilim and pregnancy were not documented.
- Regrettably, an obstetrician provided incorrect information to the woman about Epilim, namely that "Epilim is not thought to cause any cognitive issues" to an unborn child.
- A midwife breached Right 4(2) of the Code for retrospectively amending the woman's antenatal records without stating that the amendments were retrospective.

Recommendations

6. The Deputy Commissioner made recommendations to improve the accessibility of information about Epilim. These include recommending relevant professional colleges circulate the Medsafe safety alert for Epilim to all their New Zealand members and communicate the Deputy Commissioner's expectations that when prescribing Epilim, clinicians will provide written information about Epilim to their patients about the risks of Epilim in pregnancy, discuss the risks, benefits and necessary precautions to mitigate the risks, confirm the patient's understanding of these, and then document in the clinical records they have done so.

7. As a result of feedback indicating it would be useful to have written materials about anti-seizure medications available in languages other than English, particularly for use in the general practice setting, the Deputy Commissioner has made a further recommendation requesting Medsafe, ACC and the Health Quality and Safety Commission work together to consider reproducing the current information booklet *Medicines for epilepsy, mental health, and pain can harm your unborn baby* in plain English, and in other languages, with a view to making the information as accessible as possible.

8. The Deputy Commissioner recommended that the psychiatrist, the midwife and the obstetrician apologise to the woman. The Deputy Commissioner also made further recommendations, which are detailed later in this report.

Complaint and investigation

9. The Health and Disability Commissioner (HDC) received a complaint from Ms A about the services provided to her in relation to the use of Epilim. Ms A became pregnant whilst taking this medication. The following issues were identified for investigation:

- *Whether the district health board provided Ms A with an appropriate standard of care in relation to the prescribing of Epilim and provision of information about its use in relation to pregnancy.*
- *Whether Dr C provided Ms A with an appropriate standard of care in relation to the prescribing of Epilim and provision of information about its use in relation to pregnancy.*
- *Whether RM D's documentation in relation to Ms A's maternity care complied with relevant legal, professional and ethical standards.*

10. This report is the opinion of Deputy Commissioner Rose Wall, and is made in accordance with the power delegated to her by the Commissioner.

11. The parties directly involved in the investigation were:

Ms A	Consumer
Ms B	Ms A's support person[1]
District Health Board (DHB)	Provider
Dr C	Psychiatrist
RM D	Registered Midwife (RM)

12. Further information was received from:

Dr E	Obstetrician
Dr F	Psychiatrist
Dr G	Psychiatrist
Dr H	General practitioner (GP)

13. Independent expert advice was obtained from:

Obstetrician Dr David Bailey	Appendix A
Obstetrician Professor Peter Stone	Appendix B
Psychiatrist Dr Allen Fraser	Appendix C

14. In-house clinical advice was obtained from:

RM Isabelle Eadie	Appendix D
GP Dr David Maplesden	Appendix E

15. GP Dr I is also mentioned in this report.

Information gathered during investigation

Epilim

Background

Psychiatry appointments

16. On 15 Month1[2] 2017, Ms A was referred to DHB Community Mental Health Services by her GP, Dr H. Dr H identified low mood, anxiety, and stress as the issues leading to the referral. He also noted that Ms A experienced anger, and had difficulty coping with her child. Dr H recorded that a trial of SSRI antidepressants had not been tolerated.

[1] Ms B is the Executive Officer of Fetal Anticonvulsant Syndrome New Zealand (FACSNZ). Fetal anticonvulsant syndrome is a group of malformations that can affect some babies if they are exposed to antiepileptic medications (eg, Epilim) while in the womb. FACSNZ provides support, education, and awareness around fetal anticonvulsant syndrome.

[2] Relevant months are referred to as Months 1-26 to protect privacy.

17. Following the referral, on 28 Month4 Ms A was seen by Dr C,[3] who was a short-term locum for the Community Mental Health Service. Her diagnosis was recorded as: "Fits Borderline vs BPAD [Bipolar Affective Disorder] spectrum." In response to the provisional report, Dr C clarified that in her opinion, borderline personality disorder was the primary diagnosis, with a secondary differential diagnosis of BPAD Type 2.

18. Dr C commenced Ms A on Epilim 200mg in the morning and 500mg at night with concurrent weaning off 150mg quetiapine,[4] which she had been taking at night. Dr C told HDC that the quetiapine was having no apparent beneficial effect on Ms A's mood swings. Dr C did not document this, but she did record that quetiapine made Ms A "groggy".

19. Dr C's notes of this appointment are contained in a two-page clinic letter addressed to Dr H. There is no reference in the letter to any discussion had with Ms A regarding contraception or pregnancy planning in relation to Epilim. Whilst it was not documented, Dr C told HDC that Ms A was not in a relationship at the time, and that Ms A had no pregnancy plans as far as she was aware. In response to the provisional report, Dr C told HDC that at that time Ms A told her that she was not married or in an intimate relationship, and that this was not planned in the near future, with the risk of falling pregnant being highly unlikely.

20. Dr C stated that Ms A agreed to a trial of Epilim after "a full discussion of the risks and benefits of treatment". Dr C explained that her "standard operating procedure" when prescribing anti-seizure medication (such as Epilim) is to provide the client with oral and written information from Medsafe[5] regarding the possible teratogenic side effects and contraceptive requirements with this treatment option. In response to the provisional report, Dr C said that she cannot recall whether she provided Ms A with a medication safety information sheet about Epilim. However, Dr C noted that it was routine within the service for keyworkers to pass on this information, and, as a locum she "was not privy to the same resources that employed staff receive", hence "verbal information was key". It is not clear whether Dr C followed her standard procedure in Ms A's case, and this is discussed further below, most notably in paragraph 29.

21. In response to the provisional report, Dr C said that in accordance with her routine practice, she can also be confident that alternative options to Epilim were considered and discussed with Ms A during the review of 28 Month4. Dr C stated:

> "[Ms A] was already on an anti-psychotic and a benzodiazepine (as prescribed by [Ms A's] GP). She had been treated by her GP with an SSRI,[6] with no good effect. Her current treatment at the time was also having no beneficial effect. Based on the above, alternative treatment options were discussed with [Ms A] and these included options

[3] Dr C told HDC that she has a special interest in perinatal psychiatry.
[4] Used in the treatment of bipolar disorder.
[5] Dr C provided HDC with the following references:
https://www.medsafe.govt.nz/safety/EWS/2015/sodiumvalproate.asp and
https://www.medsafe.govt.nz/profs/adverse/Minutes171.htm#3.2.1.
[6] Selective serotonin reuptake inhibitors (SSRIs) are a widely used type of antidepressant.

> of medication that could be used as a mood stabilizer, such a Lamotrigine and Topiramate, vers[u]s Epilim as well as [dialectical behaviour therapy (DBT)]."[7]

22. Dr C explained that the chosen treatment was Epilim as it had the clearest evidence of being the treatment of choice for emotional dysregulation, and was the fastest acting (within five days), and this was relevant as Ms A was in a "semi crisis state". Dr C said that Ms A was agreeable to commencing this treatment, and that if she had had any doubts about Ms A wanting to proceed with Epilim, she would not have prescribed it to her. Dr C noted that Ms A did not want DBT because she was involved in enough other therapy, and reference was made to this in the next clinic letter to Dr H (for the appointment of 12 Month5).

23. On 12 Month5, Dr C reviewed Ms A again, and noted that she was finding the Epilim effective at regulating her emotions. Dr C increased the dose to 900mg at night. There is no reference to discussion regarding contraception or pregnancy planning in relation to Epilim in the clinic letter to Dr H from this appointment. Dr C did not record Ms A's serum sodium valproate levels, and she recommended further psychiatric review in three months' time.

24. In response to the provisional report, Dr C discussed Ms A's management after commencing Epilim. Dr C noted that at the time of Ms A's commencement on 700mg Epilim, she did not require blood-level monitoring as the dose is sub-therapeutic. Dr C said that at the time of her second review, the dose was increased to 900mg, which is still sub-therapeutic and therefore an immediate blood level was not required. Dr C noted in the letter to Dr H of 12 Month5 that Ms A could have a blood level done "at any point from here on in". Dr C understood that the blood level was to be left for the GP to arrange prior to Ms A's next three-monthly psychiatry review. Dr C stated:

> "[I]t was never my intention that the treatment with Epilim would be long term … I made the reasonable assumption that my successors would review the treatment plan and amend accordingly."

25. On 13 Month8 and 15 Month11, psychiatrist Dr F reviewed Ms A and increased her Epilim dose to 1000mg then 1200mg at night. Dr F told HDC that Ms A had noticed an improvement in her mood and overall mental state on the medication. On both occasions Dr F recorded Ms A's serum sodium valproate levels. There is no reference in Dr F's clinic letters to Dr H to any discussions had regarding pregnancy or contraception.

26. However, although it is not documented, Dr F told HDC that on 13 Month8 she discussed with Ms A the side effects of Epilim on pregnancy, as is her routine practice. Dr F stated:

> "I explained to her that [Epilim] could cause neural tube defects in some pregnancies if taken in the first trimester. She was made aware that it was never a best practice to fall pregnant while taking [Epilim] due to its teratogenic side effects. She was also requested to plan her pregnancy well in advance and discuss it with the specialists if and when she fell pregnant so that the drug could be safely withdrawn and another

[7] DBT is a type of cognitive behavioural therapy. Cognitive behavioural therapy tries to identify and change negative thinking patterns.

> mood stabiliser could be tried. She was also informed that if she fell pregnant, she needed to let us know right away."

27. At further reviews by Dr F on 14 Month14 and 14 Month17, Ms A's Epilim dose was maintained at 1200mg at night. Again there is no reference to discussion regarding contraception or partner status documented in the clinic letters.

28. Dr F said that she is a perinatal mental health specialist, and advising clients about contraception and the teratogenic effects of psychotropic medications comes very naturally to her. She stated: "I am of the opinion that [Ms A] had this information and had opportunity to discuss it with us at the different appointments."

29. Ms A told HDC that none of the psychiatrists gave her written information about Epilim and pregnancy. She recalls being told that there were some risks regarding Epilim and pregnancy, but not what these were. However, she does recall being asked by Dr F to take a pregnancy test. Ms A told HDC that during her initial psychiatrist appointments (pre-pregnancy) there were no discussions about other medication options as an alternative to Epilim.

Pregnancy

30. On 31 Month17, Ms A attended Dr I at an urgent care clinic after she had a positive pregnancy test at home. Dr I requested an urgent review by a perinatal specialist nurse at the DHB in relation to Ms A's Epilim prescription (via e-referral). This stated: "[T]o follow-up re tapering of Epilim and if new meds should be started in place. [Patient's] GP closed until 07 [Month18] and issue would need to be addressed sooner." Ms A was advised to continue with her current Epilim dose until contacted by the nurse.

31. Ms A saw Dr H on 7 Month18. The notes from the appointment state:

> "[P]regnancy, bipolar disorder, we discussed the pros and cons of taking Epilim while pregnant, she is already mostly through her first trimester now and I hesitate to stop this medication as we have to balance mom's mental health with the risks of her medication. I will urgently refer her to the hospital to get some input going forward. Will get antenatal bloods, start folate, iodine and organise her dating scan."

32. Dr H prescribed Ms A folic acid 0.8mg daily and iodine 150mcg daily and reduced her Epilim dose to 1000mg at night. Dr H sent an urgent referral to the DHB obstetric service requesting review of Ms A and advice regarding management.

33. The DHB's Specialist Perinatal Team reviewed the referral from Dr I on 8 Month18. The DHB said that there was not a delay in considering this referral because it fell within its timeframe of 1–2 weeks for response, and there were also statutory holidays over that period.

34. On 8 Month18, Ms A's Community Mental Health keyworker emailed Dr H and the urgent care clinic, noting that the referrals had been discussed with Dr F and that they were aware that Dr H had reduced the Epilim dose the previous day. The keyworker also advised Dr H

that Dr F was leaving at the end of the week, and psychiatrist Dr G would be joining the team after Dr F's departure.

35. The keyworker spoke with Ms A on 14 Month18, and noted that the dose of Epilim had not been decreased further. The situation was discussed at the next day's multidisciplinary team meeting, and it was decided that the dose of Epilim should remain the same until Ms A's upcoming appointment with Dr G.

36. Ms A then saw Dr G on 25 Month18. Dr G's clinic letter to Dr H noted that Ms A was 7 weeks and 4 days pregnant, and taking Epilim 1000mg at night and folic acid 0.8mg daily. Further slow weaning of the Epilim was advised "to find the lowest effective dose as she is midway through her first trimester, and the risk for congenital abnormality with [Epilim] is dose dependent". Dr G increased Ms A's folic acid dose to 5mg daily in line with RANZCOG[8] recommendations.

37. Dr G reduced the dose of Epilim to 700mg nightly for two weeks, with a further reduction to 500mg nightly also for two weeks. She recorded that Ms A was in agreement with the plan, and was aware of the medication risks and benefits. Ms A was eventually weaned off Epilim completely during the pregnancy, with her final dose in mid-Month20.

38. Ms A attended an appointment with obstetrician Dr E on 6 Month20. In her complaint, Ms A raised concern that Dr E advised her that whilst taking Epilim, there was a small increased risk of spinal tube defects (1–2%) compared to normal pregnancies, but there was no increase in risk of cognitive or developmental delays.

39. That day, Dr E wrote a clinic letter to Ms A's midwife, RM D, and copied it to Ms A and her partner. The letter was not copied to Ms A's GP, Dr H. The letter noted that Ms A's mood was well stablilised on the lower dose of Epilim. The letter also stated: "Epilim is thought to not cause any cognitive issues, so that is really good news for [Ms A]." Ms A raised a complaint with the DHB about this statement being incorrect.

40. On 3 Month22, Dr E wrote to Ms A in response to her concerns about the accuracy of this statement. Dr E acknowledged that Epilim is not safe in pregnancy, that it should be used only if there is no alternative, and that it does cause cognitive delay. He apologised to Ms A. Dr E explained that his statement was made in the context of Ms A being on a low and tapering dose of Epilim, and that there is evidence that a low dose is associated with less harm to the baby. He said that he aimed to support the position that Ms A and Dr G had agreed upon for weaning off Epilim, and his background concern was for Ms A's mental wellbeing.

41. Ms A was next seen by Dr G on 14 Month23. Dr G recorded that Ms A's mood was stable and she had been functioning well since stopping Epilim. Her next appointment was two weeks after her baby was born. Dr G's assessment was that Ms A was remaining well

[8] The Royal Australian and New Zealand College of Obstetricians and Gynaecologists.

mentally, and did not require medication, and she discharged Ms A from the Community Mental Health Team to Dr H.

42. Ms A told HDC that the baby is generally well but has some features that may be related to Epilim exposure. She said that his cognition may be mildly affected but she is yet to find this out.

Further information

DHB

43. The DHB stated: "In our view, appropriate information was given regarding side effects, effects on foetus and repeated advice to be on suitable contraception." The DHB told HDC:

> "Since 2015 we are very aware of the heightened risk posed by Epilim … This incident has highlighted the need to document that we give advice regarding the effects, side effects on foetus and the need for contraception in women of childbearing age."

44. At the time of these events, the DHB did not have a specific policy or procedure relating to the prescribing of Epilim to women of childbearing age.

Dr H

45. Dr H told HDC that he does not recall receiving specific information from Ms A's psychiatrists that she should be on contraception or that they had discussed this with her. He said that this may have been because she had been on an oral contraceptive regularly since at least 2013.

46. Dr H said that at the time of these events, he was unaware of the recommendation for a higher folic acid dose for pregnant women taking Epilim, but he is now aware of this.

Medsafe

47. Medsafe advised that the number of women who gave birth in the years 2010 to 2019 who also had one or more dispensing of Epilim in the 310 days preceding delivery peaked at 86 in 2011 and reduced to 23 in 2019.

Actions of RM D

48. During Ms A's pregnancy, her midwife was RM D. HDC asked RM D to provide a copy of Ms A's antenatal records and details of any discussion she had with Ms A about Epilim and its use during pregnancy. RM D provided HDC with a copy of Ms A's antenatal notes, which had been amended after the contact from HDC, to include further details of discussions she says that she had with Ms A about the risks of Epilim in pregnancy.

49. At the time RM D's legal advisor sent the notes to HDC, HDC was advised that these were the contemporaneous records of RM D's appointments with Ms A.

50. Ms A contacted HDC and sent screenshots of messages exchanged with RM D. One message from Ms A to RM D states:

> "You asked me to throw away the old notes because you could get in trouble due to no notes. I'm sorry but the notes you have written aren't accurate. So send the old notes is what I advise."

51. Ms A provided HDC with another copy of her antenatal records, which are less detailed than the notes provided by RM D's legal advisor.

52. RM D said that she did not at any time suggest that the old notes should be destroyed. She explained that she met with Ms A to discuss the additional information, and Ms A confirmed the changes to be made to the records.

53. RM D explained that she wrongly assumed that HDC's request expected her to add into the notes the details of discussions she had with Ms A about Epilim.

54. RM D believed that the fact that her notes had been updated would be immediately apparent because of the electronic record system. She now accepts that the additions should have been made as retrospective notes.

55. RM D said that her intention was to provide accurate and complete notes to HDC for the purpose of its investigation, there being no attempt to mislead or falsify information. She noted that some of the information that was added to the antenatal record was provided by Ms A in retrospect. For example, the dose of folic acid Ms A was taking was added to the amended notes as 5mg on 15 Month6, when the dose had not been increased from 0.8mg to 5mg until 25 Month6. RM D acknowledged that if this had been recorded as a retrospective note, the timing of when the information had been received would have been clarified and "the timeframe error placed in better context".

56. RM D said that she believed the initial description of the notes as "contemporaneous" was correct because she had ensured that the additions were made in consultation with Ms A. She now knows this not to be the case.

Responses to provisional report

57. Ms A, Ms B, the DHB, Dr C, Dr F, Dr G, Dr E, Dr H, and RM D were all given the opportunity to comment on relevant sections of the provisional report. Where appropriate, their comments have been incorporated into the report.

Ms A

58. Ms A reiterated that she was never provided written information booklets by any health professional during her pregnancy. She told HDC that she sourced the booklets about Epilim in pregnancy from Ms B, and then made the effort to share these with everyone she had been in contact with about her pregnancy. Ms A said that she is "saddened to read how often it's stated I was explained risks and benefits". She said that the only specific risk she was informed of (after she became pregnant, by Dr G and Dr E) was a 1–2% increase in neural tube defects like spina bifida, and is concerned that this is "massively minimising" all that may affect people when exposed to Epilim. Ms A stated: "I want to point out that I very

much trusted these people and that was my mistake. I did the best with the knowledge I had at the time."

Ms B on behalf of FACSNZ

59. Ms B confirmed that she gave Ms A the booklets[9] to pass on to her health professionals, after Ms A first made contact with her on 9 Month20. Ms B said that at that time, Ms A advised her:

> "that she was […] diagnosed with borderline personality disorder, and had been on 1200mg [Epilim] when she was first pregnant. [Ms A] stated that she was only advised by the psychiatrist to tell them if she got pregnant, and then once she was pregnant she was told about the chance of spinal tube defects as a slight increased chance and that the folic acid was upped because of this chance."

60. Ms B noted that given that Ms A was on 1200mg of Epilim per day, the congenital malformation risk was actually 10%, and with >1500mg per day it is 24%.[10]

61. Ms B supported Ms A in a meeting with the DHB representatives and Dr E on 18 Month23. In response to the provisional report, Ms B commented that the resources that the DHB had been able to find within the hospital regarding Epilim and pregnancy were at that time outdated, and the staff were unaware of newer resources available until FACSNZ brought them to their attention.

62. Ms B stated: "FACSNZ would like to thank [the DHB] for being open minded about education, upskilling, and improving their knowledge around anti-seizure medicines during pregnancy."

63. Ms B noted that Epilim exposure is dose related, with the risk of harm in doses of 800mg and above being that up to 40% of babies exposed will have developmental delays. She noted that lower doses are associated with a lower risk of being affected, not less harm.

64. Ms B stated:

> "[Ms A's] is just one case. There will be literally hundreds (if not thousands) of people out there not receiving informed consent or informed choice regarding anti-seizure medicine use in pregnancy. This needs to be addressed at a systemic level, because without doing so we are going to continue with the harm that has been going on for years. The fact of the matter is that since 1966 the Committee on Adverse Drug Reactions in New Zealand have known that anti-seizure medicines can cause congenital effects."

[9] "Are you taking medicines for epilepsy, mood or pain? Information for females their family and whānau", published September 2017, and "Benefits and risks of taking antiepileptic medicine for females. Information for healthcare professionals" published September 2017.

[10] "Benefits and risks of taking anti-seizure medicines for epilepsy, mental health, or pain. Information for healthcare professionals to discuss with anyone who could get pregnant." ACC May 2020.

Dr C

65. Dr C respectfully disagreed with the provisional finding that Ms A was not fully informed, and that alternative treatment options, risks, and benefits were not discussed with her during the appointment of 28 Month4. Dr C submitted that Ms A's recollection of what was discussed might not be accurate, stating: "[A]ccurate patient recollections are notoriously difficult, particularly where there is a substantial emotional element."

66. Dr C said:

> "I can be confident that the risks of pregnancy and hormonal changes were discussed with [Ms A], and she indicated to me that she was aware of the risks and possible side effects. This is because it was and still is my standard practice when starting a patient on any treatment, that the major side effects of proposed medication is discussed with patients. This is even more so because of my interest in perinatal psychiatry and commencing [Ms A] on a treatment plan that had potential teratogenic side effects, would have been a priority for me."

67. Dr C acknowledged that her documentation is lacking in detail, and accepts that discussions around risks and benefits of Epilim should have been recorded.

Other parties

68. The DHB, Dr F, Dr G, Dr E, and Dr H confirmed that they did not have any comments on the provisional report.

69. RM D did not respond to the provisional report, despite being given the opportunity to do so.

Opinion: Introduction

70. I would like to thank Ms A for bringing this important matter to my attention. I appreciate Ms B's advocacy for Ms A and her work with FACSNZ.[11] It is clear that their motivations are to ensure that correct information about the risks of Epilim in relation to pregnancy is readily available to both prescribers and consumers. The agencies with a responsibility for patient safety and the various health professional groups involved in patient care in circumstances such as this must take heed of Ms A's experience and ensure that the required safety-netting mechanisms are in place, universally understood, and correctly followed to mitigate the risk of avoidable complications occurring.

71. This investigation has served as an excellent opportunity to ensure that information about Epilim and other teratogenic medications is shared widely, and I hope that my

[11] Fetal Anticonvulsant Syndrome New Zealand.

recommendations and publication of this report reflect my commitment to ensuring that this happens as a result of Ms A's experience.

72. I am pleased that in the years following Ms A's experience, there has been a concerted effort from multiple organisations to ensure that there is clear information available about the risks of Epilim and pregnancy. These are discussed in more detail in the "changes made since these events" section of this report below. I also note that based on the information provided by Medsafe, the numbers of women being dispensed Epilim in the ten months prior to delivering a baby has reduced significantly over the past ten years. While this reduction is encouraging, it remains disappointing that it is still allowed to occur unnecessarily in any circumstance. For this reason I consider that there is still work to be done.

Opinion: District health board — adverse comment

73. Ms A had Epilim prescribed to her initially by Dr C. The prescription was continued by Dr F, and by Dr G once Ms A's pregnancy had been confirmed. Dr G supported Ms A in reducing the dose of Epilim during her pregnancy until it was stopped completely.

74. The prescriber of a medication has primary responsibility for ensuring that the prescription is appropriate and that the consumer has been adequately informed of the risks and benefits.[12] Therefore, I consider that the responsibility for ensuring that the prescription was suitable, and that Ms A received appropriate information about the risks of Epilim and pregnancy, lay with her mental health clinicians who were prescribing the medication. I have discussed their involvement in Ms A's care in turn in the sections that follow.

System issues

75. One overarching factor that made it very difficult to assess whether the standard of information provided to Ms A about the risks of Epilim and pregnancy was adequate was the practice of using the clinic letter from the psychiatrists to the GP as the record of assessment and treatment, rather than more fulsome clinical notes. I note the advice of my expert psychiatry advisor, Dr Allen Fraser:

> "The apparent practice in [the DHB] of there being no clinical notes made by psychiatrists, and the only record of their assessments, opinions and interventions being letters to the General Practitioner, is a practice which has in this case resulted in concerns that could have been prevented by good note keeping."

76. Dr Fraser commented that the practice of using a letter to the referring GP as the record of a psychiatrist's assessment and treatment plan resulted in relatively sparse notes.

[12] https://www.mcnz.org.nz/assets/standards/ceae513c85/Statement-on-good-prescribing-practice.pdf.

77. I accept Dr Fraser's advice. This was a factor apparent in assessing the care provided by all of the psychiatrists involved in Ms A's care, and therefore I regard this as being the accepted or normal practice at the DHB at that time. I am critical that this was the case, and I expect the DHB to reflect on these comments and whether they are more widely applicable, and whether any service level changes need to be made as a result.

78. I am also aware that at the time of these events, the DHB did not have a specific policy or procedure relating to the prescribing of Epilim to women of childbearing age. In the absence of a clear set of guidelines for its clinicians to follow consistently, particularly those who were working as locums, the DHB must bear some responsibility for the events that transpired, and the inadequacy of the information given to the consumer.

79. I consider that the practice of using a letter to the GP rather than recording fulsome clinical notes, and the absence of a policy relating to the prescribing of Epilim to women of childbearing age were systemic factors at the DHB that contributed to the lack of information provided to Ms A.

80. I appreciate the DHB's acknowledgement that this complaint has highlighted the need to document advice given regarding the effects, side effects on the fetus, and the need for contraception in women of childbearing age who are prescribed Epilim.

Opinion: Dr C — breach

Appropriateness of initial prescription of Epilim

81. I sought advice from Dr Fraser regarding Dr C's initial prescription of Epilim to Ms A. Dr Fraser noted that Dr C had recorded a differential diagnosis of either borderline personality disorder or bipolar disorder, and decided to treat Ms A with a mood stabiliser. Dr Fraser expressed some concern that Dr C would use a differential diagnosis as a diagnosis upon which to base treatment, but accepted that this would not be regarded by colleagues with disapproval. He commented:

> "Although many psychiatrists would regard the original diagnosis ('Fits Borderline vs BPAD spectrum') with at least mild disapproval, some who have perhaps been influenced by the trans-diagnostic approach to psychiatry (most exemplified by Early Psychosis Intervention services) would find it acceptable. This has led to a practice of treating symptoms rather than disorders."

82. While I note Dr Fraser's reservations about Dr C's differential diagnosis, given that he has expressed that this would not be regarded by colleagues with disapproval, in the circumstances I am not critical of Dr C's choice of treating Ms A's symptoms with a mood stabiliser, and I note that over the following months, Ms A did find the Epilim beneficial. I also note that in response to the provisional report, Dr C clarified that borderline personality disorder was her primary diagnosis, with a secondary differential diagnosis of BPAD Type 2.

My primary concern is the lack of information Dr C gave to Ms A about Epilim, including its implications if she were to become pregnant, and about other options for her treatment.

83. Dr C commenced Ms A on Epilim on 28 Month4, and concurrently weaned her off quetiapine, which apparently had not been effective in treating her mood swings. Ms A told HDC that during her initial psychiatrist appointments (pre-pregnancy) there were no discussions about other alternative medication options to Epilim. There is also no documented evidence that Dr C gave Ms A information on alternatives to Epilim. In response to the provisional report, Dr C stated that she is confident that alternative medication options of mood stabilisers lamotrigine and topiramate were discussed with Ms A, as well as the option of DBT.

84. While I accept that the option of DBT was discussed with Ms A, I am concerned about the timing of this discussion, and note that this was referred to only in the clinic letter to Dr H from 12 Month5, after Ms A had already commenced Epilim. In the circumstances of Ms A recalling no other alternative medication options being discussed with her when she saw Dr C on 28 Month4, and in the absence of any supporting documentation suggesting this was the case, I remain of the view that it is more likely than not that Dr C did not provide information to Ms A about alternative treatments prior to Ms A starting Epilim.

85. In light of the Medsafe safety alert information (September 2015), I would have expected Dr C to have discussed other potential options with Ms A before commencing the medication, and I am critical that this did not occur. A factor mitigating this criticism is that Ms A had already tried quetiapine, which apparently had not been effective.

Appropriateness of information provided about Epilim

86. Dr C stated that Ms A agreed to the trial of Epilim after "a full discussion of the risks and benefits of treatment". Dr C explained that her "standard operating procedure" when prescribing anti-seizure medication therapy such as Epilim is to provide the client with oral and written information from Medsafe regarding the possible teratogenic side effects and contraception requirements. However, there is no evidence in Dr C's clinic letters to Dr H (which comprised the totality of the clinical record of her consultations with Ms A) that any risks about Epilim were discussed, including no evidence that Ms A was given verbal or written information about the risks of taking Epilim during pregnancy and the need for contraception.

87. Dr C initiated the prescribing of Epilim to Ms A. As such, Dr C was responsible for the provision of information about the risks and benefits of Epilim to Ms A. In response to the provisional report, Dr C said that she cannot recall giving Ms A a medication safety information sheet about Epilim. However, Dr C stated:

> "I can be confident that the risks of pregnancy and hormonal changes were discussed with [Ms A], and she indicated to me that she was aware of the risks and possible side effects."

88. Dr C said that it would have been a priority for her to discuss these with Ms A because she was commencing Ms A on a treatment plan that had potential teratogenic side effects.

89. Ms A told HDC that none of the psychiatrists gave her written information about Epilim and pregnancy. She said that she recalls being told that there were some risks regarding Epilim and pregnancy, but not what these were.

90. It is unfortunate that the details of the discussions between Dr C and Ms A regarding the risks of Epilim, including as they related to pregnancy, were not documented anywhere by Dr C, and for this I am critical. This makes it difficult to assess whether the standard of information given to Ms A was adequate. I accept Dr Fraser's advice that documentation of the discussions around the risks and benefits of Epilim would be expected practice.

91. I acknowledge Dr C's repeated reassurance in response to the provisional report that she discussed the risks and benefits of Epilim treatment with Ms A. However, in the circumstances of Ms A's recollections, and in the absence of any written documentation supporting there being a discussion about the risks of Epilim, including as they related to pregnancy, I find it is more likely than not that Dr C did not provide this specific information to Ms A either verbally or as written information. Ms A was of childbearing age, and this was the first occasion on which Epilim was being prescribed. As such, given the significant risks to Ms A's child if Ms A were to become pregnant, it was imperative that this information be discussed and a record made of the information provided.

Conclusion

92. In the circumstances, I am not satisfied that Dr C provided Ms A with information that a reasonable consumer in Ms A's circumstances would expect to receive at a critical point in her care. This includes an explanation of the options available to Ms A other than Epilim, and the specific risks of Epilim in relation to pregnancy. Accordingly, I find that Dr C breached Right 6(1)(b) of the Code.[13]

93. It follows that Ms A was not in a position to make an informed choice and give informed consent to the treatment with Epilim, and accordingly I find that Dr C breached Right 7(1) of the Code.[14]

Management after commencement of Epilim — adverse comment

94. Dr C reviewed Ms A two weeks after first prescribing Epilim, and noted a good response. Dr C did not record Ms A's serum sodium valproate levels, and she increased Ms A's dose and recommended further psychiatric review in three months' time.

[13] Right 6(1)(b) states that every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option.

[14] Right 7(1) states that 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 the Code provides otherwise.

95. Dr Fraser advised that even though there is not a close relationship between serum valproate levels and response, it would not be appropriate to defer checking the response to the increase in dose for three months, and not measure the serum valproate levels. I acknowledge Dr C's view that a serum valproate level was not required as the dose of 900mg was still sub-therapeutic, and she believed that the GP would arrange a sodium valproate level ahead of Ms A's next three-monthly psychiatry review. However, I accept Dr Fraser's advice, and I remain critical that Dr C did not record Ms A's serum sodium valproate levels at the time of the second appointment, and deferred psychiatric review for three months.

Opinion: Dr F — adverse comment

96. Dr F took over Ms A's care from Dr C. Dr F saw Ms A on four occasions, and Ms A remained on Epilim as this was reportedly helping her mood and overall mental state.

97. Dr F told HDC that on 13 Month8, as is her routine practice, she discussed with Ms A the side effects of Epilim on pregnancy. Dr F said that she explained the risk of neural tube defects, that it was never best practice to fall pregnant while taking Epilim, and that Ms A should plan any pregnancy well in advance and let the team know right away if she did fall pregnant so that the drug could be withdrawn safely.

98. Dr F's notes of her consultations with Ms A are contained in her clinic letters to Dr H, and Dr F's clinic letters to Dr H contain no mention of any discussions about pregnancy or contraception.

99. Ms A recalls being told that there were some risks regarding Epilim and pregnancy, but not what these were, and she also recalls being asked by Dr F to take a pregnancy test.

100. Dr Fraser commented:

> "[Dr F] reports the nature of the information and discussions she had with [Ms A]. It is unfortunate that this was not documented at the time, as would be expected practice."

101. Dr Fraser advised that what Dr F states she discussed with Ms A is reasonable, especially given that the sodium valproate had been started and was seen by Ms A as being of benefit.

102. I agree with Dr Fraser that it is unfortunate that the details of the discussions between Dr F and Ms A regarding the risks of Epilim and pregnancy were not documented anywhere by Dr F, and for this I am critical. This makes it difficult to assess whether the standard of information given to Ms A was adequate. However, I accept that there must have been some discussion to this effect because of Ms A's recollection, particularly regarding undertaking a pregnancy test.

Opinion: Dr G — adverse comment

103. Dr G was involved in Ms A's care after her pregnancy was confirmed. Dr G supported Ms A in reducing the dose of Epilim during her pregnancy until it was stopped completely. Dr G recorded that Ms A was in agreement with the plan, and was aware of the medication risks and benefits.

104. Dr Fraser advised me that Dr G gave sound advice to Ms A. He stated: "[Dr G's] documentation, and careful management of the withdrawal from valproate showed appropriate practice."

105. I accept Dr Fraser's advice and I consider that Dr G provided appropriate support to Ms A as she reduced her dose of Epilim during her pregnancy.

106. In response to the provisional opinion, Ms A clarified that the only specific risk she was informed of by Dr G (after Ms A became pregnant) was a 1–2% increase in neural tube defects like spina bifida. I note that the ACC information booklet available in 2017 states that 4 to 7 out of 100 babies (4–7%) exposed to antiepileptic medicines of any dose will have malformations such as spina bifida. Further, the more recent ACC publication available in May 2020 states that "sodium valproate carries a 10% risk of congenital malformation". I ask Dr G to reflect on the advice provided to Ms A in light of this information.

Opinion: Dr E — adverse comment

107. On 6 Month20, obstetrician Dr E saw Ms A in clinic and then wrote a letter to Ms A stating: "Epilim is not thought to cause any cognitive issues so that is really good news for [Ms A]."

108. Dr E has since acknowledged that Epilim is not safe in pregnancy and should be used only if there is no alternative, and that it can cause cognitive delay. He has apologised to Ms A. Dr E explained that his statement was made in the context of Ms A being on a low and tapering dose of Epilim, and that there is evidence that a low dose is associated with less harm to the baby. He said that he aimed to support the position that Ms A and Dr G had agreed upon for weaning off Epilim, and his background concern was for Ms A's mental wellbeing.

109. I sought independent advice from obstetrician Professor Peter Stone regarding Dr E's care. Professor Stone stated:

> "I have concluded that the actual advice that [Dr E] gave to [Ms A] was incorrect regarding non-structural effects of [Epilim]. The advice was not up to date, nor reflected what I had taken to be general obstetric knowledge and this has been affirmed by the Medsafe data sheets.
>
> [Dr E] did arrange to have the issue of structural anomalies investigated expeditiously. I do not believe that [Dr E's] actions led to increased exposure of the fetus to [Epilim]

> because a) the dose reduction-weaning was already underway and b) the dosage at the start of that process was below the therapeutic range, and his advice did not lead to any increase in dose."

110. Professor Stone is of the opinion that Dr E was not responsible for initiating or continuing to prescribe Epilim. Professor Stone stated:

> "[W]hilst incorrect information was given, it could be reasonably argued that the obstetrician was not taking primary responsibility for the mental care of [Ms A] and indeed [Ms A] saw the psychiatrist the week after."

111. I also received advice from obstetrician Dr David Bailey. Dr Bailey similarly advised that the advice provided by Dr E that Epilim was not thought to be associated with cognitive problems was incorrect. Dr Bailey stated:

> "Providing obstetric advice for women who are taking medication for serious medical disorders is often problematic, as the Obstetrician cannot make decisions about changing or discontinuing treatment. The main responsibility for advising women about the risks of medications such as [Epilim] resides with the clinicians managing the medical problem and prescribing the medication, in this case the Mental Health team."

112. Dr Bailey acknowledged that Dr E's advice caused Ms A considerable distress when she found that the advice was incorrect. However, Dr Bailey considered that it was only a minor departure from acceptable practice when considering the following:

1. Dr E was not responsible for prescribing the Epilim and was not primarily responsible for advising about doses and the risks of treatment — this was the responsibility of the Mental Health team.
2. Ms A was already reducing her dose of Epilim and was close to discontinuing it by the time she saw Dr E.

113. The information that Dr E gave to Ms A was clearly incorrect, and naturally this would have been upsetting for Ms A once she became aware of it. While I am critical of Dr E for providing incorrect information about the risks of Epilim, I note that the prescribing of Epilim at that point was the responsibility of Dr G, and Dr G and Ms A had together made a plan to wean Ms A off Epilim. The primary responsibility for discussing the risks and benefits of Epilim lay with the mental health clinicians, not Dr E. However, given that Dr E had taken it upon himself to provide Ms A with information, he needed to ensure that the information was correct. It is regrettable that Dr E did not do so.

114. I also note that in response to the provisional opinion, Ms A clarified that the only specific risk she was informed of by Dr E (after she became pregnant) was a 1–2% increase in neural tube defects like spina bifida. I note that the ACC information booklet available in 2017 states that 4 to 7 out of 100 babies (4–7%) exposed to antiepileptic medicines of any dose will have malformations such as spina bifida. Further, the more recent ACC publication available in May 2020 states that "sodium valproate carries a 10% risk of congenital

malformation". I ask Dr E to reflect on the advice provided to Ms A in light of this information.

Opinion: Dr H — other comment

115. My in-house clinical advisor, GP Dr David Maplesden, stated that the prescriber of Epilim has primary responsibility for ensuring that the prescription is appropriate and that the consumer has been adequately informed of risks and benefits. As I have discussed previously, I am therefore satisfied that the primary responsibility for provision of this information lay with the mental health service, rather than Dr H.

116. Ms A saw Dr H on 7 Month18, having recently found out she was pregnant. Dr H made an urgent referral to the DHB for advice regarding the management of Ms A's medication, because of the risks of taking Epilim while pregnant. Dr H prescribed Ms A folic acid 0.8mg daily and iodine 150mcg daily and reduced her Epilim dose to 1000mg at night.

117. Dr H said that at the time of these events he was unaware of the recommendation for a higher folic acid dose for women taking Epilim, but he is now aware of this.

118. In October 2018, bpac^{nz} had produced an article on balancing benefits and risks of prescribing antiepileptic medication to women.[15] This included advice that a higher than usual dose of folic acid (5mg per day) is recommended for females taking antiepileptic medicines, as this reduces the background risk of spontaneous neural tube defects. However, it does not reduce the teratogenic effects of antiepileptic medicines.

119. Dr Maplesden reviewed Dr H's care and advised:

> "I believe [Dr H's] management of [Ms A] on 7 [Month18] was reasonable although as noted above, best practice would have been to prescribe 5mg folic acid rather than 0.8mg."

120. I accept Dr Maplesden's advice that it would have been best practice for Dr H to prescribe Ms A a higher dose of folic acid. I note that the bpac^{nz} article with the higher folic acid recommendation was produced only three months before Dr H saw Ms A, and two and a half weeks later Dr G commenced Ms A on the higher dose.

121. I am satisfied that Dr H is now well aware of this recommendation and will incorporate it into his practice as required.

[15] https://bpac.org.nz/2018/antiepileptic.aspx; bpac^{nz} advocates for best practice in healthcare treatments and investigations across a wide range of health service delivery areas.

Opinion: RM D — breach

122. I have considered the standard of care provided to Ms A by RM D during Ms A's pregnancy and am satisfied that it was reasonable in the circumstances. My in-house midwifery advisor, RM Isabelle Eadie, stated:

> "Based upon the *original* antenatal notes, I do not find that the care provided by [RM D] failed to meet expected standards of midwifery care towards a woman with a medicated mental health condition."

123. My opinion therefore considers only RM D's actions in relation to Ms A's antenatal notes, after the complaint had been made to HDC.

124. RM D provided HDC with a copy of Ms A's antenatal notes, which had been amended after the contact from HDC to include further details of discussions she says that she had with Ms A about the risks of Epilim in pregnancy. RM D said that she met with Ms A to discuss the amendments, and Ms A confirmed the changes. RM D explained that she wrongly assumed that HDC's request expected her to add into the notes the details of discussions she had with Ms A about Epilim.

125. Ms A provided HDC with a copy of a message she sent to RM D, which stated:

> "You asked me to throw away the old notes because you could get in trouble due to no notes. I'm sorry but the notes you have written aren't accurate. So send the old notes is what I advise."

126. RM D denies asking Ms A to destroy the original antenatal records, and stated that there was no attempt to mislead HDC or falsify information. RM D noted that some of the information that was added to the antenatal record retrospectively was provided by Ms A (for example, the dose of folic acid she was taking). RM D acknowledged that if the information had been recorded as a retrospective note, the timing of when the information was received would have been clarified, and the timeframe error placed in better context.

127. When RM D's legal advisor provided the amended notes to HDC, they were described as contemporaneous records. RM D believed this to be correct because she had ensured that the additions were made in consultation with Ms A. RM D is now aware that this is not correct and that these notes should have been added retrospectively.

128. My in-house midwifery advisor, RM Isabelle Eadie, advised that based on the original antenatal notes, RM D met the expected standards of midwifery care towards a woman with a medicated mental health condition. However, she advised that amending the clinical notes, falsifying the information within them, and failing to acknowledge this (in describing them as contemporaneous) reflects a severe departure from expected midwifery practice. RM Eadie also advised that in the event RM D asked Ms A to throw away her copy of the original antenatal record, this would represent a moderate to severe departure from accepted practice.

129. I acknowledge RM Eadie's advice. On the face of it, it would clearly be inappropriate professional conduct to make retrospective amendments to antenatal records without stating that these were retrospective, and to request that a client destroy the original copy of the records.

130. The New Zealand Midwifery Council guideline, "Be Safe. Documentation and Record Keeping" (Month8) states: "Documentation should occur at the time that care is provided. Notes written in retrospect should be identified as such" and "never amend or falsify records".

131. I acknowledge RM D's explanations for why she provided an amended copy of the notes to HDC. I note that this was the first time she had been asked to provide information to HDC, and I believe that she made a fundamental error regarding what was expected of her. Notwithstanding this, I am critical that RM D did not follow appropriate documentation practices specified by the Midwifery Council when updating her records retrospectively. I therefore find that RM D breached Right 4(2) of the Code.[16]

132. I note that RM D has undertaken significant learning and reflection on documentation practices since this event (detailed below under paragraph 151), which I believe is necessary and appropriate.

133. Given that Ms A and RM D have different versions of events regarding whether RM D asked Ms A to destroy the original antenatal records, I am unable to make a finding as to whether or not this occurred.

134. In light of my concerns about RM D's conduct, I have asked the Midwifery Council to consider whether a review of her competence is necessary.

Changes made since events

Medsafe

135. Mesdafe confirmed that the Epilim Data Sheet and Consumer Medicine Information documents are publicly available on the Medsafe website.

136. Sanofi is the pharmaceutical company responsible for marketing Epilim in New Zealand. In Month17, Sanofi updated its educational materials for patients and healthcare professionals. These materials are specific to reducing the risk of Epilim exposure during pregnancy, and reinforce the information in the above Medsafe documents.

[16] Right 4(2) states that every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.

137. On 14 Month17, Medsafe published on its website an open letter to healthcare professionals[17] from Sanofi, which provided the link to access the above materials.

138. In September 2019, Medsafe approved the addition of a QR code on the Epilim box that links directly to the Sanofi educational materials. The Epilim box also contains a pregnancy symbol and warning (which had been in place since April 2017), and the pregnancy symbol and warning was added to the blister foil packaging in September 2019. In response to the provisional report, Ms B noted that FACSNZ had to advocate both Medsafe and Sanofi to put the warning on the Epilim box and the pictogram on the foil of the Epilim tablets.

139. In March 2019, a safety alert was published on the Medsafe website[18] to communicate the updated indication for the use of Epilim for bipolar disorder in women. This was accompanied by a media release to disseminate the message as widely as possible.

Health Select Committee

140. In August 2020, the Health Select Committee released its findings in response to Ms B's petition for an inquiry into the numbers harmed by anti-seizure medicines during pregnancy. The Committee recommended that the Government ensure that any warnings on original packaging be transferred to generic packaging when medicines are dispensed, and that the review of the Medicines Act 1981 explore appropriate mechanisms for ensuring that contraindications for pregnancy are clearly displayed on packaging in a way that consumers understand.

141. The Government responded to the recommendations [19] by convening a hui on safer prescribing and safer dispensing in October 2021. Four workstreams resulted relating to system-level actions of developing a prescribing and dispensing communications framework, scoping of support for equitable access to clinical pharmacists, defining processes for sharing risk of harm data, and establishing a prescriber database. The Government also proposes to consider the Committee's recommendations throughout the drafting of the Therapeutic Products Bill and in the development of other regulations.

DHB

142. The DHB told HDC that all patients now receive the necessary information relating to the use of Epilim in pregnancy at their initial psychiatrist consultation and prior to the medication being prescribed, so that they are aware of the risks, which then enables and supports them to make an informed choice about their health care. In addition to verbal information, the following written information is available to patients:

1. The Sanofi "Patient Information Booklet — Valproate", and the "Guide for Healthcare Professionals — Valproate".

[17] https://www.medsafe.govt.nz/safety/DHCPLetters/epilim-educational-materials.pdf.
[18] https://www.medsafe.govt.nz/safety/Alerts/Epilim.asp.
[19] https://www.parliament.nz/resource/en-NZ/PAP_121497/701872eb938eff1516e07c59a04d7293576e4079

2. ACC, MOH, FACSNZ, and the Health Quality & Safety Commission (HQSC) patient information booklets (September 2017): "Benefits and risks of taking anti-epileptic medicine for females" and "Are you taking medicines for epilepsy, mood or pain?".
3. The Medsafe March 2019 safety information regarding taking sodium valproate in pregnancy.
4. The ACC, MOH, FACSNZ, and HQSC May 2020 documents:
   a. "Have the conversation: Benefits and risks of taking anti-seizure medicines for epilepsy, mental health, or pain";[20] and
   b. "Medicines for epilepsy, mental health and pain can harm your unborn baby".[21]

143. The DHB confirmed that Medsafe prescriber alerts are distributed to the Chief Medical Advisors and Chief Pharmacists in the DHB. These alerts are subsequently forwarded on, by email, to pharmacists and prescribers within the DHB.

144. The link to the Medsafe alert of March 2019 about the use of sodium valproate (Epilim) in pregnancy was disseminated to all the DHB medical consultants and GPs in the district, and to lead maternity carers and the DHB employed midwives.

145. The DHB is exploring the development of a guidance document regarding the use of anti-seizure medication in women of childbearing age in line with best practice. The DHB is considering adding Epilim prescribing resources to an "app hub" at the DHB. While the DHB explores these options, prescribers continue to follow best practice guidelines (from ACC, MOH, FACSNZ, and HQSC).

Dr C

146. Dr C told HDC that she now ensures that she is more specific with her documentation around informed consent and intended courses of treatment for subsequent doctors to follow.

147. Dr C stated that she now ensures that she personally provides written information on any new medications prescribed to a client, and, where verbal information is provided, she always documents what information has been provided.

148. Dr C said that going forward, if her intention is for a prescribed treatment to be "short term", she will document this clearly, so that her successor understands her intentions at the time of prescribing.

149. Since 2017, Dr C has attended training for ongoing education, which included issues of informed consent and documentation.

[20] https://www.acc.co.nz/assets/provider/benefits-risks-anti-seizure-medicines-epilepsy-mental-health-pain-acc7809.pdf
[21] https://www.acc.co.nz/assets/provider/medicines-epilepsy-mental-health-pain-harm-unborn-baby-acc7810.pdf

Dr H

150. Dr H provided evidence to HDC that he undertook a review of his female patients of childbearing age who are taking Epilim for the purpose of ensuring that they had been provided with appropriate information about Epilim and pregnancy. He stated: "[A]s part of my practice now I will routinely make sure that all of my female patients are provided with adequate information if they are prescribed this medication."

RM D

151. RM D advised HDC that since these events:

a) She has attended a course on documentation, and now has a thorough understanding of what contemporaneous note-taking requires.

b) She has undertaken significant reflection and has revisited the Referral Guidelines,[22] the Midwives Handbook for Practice, and the NZCOM Code of Ethics and Standards of Care.

c) She has engaged a professional mentor to help develop her documentation skills.

d) She has started using a client portal to more accurately capture times and dates on which topics are discussed. This also means that all clients in her care are now able to access their personal notes online.

e) She has shared her learning from this event with her practice partners.

New Zealand College of Midwives

152. The New Zealand College of Midwives has published on its website the bpac[nz] article on the use of anti-seizure medications in pregnancy.[23]

Recommendations

153. I acknowledge the significant effort invested by multiple organisations, including the DHB, to strengthen information sharing to ensure that information about Epilim and its risks in pregnancy are well known to prescribers and consumers. I am also conscious that currently HQSC is leading a further programme of work with relevant agencies to prevent FACS in the future and ensure that there is timely provision of information about health risks to people who could get pregnant. I am fully supportive of this quality improvement initiative and the likely benefits it will bring to consumers. I also recognise that the learnings from this case involving Epilim could equally be applied to other teratogenic medications that have the potential to disturb the development of the embryo or fetus.

[22] Ministry of Health. 2012. *Guidelines for Consultation with Obstetric and Related Medical Services (Referral Guidelines)*. Wellington: Ministry of Health.
[23] https://www.midwife.org.nz/wp-content/uploads/2018/10/antiepileptic-medicine-advice.pdf.

154. I recommend that the Royal Australian and New Zealand College of Psychiatrists (RANZCP), the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), the Royal New Zealand College of General Practitioners (RNZCGP), the Royal Australasian College of Physicians (RACP), and the New Zealand College of Midwives (NZCOM) circulate the March 2019 Medsafe safety alert for Epilim to all New Zealand members.

155. I recommend that the RANZCP consider whether its Clinical Practice Guidelines for Mood Disorders (2020) are consistent with the 2019 Medsafe safety alert, which states that sodium valproate must not be used in girls or women of childbearing potential unless other treatments are ineffective or not tolerated, or during pregnancy for the treatment of bipolar disorder.

156. As a result of feedback I received on the recommendations indicating it would be useful to have written materials about anti-seizure medications available in languages other than English, particularly for use in the general practice setting, I ask that Medsafe, ACC and HQSC work together to consider reproducing the current information book *Medicines for epilepsy, mental health, and pain can harm your unborn baby* in plain English, and in other languages, with a view to making this information as accessible as possible.

157. While acknowledging the programme of work HQSC has underway, in the meantime I ask that RANZCP, RNZCGP, and RACP communicate with their members HDC's recommendation that clinicians in New Zealand who prescribe Epilim to women of childbearing potential will do the following before commencing the medication:

a) Provide **written** information to their patients about the risks of Epilim and pregnancy.

b) Discuss the risks and benefits of the medication, and the necessary precautions to mitigate the risks, and confirm that the patient has understood these.

c) Document in the clinical records that they have done a) and b).

158. I also ask that the DHB communicate with its psychiatrists HDC's recommendation that clinicians who prescribe Epilim to women of childbearing potential will do the following before commencing the medication:

a) Provide **written** information to their patients about the risks of Epilim and pregnancy.

b) Discuss the risks and benefits of the medication, and the necessary precautions to mitigate the risks, and confirm that the patient has understood these.

c) Document in the clinical records that they have done a) and b).

159. I recommend that the DHB share my commentary about sparse note-keeping with its psychiatrists.

160. I recommend that the DHB report back to HDC on whether it has now developed and implemented a guidance document regarding the use of anti-seizure medications in women of childbearing age.

161. I recommend that the DHB consider Dr Fraser's comment below and whether further information should be shared with its psychiatrists (and, in turn, their female patients of childbearing potential who are taking Epilim for treatment of bipolar disorder) in light of this:

> "On the basis of evidence that there are different risks in women taking valproate for bipolar disorder [rather than epilepsy], the risk of hormonal disruption and the high prevalence of Polycystic Ovarian Syndrome in women should have been mentioned. In 2003 McIntyre et al reported significantly increased risk of menstrual abnormalities, hyperandrogenism, and metabolic abnormalities."

162. I recommend that Dr C provide a written apology to Ms A for the issues identified in this report. The apology should be sent to HDC within three weeks of the date of this opinion, for forwarding to Ms A.

163. I recommend that Dr E provide a written apology to Ms A for having provided her with incorrect information about the risks of Epilim and cognition. The apology should be sent to HDC within three weeks of the date of this opinion, for forwarding to Ms A.

164. I recommend that within three months of the date of this opinion, Dr E undertake a self-directed review of the Mesdafe and ACC, FACSNZ, HQSC, and MOH materials relating to Epilim and pregnancy, and confirm to HDC that he has done so.

165. I recommend that RM D provide a written apology to Ms A for the way in which her notes were subsequently updated and provided to HDC. The apology should be sent to HDC within three weeks of the date of this opinion, for forwarding to Ms A.

166. I recommend that the Midwifery Council of New Zealand consider whether a review of RM D's competence is warranted.

167. I request that the Ministry of Health provide an update to HDC within 12 months of the date of this opinion on the work undertaken in the four workstreams that were developed in response to the Health Select Committee's recommendations.

Follow-up actions

168. A copy of this report with details identifying the parties removed, except the names of the experts who advised on this case, will be sent to the Ministry of Health, Medsafe, ACC, HQSC, FACSNZ, RANZCP, RANZCOG, RACP, RNZCGP, and NZCOM.

169. A copy of this report with details identifying the parties removed, except the names of the experts who advised on this case, will be sent to the Midwifery Council of New Zealand, and it will be advised of RM D's name in covering correspondence.

170. A copy of this report with details identifying the parties removed, except the names of the experts who advised on this case, will be sent to the Medical Council of New Zealand, and it will be advised of Dr C's name in covering correspondence.

171. A copy of this report with details identifying the parties removed, except the names of the experts who advised on this case, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent clinical advice to the Commissioner

The following expert advice was received from obstetrician and gynaecologist Dr David Bailey:

> "I have been asked to provide expert advice to the Health and Disability Commissioner regarding the care provided by [Dr E] at [the district health board] to [Ms A] in [Month20] regarding treatment with Epilim (Sodium Valproate) during pregnancy. I have read the Guidelines for Independent Advisors provided by your office and agree to follow these guidelines.
>
> I am a Consultant in Obstetrics & Gynaecology at Northland District Health Board. I graduated in Medicine from London University in 1985 and trained in Obstetrics & Gynaecology in the United Kingdom and New Zealand, with advanced training in Maternal Medicine and Fetal Medicine in Newcastle upon Tyne. I became a Member of the Royal College of Obstetricians and Gynaecologists in 1999 and a Fellow of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists in 2005. I have a Diploma in Advanced Obstetric Ultrasound from the Royal College of Obstetricians and Gynaecologists. My main interest is in quality improvement in maternity care.
>
> **Background**
>
> [Dr E] saw [Ms A] in the Antenatal clinic on 6 [Month20]. She had been referred to clinic by her General Practitioner [Dr H] because she had conceived while taking Epilim. She was under the care of the [the DHB] Mental Health Service and had been prescribed Epilim as a mood-stabilizing treatment for bipolar disorder. According to her Psychiatrist, [Dr G], [Ms A] had been very unwell before starting Epilim and this medication had been associated with a marked improvement in her symptoms and wellbeing. By the time [Dr E] saw [Ms A] she was 13 weeks pregnant. She had been advised that taking Epilim in pregnancy may be harmful to her unborn child and she was in the process of reducing the dose of Epilim with an aim to discontinue it.
>
> In his letter [Dr E] documents that his main concern was fetal structural abnormality, specifically abnormalities of the spine and spinal cord (spina bifida). He advised [Ms A] that Epilim is not thought to cause cognitive problems and that he thought that an increase in dose would not be harmful.
>
> **Advice**
>
> Sodium valproate has been used for about 50 years as an anticonvulsive drug in the treatment of epilepsy. More recently it has been used in selected cases for patients with bipolar disorder as a mood-stabilizing drug. There has been concern regarding the harmful effects of Valproate on the developing fetus for many years and there is general agreement it should only be used in women of childbearing age when there are no effective alternatives. It is associated with an increased incidence of various structural abnormalities, of which the most well-known is neural tube defects (particularly spina bifida). It is likely that the risk is dose-dependent and patients should be managed on

the lowest effective dose. Unfortunately, if patients on Valproate have an unplanned pregnancy it is likely that the drug may already have caused harm before they realise they are pregnant, as the critical stages of organ formation occur very early. There is also evidence that Valproate in pregnancy is associated with an increased incidence of cognitive and behavioral problems later in childhood, including autism. These risks are well known and are described in detail in the datasheet for Sodium valproate. The Accident Compensation Corporation (ACC) produced an information leaflet for women regarding the risks of antiepileptic medications in 2017 and promoted this to health professionals. Most information comes for studies in patients with epilepsy, and it is known that children of women with epilepsy have higher rates of abnormalities and developmental problems compared to the general population, independent of medication. There is less information regarding the risks to the unborn child of Valproate in bipolar disorder, but it is assumed it may be similar.

The advice provided by [Dr E] that Valproate was not thought to be associated with cognitive problems was incorrect. In subsequent correspondence it is apparent that [Dr E] has reflected on this and has accepted his advice was incorrect and has apologised.

Providing obstetric advice for women who are taking medication for serious medical disorders is often problematic, as the Obstetrician cannot make decisions about changing or discontinuing treatment. The main responsibility for advising women about the risks of medications such as Valproate resides with the clinicians managing the medical problem and prescribing the medication, in this case the Mental Health team. The advisor was not provided with correspondence from the Mental Health specialists predating conception to see what advice [Ms A] was given regarding treatment options, the risks of Valproate in pregnancy and the importance of avoiding pregnancy on Valproate. She should only have been prescribed Valproate if all other treatment options had been tried and found to be ineffective or were not tolerated.

In summary I think it is regrettable that [Dr E] stated an opinion that Valproate exposure in pregnancy did not cause childhood cognitive problems. It is apparent that this caused [Ms A] considerable distress when she found the advice was incorrect. However, I think this was only a minor departure from acceptable practice when considering the following:

[Dr E] was not responsible for prescribing the Valproate and was not primarily responsible for advising about doses and the risks of treatment — this was the responsibility of the Mental Health team.

[Ms A] was already reducing her dose of Valproate and was close to discontinuing it by the time she saw [Dr E].

Kind regards

Dr David Bailey”

Appendix B: Independent clinical advice to Commissioner

The following expert advice was obtained from obstetrician and gynaecologist Professor Peter Stone:

"My summary of the case to date is as follows.

[Ms A] was a woman who had been on Sodium valproate. A medical practitioner must have prescribed this for her. It would be an expectation nowadays that a practitioner would counsel any woman in the reproductive age group about the risks and benefits of the medication with respect to pregnancy and if the risks were deemed high, then to specifically mention contraception and/or provide an alternative drug. Thus, *my first question is, who prescribed the drug and what information was given?*

[Ms A] was referred to the hospital to see the specialist, [Dr E]. It is unclear the role of the person who referred her. *Was it the LMC, as it appears that [Dr E] wrote to a [local] Hospital midwife?* However, whoever it was, presumably had been providing maternity care and was seeking a specialist opinion, not a transfer of care. Thus, *my next question is who was taking responsibility for the maternity care up to the point of referral and what had that person advised [Ms A]?*

It is unclear at what gestation the referral to the hospital was made and at what gestation [Ms A] was seen by [Dr E]. *Could this be clarified?*

The next question is, *did the maternity carer have [Ms A] on a high dose of folate (and iodine) as would be standard practice and would be expected to be known by the carer?*

With respect, given that [Ms A] had been on sodium valproate before the pregnancy by all accounts, *what did she seek from [Dr E]? What were realistic options, should no structural abnormality be found on scan?*

[Dr E's] typed letter briefly covers some issues, *but are there more (maybe handwritten) hospital notes that can be provided to ensure that the content of the consultation has been accurately captured?*

Sodium valproate is used not only for forms of epilepsy but it has also been used for some anxiety and mood disorders (such as bipolar disorders). As with all medications, but especially in women of childbearing age and even more so where a further pregnancy is a possibility, a careful risk benefit analysis needs to be done to ensure that either there are no alternative safer medications should pregnancy occur, or that the medication is truly needed. I would expect that all the carers including the person who prescribed the drug as well as [Dr E] would have considered these two related issues. Of course for [Dr E], [Ms A] was already pregnant and was planning to continue the pregnancy, taking the medication unless advised to the contrary. It does not seem to have been an option to end the pregnancy due to the use of the drug in question.

It also needs to be clarified what health knowledge [Ms A] had about her anxiety-mood condition and the treatment for it. Ideally in these situations, pre-pregnancy counselling occurs such that informed decisions can be made about the suitability or otherwise of any medications in pregnancy.

Recently, Medsafe published a revised 'Alert Communication' about the use of sodium valproate in girls and women. This was done on 4 March 2019. (1) https://www.medsafe.govt.nz/safety/Alerts/Epilim.asp (accessed 17/07/2019). I, for one, as a registered medical practitioner, did not receive any notification about the revision and it remains to be determined how Medsafe communicates with health carers generally. The advice given by Medsafe is consistent with previous concerns about the use of Sodium Valproate and in particular its use in pregnancy.

Given that [Dr E] saw [Ms A] on 6 [Month20], unless [Dr E] can confirm to the contrary, I suggest it is unlikely that he was aware of the change to the Medsafe guideline. However, there are other Medsafe guidelines for example from 2014 (2) (https://www.medsafe.govt.nz/profs/PUArticles/December2014SodiumValproate.htm) (accessed 17/07/2019), which clearly state that Sodium valproate is contraindicated in pregnancy unless other treatments are 'ineffective or not tolerated'. As uncontrolled epilepsy is a major risk in pregnancy, it is possible that there could be rare occasions when the drug was used in pregnancy, but it would be very unlikely that it would be needed for its other indications.

It is not clear from [Dr E's] letter (in paragraph 2) when he states '… and the lower dose of Epilim seems to be stabilizing her mood as much as they would want' whether there has been a plan to reduce the dose and how severe [Ms A's] mood problems were. He goes on to state in the 3rd paragraph '… we need a plan if her ups and downs get out of control, or plan to increase the Epilim dose even by 200mg or so, but I think [Ms A] is the best one to judge that in conjunction with […] …'.

I cannot ascertain from these comments above just how severe the mood problems that [Ms A] had in fact were. I cannot tell whether [Dr E] was not concerned about the use of sodium valproate if a neural tube defect had been excluded, or whether [Ms A] had been seriously unwell and that the sodium valproate was the best treatment for her. This needs to be clarified.

[Dr E] however goes onto state that '… Epilim is thought to not cause any cognitive issues so that is really good news for [Ms A]'. Just exactly what is called a cognitive disorder may be debated, but Sodium Valproate is thought to be associated with developmental effects, autism spectrum disorders. This information has been known for a long time now and predates the Medsafe document of 4 March 2019. Thus, though in paragraph two of [Dr E's] letter I could not ascertain the severity or otherwise of [Ms A's] mental illness, I believe it is incorrect of [Dr E] to say that Sodium valproate is 'thought to not cause cognitive issues'. Unless he can produce evidence to the contrary, on the basis of what information that we do have, (in addition to the latest strong Medsafe Safety Information Alert Communication), Sodium Valproate would not be

prescribed in pregnancy and further, it would be ceased if it were being taken and an alternative sought.

A number of references are provided which all suggest that Sodium Valproate is contraindicated (or relatively contraindicated) in pregnancy.

Thus, I am concerned about the pre-pregnancy information and the early pregnancy care that was provided to [Ms A]. I am also concerned about her health literacy given the nature of the drug and what it was being used for. But, finally, I am also concerned about the statements that [Dr E] made about the use of and dosage of Sodium valproate in this case. Either there was a lack of knowledge about the drug or a serious concern about [Ms A's] mental state and a desire not to cause her further anxiety, given that she was already well into the pregnancy. Unless these last issues were of a very serious nature, it would have been general practice to cease the medication. Should the patient have serious mental health issues, then this is the situation where an opinion from a psychiatrist (preferably with maternal mental health experience) would be warranted.

The literature would suggest that some women after counselling still prefer to continue with Valproate (3) and that shared decision making may empower women to make choices about therapy (4). In this situation, given the many beneficial effects of Valproate in some conditions, women may choose to continue using it.

A recent New Zealand study has also shown developmental effects of monotherapies for epilepsy, but Valproate and others such as Lamotrigine had similar effects (5). However, a large USA and UK collaborative study of cognitive function in children whose mothers took monotherapy has shown that Valproate had more effects than other drugs (6). It must be noted that most of the studies have been done in women with epilepsy and epilepsy per se has effects for the child.

There is a relative paucity of data on the use of Valproate for mood disorders. However, what literature there is has tended to validate the concerns about the use of the drug in pregnancy and further, that with few exceptions, there are other and better alternatives to Valproate in pregnancy for mood stabilization (7, 8).

What is apparent is that there are few studies examining the effect of reducing and stopping Valproate on the subsequent outcome for the child. Thus in [Ms A's] case, it would have been difficult to comment on the likelihood of any effects on the baby should she stop the drug.

In summary, in the absence of a clear diagnosis of [Ms A's] mental health issues it is difficult to assess the benefit versus the risks of continuing with Sodium Valproate once the pregnancy was established. A number of clinicians (as well as the patient) have responsibilities in this case. On the face of it, without the extra information that may be able to be provided by the Commissioner's Office, it would appear that, notwithstanding any reasons to continue the Valproate, the actual statement given by [Dr E] that it does not cause — or be associated with — cognitive issues is incorrect.

References:

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4. Turner K, Cutica I, Riva S, Zambrelli E, Canevini MP, Pravettoni G. Level of empowerment and decision-making style of women with epilepsy in childbirth age. Epilepsy and Behavior. 2019;93:32–37
5. Richards N, Reith D, Stitely M, Smith A. Developmental outcomes at age four following maternal antiepileptic drug use. Epilepsy and Behavior. 2019;93:73–79
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7. Womersley K. Prescription of Sodium Valproate as a Mood Stabiliser in Pregnancy. Psychiatr Danub. 2017 Sep;29(Suppl 3):679–684.
8. Haskey C, Galbally M. Mood stabilizers in pregnancy and child developmental outcomes: A systematic review. Austr NZ J Psychiatry. 2017;51:1087–1097."

HDC sought a response to Professor Stone's queries from the DHB. The following further advice was received from Professor Stone:

"Thank you for obtaining a letter with information from [the district health board] in a letter to you dated [2019].

The letter and files in part provide some assistance to my questions.

I will address each question from that letter and then provide a summary comment.

The information provided now goes some way to clarify issues for me, but some elements of the complaint remain somewhat unclear. My previous initial 'draft' report to you still stands but within the context now of this further and final information that has been received.

Question 1: Who prescribed the drug and what information was given:

According to the letter provided, it is very clear that the Psychiatric Services prescribed the Sodium Valproate (Epilim) and that they also provided clear instructions and advice regarding pregnancy. Given that [Ms A] had had at least a 2 year relationship with the Mental Health Services, it would seem that the Service would consider that [Ms A] was well informed about Epilim and possible future pregnancy. It would seem to be a reasonable expectation that [Ms A] could be expected to have and understand the information about the drug in question. (Though although this was implied perhaps in the response from [the DHB] to question one, as you will read later, the first actual documentation I can find would be from [Dr G] in 2019.)

It would also seem reasonable to suggest that between the Mental Health Services and primary care, that is the General Practitioner, these two care givers were taking clinical responsibility for the prescription medicines being prescribed for this patient.

(As a note, since my previous comments via HDC, it would seem that [the DHB] has disseminated up to date information about Epilim and pregnancy. This is to be commended.)

Question 2:

Person who referred [Ms A] to the Obstetric Specialist.

It is clearly stated and documentation shows that this was the GP, [Dr H]. Whilst it is likely that this was because of concerns regarding structural fetal abnormality, it would have been prudent for the GP to have also involved the Mental Health Services at this stage as not only are they the 'experts' in these aspects of the patient's care, but they were prescribing the drug. In the modern world, with discipline based rather than holistic specialist care, it would not usually be expected that an obstetrician would manage a mental health illness in isolation. [Dr H] did not actually state a specific concern about structural defects in particular and I deal with this point later.

Question 3:

Following on from the above, it is clear up until the time of referral to the obstetric service, the GP was taking responsibility for the care of the patient. The midwife, [RM D] became involved before the Obstetric specialist had seen the patient. Had she had concerns it is possible she could have expedited the appointment with the obstetrician. It would not be unreasonable to do that, especially in a smaller centre such as [this].

Question 4:

It would appear that on 7 [Month18], the GP referred [Ms A] for a secondary maternity consultation. [Ms A] was seen by [Dr E] on 6 [Month20] at around 13–14 weeks' gestation. This is a considerable delay between referral and consultation. The consultation was sent as a Gynaecology Urgent with the reasons for referral being 'bipolar disorder, doing well on Epilim. I hesitate to stop this as it is important for her mental health and would be grateful for your evaluation and recommendations …' (what was not in the letter of referral was that [Ms A] had had a previous large baby, delivered in […], the birth being complicated by a postpartum haemorrhage).

It is unfortunate that whoever or however this referral was triaged, the obstetric specialist consultation did not occur until 6 [Month20]. This was presumably because the reason for the consultation was considered to be risk of fetal structural abnormality (or that there were no acute obstetric issues) and indeed [Dr E] stated in his letter (which was sent to the midwife and not the GP referrer) 'the issue is to check for spina bifida …'.

It must be noted that in the interim between sending the referral to the obstetric specialist, [Ms A] had been seen by the psychiatrist, [Dr G] (on 25 [Month18]) so there had been a further opportunity to modify or stop the Epilim. A week after the obstetric consultation, on 15 [Month20], [Ms A] was seen again by [Dr G], psychiatrist and the Epilim was stopped, that is by 14–15 weeks the Epilim ceased. It is also noted that in Month18, the blood level of Epilim (Valproate) was 204pmol/L which is below the therapeutic range of 350–700pmol/L — at least for seizure prevention, but also to avoid toxicity.

Therefore, prior to seeing [Dr E] there were opportunities to stop Epilim, by those who were taking responsibility for its use.

The letter of [Dr E], 6 [Month20], is incorrect in stating that 'epilim is thought to not cause any cognitive issues, so that is really good news for [Ms A]'. In [the DHB] correspondence including comment from [Dr E], there is the impression that [Dr E] was considering the risk benefit and was concerned about [Ms A's] mental health, which whilst being a reasonable and laudable concern should not be taken to completely over ride risks. [Dr E], [Dr G] and [Dr H] could have (jointly) considered all the above issues and decided if there was no other alternative to Epilim, then the risk is acceptable, or that there may be other options, in which case it would not be acceptable to continue in the face of alternative approaches.

Thus whilst incorrect information was given, it could be reasonably argued that the obstetrician was not taking primary responsibility for the mental care of [Ms A] and indeed [Ms A] saw the psychiatrist the week after. The psychiatrist stopped the drug, seemingly without adverse effect on the patient.

Question 5:

Neither [Dr H], nor the midwife prescribed the high dose (folate 5mgm) of folate. In fact it was [Dr G] who did so, but of course by the time this was done, the risk of neural tube defect had passed.

What is stated by [Dr G], very clearly in a letter of 25 [Month18] to [Dr H] is that there had been a discussion with [Ms A] and that 'she is aware of the medication risks and benefits and is in agreement with the above plan' which was to reduce the Valproate and also increase the folate. This was more than a month before she saw [Dr E]. The information that he gave her may have contradicted what she had been told by the other caregivers, but that was an opportunity to at least review the advice.

Question 6:

It remains unclear what she sought from [Dr E]. Certainly, the GP referral did not specifically ask to exclude fetal anomaly. What the GP wrote was a summary of the issues around [Ms A's] mental health and medication and in effect then was leaving it up to the obstetric service to decide what it thought was relevant with regards to the pregnancy. It seems the obstetric service was not provided with obstetric history, nor it

seems asked, because at least the prior postpartum haemorrhage is not mentioned in the letter back to the midwife. Why a copy did not go to the GP, considering it was the GP who did the referral is not known. *(This is a very common issue in New Zealand and it is one reason why the GPs are not involved in components of maternity care and frequently say that after the birth they have little or no knowledge about events during and after the pregnancy. It is an issue that I have raised and continue to raise with the HDC as it needs addressing at a national level.)*

Question 7:

The DHB informs us that no handwritten notes are available hence we cannot anticipate what if any other considerations were discussed with [Ms A] and we can only accept what has been provided by [the DHB]. There is no reason not to accept the documentation provided and the letters from the mental health services in particular are detailed and clear. Also, despite brevity, [Dr E] was very clear in what he saw as the issues and what advice he gave. What is missing is any views he may have had on the context in which he was providing his advice. Context is critical and hence it is a gap that cannot now be filled.

Question 8:

The answers provided to Question 8 are full and helpful. Within the context of this case, it would seem that there was some advice given to [Ms A]. Whether specific advice regarding pregnancy and folate, for example, was given in 2017 is undocumented but the letter from [Dr C] dated 28 [Month4] records past obstetric history but for an unexplained reason, does not use that opportunity to discuss future pregnancy, noting not only prescribed medications but marijuana and alcohol use, both of which would not be recommended in pregnancy.

Question 9:

The answer to my question has, in my view been answered adequately, namely, that the issue of adjusting the dosage of Epilim was between [Ms A] and her psychiatrist.

As per previous comments, this would be standard practice and it would not be expected that an obstetrician would be prescribing psychotropic medications when the local psychiatrist already had a treatment plan in place. As it states that [Ms A] told [Dr E] that she was weaning off the drug and indeed did so soon afterwards, it would be apparent that she had made up her own mind and had in effect (and correctly) rejected [Dr E's] advice. In the light of this, it is not clear why she has made this complaint except to point out the erroneous information that [Dr E] provided. In the event, it is clear that whatever he said or did, did not affect her care and the exposure of the fetus to Valproate. The exposure of the fetus was due to prescribing by [Dr G], [Dr C] and possibly [Dr H]. The duration of exposure during the pregnancy may have been prolonged because of the time between the GP referral and her being seen in the obstetric service. This duration might have been shortened by better, more assiduous and experienced triaging. I have not enquired how the triaging is done in [the DHB]. The Commissioner may wish to do so.

Question 10:

In the absence of any other documentation, I have taken that there was some concern about [Ms A's] mental health from [Dr E]. I had thought that there might have been some handwritten jottings that could possibly have shed additional light on his views of [Ms A's] health. In the absence of any evidence about this, it is not possible to progress this and as the medical record has to be taken as read, I have to conclude that apart from exclusion of a structural problem, [Dr E] was not particularly concerned about the use of Epilim, was not taking responsibility for this but wanted to reassure [Ms A] that if she became more unwell mentally, she could increase the dose. My comments above have addressed the view that this would not be best practice unless the risk benefit clearly supported the use of Valproate as the only suitable drug and in the light of the Medsafe guidelines and other established evidence, this would be very unusual.

Question 12:

[The DHB's] ([Dr E]) reply to my question seems to suggest that notwithstanding [Dr E's] advice, he did acknowledge that risks were present and he seems to have suggested [Ms A] go on line. Whilst that is an option, without giving creditable websites, it might not be helpful just to say go on line as there is much unsolicited information on line.

Question 13:

It is encouraging that [the DHB] has taken action already to disseminate the up to date information about Valproate and this is to be commended.

In summary:

The additional information that I sought has been provided in as much detail as seems possible.

I have concluded that the actual advice that [Dr E] gave to [Ms A] was incorrect regarding non-structural effects of Valproate. The advice was not up to date, nor reflected what I had taken to be general obstetric knowledge and this has been affirmed by the Medsafe data sheets.

[Dr E] did arrange to have the issue of structural anomalies investigated expeditiously. I do not believe that [Dr E's] actions led to increased exposure of the fetus to Valproate because a) the dose reduction-weaning was already underway and b) the dosage at the start of that process was below the therapeutic range, and his advice did not lead to any increase in dose.

This case illustrates the problems of multidisciplinary care and a number of health care professionals providing incomplete (or siloed) information. If not before (it is not possible to determine this with surety) then by [Month18], [Ms A] had been made aware of the risks of Valproate by the psychiatrist and maybe the GP because it was he who initiated the obstetric referral.

I would opine that the responsibility for the prescription of Valproate in this case was not that of [Dr E].

I would also politely suggest that the complainant, [Ms A] has some responsibilities for her health in pregnancy. What I have been unable to determine is to what extent her health literacy about the effects of Valproate (and indeed any other medications and life style) had been discussed by carers prior to her visit to [Dr E], excepting the consultation with [Dr G] in [Month18].

I trust that my two reports will assist the Commissioner. Please contact me should clarification be needed.

Yours sincerely

Professor Peter Stone
Professor Maternal Fetal Medicine
Acting Head of Department
The University of Auckland"

Appendix C: Independent clinical advice to Commissioner

The following expert advice was received from psychiatrist Dr Allen Fraser:

"INTRODUCTION

I have been asked to provide an opinion to the Commissioner on case number C19HDC00773. I have read and agree to follow the Commissioner's Guidelines for Independent Advisors. To the best of my knowledge I have no conflict of interest.

After graduating MB ChB (Otago) in 1969, I trained in psychiatry in Auckland and London from 1972 to 1977. My specialist qualifications are DPM (Otago; 1973), MRCPsych (1976) and FRANZCP (Membership in 1978, Fellowship in 1981). In 1998 I was awarded the Diploma in Professional Ethics. I am a vocationally registered specialist psychiatrist.

Since 1977 I have worked as a consultant psychiatrist in Auckland. My experience has included acute inpatient psychiatry, community mental health work, liaison psychiatry, Clinical Director in Psychiatry, Chief Medical Officer at Waitematā DHB, and solo private practice. From February 2017 until 30 September 2020 I was employed by Auckland District Health Board as (temporary) Medical Director Mental Health. Since Month21 I have worked in Te Whetu Tawera, the ADHB acute adult inpatient unit, initially as my clinical time while Medical Director and latterly as the lead clinician with clinical responsibility for the intensive care ward.

From 2008 until 2017 I was a member of the Medical Council of New Zealand. I have held office within the Royal Australian and New Zealand College of Psychiatrists.

The instructions I received from the Commissioner were:

While [Ms A] has complained about advice she received from a [DHB] obstetrician about Epilim and pregnancy, the Deputy Commissioner is considering whether the initial prescribing of Epilim and counselling on its use, by [DHB] psychiatric clinicians, was reasonable in the circumstances.

Please review the enclosed documentation and advise whether you consider the care provided to [Ms A] was reasonable in the circumstances and why.

In particular, please comment on the following:

1 Given [Ms A's] age and psychiatric diagnostic formulation, was it clinically appropriate to trial treatment with Epilim (in preference to any other treatment) from Month4 and to continue to prescribe it at increasing doses subsequently?

2 Are you able to comment on the adequacy of the information provided to [Ms A] regarding risks and benefits of Epilim and need to avoid pregnancy based on:

The [DHB's] responses; and

The content of the relevant clinical documentation

Please consider this question in relation to each psychiatrist involved in [Ms A's] care.

3 Do you have any comments on the actions taken by [the DHB] following this complaint in relation to use of Epilim for psychiatric diagnoses in women of child-bearing age?

4 Are there any additional matters in this case you consider warrant comment?

The documentation provided to me (electronically) was:

1 Complaint from [Ms A]
2 Response from [the DHB] dated [2019], enclosing [Ms A's] clinical records
3 Response from [the DHB] dated [2019] and supporting documentation.
4 Response from [the DHB] dated [2019], and Mental Health & Addictions Service records.

BACKGROUND

On 15 [Month1] [Ms A] was referred to [the DHB] Community Mental Health Services by her General Practitioner, [Dr H]. [Dr H] identified low mood, anxiety and stress as the issues leading to referral. He also noted anger, and difficulty coping with her child. He noted that a trial of SSRI antidepressant had not been tolerated. It appears that quetiapine was commenced during the three months before she was seen.

She was seen on 28 [Month4] by [Dr C], Medical Officer working in psychiatry. The record of that assessment, which is confined to [Dr C's] letter to [Dr H], noted that anger symptoms were the most prominent complaint. The record of the Mental Status Examination reported that [Ms A] talked mainly about '*emotional dysregulation'* as well as anger and anxiety.

[Dr C] entered '*Fits Borderline vs BPAD Spectrum'* as the diagnosis. She prescribed sodium valproate 200 mg in the morning and 500 mg at night '*to see how she takes to this'*. She also advised a stepwise reduction of the morning dose of quetiapine.

[Ms A] was reviewed by [Dr C] two weeks later, when she reported being improved, and [Dr C] commented that she was '*definitely emotionally regulated'* on the valproate. She noted that [Ms A] was '*questioning whether it could be wearing off a bit*'. In a section headed Medications, [Dr C] recorded that she had discussed possible cognitive impairment from long term use of benzodiazepines.

[Dr C] formed the impression that [Ms A] was '*stable at the moment and treatment is working adequately for her*', and increased the dose of valproate to 900 mg at night. She advised follow up by a psychiatrist in three months.

The next psychiatric assessment by [Dr F] on 13 [Month8] found that [Ms A] was stable, and that the valproate level was 321 µmol/l. The dose was increased to 1,000 mg each night. At the next appointment on 15 [Month11] [Ms A] was again assessed as being '*currently stable*', although there were some indications that she may have been experiencing a downward swing of mood. The valproate level was noted to be 338 µmol/l, and the dose was increased to 1,200 mg at night. A further appointment was arranged for three months. Thereafter, [Ms A] remained stable with a valproate level just above the bottom of the therapeutic range; the dose of valproate was continued at 1,200 mg per day.

On 31 [Month17] [Ms A] was referred urgently for a psychiatrist review by [Dr I] after she had presented in the early stage of pregnancy. [Dr I] noted that she had done a home pregnancy test that day and it was positive, and she was concerned because she was taking valproate 1,200 mg each night. The question was raised of tapering the dose of valproate, and replacing it with other medication. [Dr I] was concerned that the '*issue would need to be addressed sooner'* than it could be by her regular General Practitioner, who was away until 07 [Month18].

On 07 [Month18] [Ms A] contacted her keyworker at [the] Community Mental Health Team wanting consultant advice about stopping valproate as she was '*aware she will need to cease [valproate]'*. The keyworker advised that she should take [Dr H's] advice. [Dr H] reduced the dose of valproate to 1,000 mg.

On 08 [Month18] [Dr F] advised [Dr H] to request an urgent ultrasound scan, and to prescribe folic acid. The keyworker also advised [Dr H] that [Dr G] was to replace [Dr F] after the end of that week, and encouraged contact if there were any urgent matters.

The keyworker made telephone contact with [Ms A] on 14 [Month18], and noted that the dose of valproate had not been further decreased nor had an ultrasound scan been done. The situation was discussed at the next day's Multidisciplinary team meeting, and it was decided that the dose of valproate should remain the same until [Ms A] was seen by [Dr G].

[Dr G's] first meeting with [Ms A] was on 25 [Month18]. Apart from reportedly long standing occasional episodes of irritability and anger there was no abnormality noted by [Dr G]. It was recorded that [Ms A] asked '*pertinent questions regarding the risk vs benefit of taking valproate while pregnant'*. It was also noted that the serum valproate level on 07 [Month18] (before the reduction in dosage) was 204 µmol/l. [Dr G] reduced the dose of valproate to 700 mg per day for two weeks, with a further reduction then to 500 mg each night also for two weeks. She also increased the dose of folic acid to 5 mg daily. She noted that [Ms A] was in agreement with the plan.

The next appointment was on 15 [Month20] (seven weeks later). [Dr G] recorded that [Ms A] had ceased taking valproate earlier that week. She also recorded that [Ms A] was angry with some of her clinicians over information sharing about the health risks of

sodium valproate. [Ms A] was also anxious about not having post natal depression as she had after her first child was born.

She was next seen by [Dr G] on 14 [Month23], and was doing well, with no indication of mood or other problems since stopping valproate. Her next (and last) appointment, as she was then discharged to GP care, was [several weeks later], two weeks after her second child was born. The assessment that day was that she was remaining mentally well, and not needing medication.

OPINION

1 Given [Ms A's] age and psychiatric diagnostic formulation, was it clinically appropriate to trial treatment with Epilim (in preference to any other treatment) from Month4 and to continue to prescribe it at increasing doses subsequently?

[Dr C] entertained two diagnoses (bipolar disorder and borderline personality disorder) without apparently favouring one or the other. For neither possible diagnosis was there any formulation which would allow anyone else to question the appropriateness or not of what was essentially a differential diagnosis between two disorders which not uncommonly need to be distinguished from each other.

From the letter to [Dr H], a diagnosis of bipolar disorder could be supported by the referral being on the basis of '*low mood*', and [Ms A] saying that she had been depressed for a few days some weeks before, and that at other times she is '*quite elevated*'. Further support comes from observations made during the interview of: (i) physical restlessness (ii) cheerful mood (iii) very reactive affect; (iv) continuous speech which was rapid. Borderline Personality Disorder may have been based on what [Dr C] termed '*emotional dysregulation*'.

[Dr C] may have prescribed sodium valproate as a sort of diagnostic test, as she wrote that the prescription was '*to see how she takes to [the valproate]*'. Rather than depend upon the response to a medication to determine diagnosis, further assessment would have been more appropriate. If [Dr C] was of the stronger opinion that the diagnosis was borderline personality disorder, no medication should have been prescribed without a period of trying non pharmacological treatments.

On the other hand, had she been of the opinion that [Ms A's] problems were best encompassed by a diagnosis of bipolar disorder, it would have been appropriate to prescribe a mood stabiliser, given that she had been distressed by her mental state for some months at least.

[Ms A] is a young woman who was in an intimate relationship, and therefore potentially at risk of becoming pregnant. In 2014 Medsafe New Zealand had published a Prescriber Update on sodium valproate and pregnancy in which the second key message was '*Sodium valproate should not be used in women of child bearing potential unless other treatments are ineffective or not tolerated*'. That advice from Medsafe was well supported by the literature, and it was widely known before 2017 that valproate has a high potential for teratogenicity. There is nothing in writing to indicate that [Dr C]

discussed the risks and benefits of valproate with [Ms A], and that she was aware of all the risks as well as benefits of the medication.

Prescribing a mood stabiliser may have been appropriate, but prescribing sodium valproate was inappropriate in view of her age, gender, and the uncertainty about diagnosis.

[Dr C] did review the effect of valproate two weeks after prescribing it, which is good practice. She noted that [Ms A] reported benefit, but perhaps less so in the days before the second appointment. [Dr C] increased the dose without (it seems) checking the serum level, and with still no indication of discussing the risks of the medication. She also recommended that the next appointment be in three months.

Even though there is not a close relationship between serum valproate levels and response, not measuring them would not be appropriate practice. Nor is deferring checking response for three months after a change of dose.

[Dr F] was the psychiatrist who replaced [Dr C]; she inherited a patient who was feeling better on valproate. Although there is nothing in the clinical notes and letters to support [the DHB's] statement in their response, what was reportedly done would have been expected practice. It is likely to have been done, if this was a familiar clinical situation for [Dr F]. However, the diagnostic confusion appears to have not been questioned, although the fact that valproate was continued may indicate that [Dr F] was not confused, and that she was treating [Ms A] for bipolar disorder.

Assuming that to be the case, and given that [Ms A] was continuing to report being better on valproate, it is appropriate that the valproate was continued. Also assuming that [Dr F] had appropriately advised [Ms A].

Because she recorded on each occasion that she saw [Ms A] that her mood was stable (apart from one time when she was understandably upset), it may have been more appropriate to not increase the dose of valproate seemingly for the purpose of getting a level within the 'therapeutic range', especially given the poor correlation between serum levels and response.

Although knowledge of [Ms A's] pregnancy occurred during [a] period when staff are often on leave, it does seem that [Dr F] deferred making important decisions about stopping valproate to her replacement and the General Practitioner. The serum level was already below the therapeutic range, and as there is evidence supporting a dose relationship between serum levels of valproate and the teratogenic effect, caution about avoiding a major mood episode was not inappropriate.

[Dr G's] involvement with [Ms A's] care was during the tapering and cessation of valproate, and her care of [Ms A] was appropriate during that time. However, I do question the decision to discharge someone only two weeks post delivery, who may have bipolar disorder, and did have a post natal depression after the birth of her first child, a repetition of which she was keen to avoid.

2 Are you able to comment on the adequacy of the information provided to [Ms A] regarding risks and benefits of Epilim and need to avoid pregnancy based on:

a) The [DHB's] responses; and

b) The content of the relevant clinical documentation

Please consider this question in relation to each psychiatrist involved in [Ms A's] care.

(i) [Dr C's] record of her consultations would appear to be the two letters to [Dr H]. In neither letter was there any mention of a discussion with [Ms A] of benefits or potential harm from the valproate. Specifically, there is no record of [Dr C] giving advice to ensure she did not become pregnant.

The [DHB's] response stated that '*[They were] unable to find documentation regarding information given to [Ms A] however it is standard practice to discuss contraception, risks and benefits with regard to pregnancy.'* In a further letter [the DHB] included a response from [the Clinical Director Mental Health & Addictions]. He stated that [Dr C] '*usually worked in Perinatal Psychiatry and her usual practice was to inform patients of risks and discuss those risks and benefits of Epilim'*.

There is no evidence that [Dr C] either did or did not discuss these matters with [Ms A]. In neither letter from [the DHB] did they do more than say that such discussions were '*usual'* or '*standard'* practice. It is not possible to make any assessment of the adequacy of information given to [Ms A] by [Dr C].

(ii) [Dr F] inherited a patient who was already taking sodium valproate, and who was reporting that it was helpful. None of her letters to [Dr H] mentioned a discussion with [Ms A] of the risks associated with valproate; these letters are the only record I could find of her assessment and treatment. The keyworker was recorded as present at each of the assessments, and made no notes herself.

[The DHB] state[s] that [Dr F] '*in the presence of her keyworker, discussed these issues and asked her to be [using contraception]'*. This was said to have occurred '*during her three monthly appointments'*, rather than at one particular appointment. [The DHB's] letter also records that [Dr F] '*has a special interest in perinatal psychiatry'*.

[The Clinical Director Mental Health & Addictions] gave more detailed information about the extent of the discussion which [Dr F] had with [Ms A] (in the presence of the keyworker). It is unfortunate that neither [Dr F] nor the keyworker made any record of these discussions.

The absence of any record of discussions between [Ms A] and [Dr F] regarding the risks and benefits of valproate, mean that I cannot assess the adequacy of any such discussions. [The DHB] provide[s] more information about what was discussed, especially in the response dated […]. Although mention of possible adverse effects on cognitive function was not mentioned by [the Clinical Director Mental Health &

Addictions], this was a reasonable discussion, and would be viewed as adequate by colleagues.

(iii) [Dr G] took over the care of [Ms A] after she was known to be pregnant, and indeed after the tapering of the dose had been started by the General Practitioner. In her first letter dated 25 [Month18] (again the only record of the assessment), [Dr G] states clearly that she had discussed concerns about valproate and pregnancy with [Ms A]. She further stated that [Ms A] was well aware of the risks, although this was in connection with tapering the dose and possibly continuing a low dose throughout the pregnancy. The Clinical Director Mental Health & Addictions's] response (in [the DHB's] letter of […]) emphasises that '*a risk/benefit analysis discussion'* had occurred.

The evidence is clear that [Dr G] gave adequate information and sound advice to [Ms A].

3 Do you have any comments on the actions taken by [the DHB] following this complaint in relation to use of Epilim for psychiatric diagnoses in women of child-bearing age?

The actions taken by [the DHB] were appropriate to the issue of sodium valproate use during pregnancy, especially for epilepsy.

However, on the basis of evidence that there are different risks in women taking valproate for bipolar disorder, the risk of hormonal disruption and the high prevalence of Polycystic Ovarian Syndrome in women should have been mentioned. In 2003 McIntyre et al reported significantly increased risk of menstrual abnormalities, hyperandrogenism, and metabolic abnormalities. These adverse effects on women of child-bearing age should also have formed part of the advice to psychiatrists.

4 Are there any additional matters in this case you consider warrant comment?

There has not been any clear statement of the diagnosis for which [Ms A] was being treated. The accepted standard of practice is that a psychiatrist will make a diagnosis usually using the DSM criteria. It would also be normal practice to justify that diagnosis in the notes by way of history and mental status examination. Standard practice would then result in appropriate treatment for the working diagnosis.

Although many psychiatrists would regard the original diagnosis ('*Fits Borderline vs BPAD spectrum'*) with at least mild disapproval, some who have perhaps been influenced by the trans-diagnostic approach to psychiatry (most exemplified by Early Psychosis Intervention services) would find it acceptable. This has led to a practice of treating symptoms rather than disorders.

The practice of using a letter to the referring General Practitioner as the record of a psychiatrist's assessment and treatment plan, resulted in relatively sparse notes

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PSYCHIATRIST

References:

Use of sodium valproate in pregnancy. Prescriber Update (2014);35:46–48

MacIntyre RS et al, Valproate, bipolar disorder and polycystic ovarian syndrome. Bipolar Disord (2003);5:28–35."

The following further advice was received from Dr Fraser:

"INTRODUCTION

This supplementary advice to the Commissioner should be read in conjunction with my initial advice dated 11 October 2020.

On 15 October 2020 I was provided with a further response by [the DHB], and responses by the psychiatrists who had assessed and treated [Ms A]. I was asked to review the information therein and if appropriate, to update my opinion.

Rather than rewrite the original opinion, which was based upon the information available to me at that time, I have chosen to comment on [the DHB's] response and the individual doctors' responses.

RESPONSE BY [THE DHB]

1 [The DHB] has provided information about the collaboration between services, which is reassuring.

2 [The DHB] reasonably emphasises that cessation of medication is not always appropriate, and reduction of dose can be the best response to a situation.

3 [The DHB] acknowledges the need to document such matters as the information and advice given to patients.

4 The delay in response to the referral from [Dr I] was an unfortunate coincidence of a written referral through non urgent pathways, and closure of services over the holiday season.

5 [The DHB] has provided comprehensive information about the approach being taken currently with respect to the use of sodium valproate.

6 [The DHB's] position at the time of the events (dissemination of the advice of Medsafe) was likely standard practice. It is commendable that they are in the process of developing a guideline, as there are many reasons for NOT using sodium valproate in young women in particular.

RESPONSE BY [Dr C],

1 In her response [Dr C] states clearly her usual approach, and also asserts that she followed her usual practice in this case. It is unfortunate that she did not document that at the time, as would be expected practice.

2 The fact that [Ms A's] complaint was not about the Mental Health services she received, does suggest that she was given appropriate information and thence advice.

3 [Dr C] repeats her use of a differential diagnosis as a diagnosis. This is particularly concerning, in that while she apparently felt unable to differentiate between bipolar disorder and borderline personality disorder, she *'followed the January 2009 NICE guideline'* for borderline personality disorder, and prescribed a medication usually used in bipolar disorder.

4 In 2017 there was sufficient evidence readily available to discourage the use of valproate in young women, and it does not appear from her response that [Dr C] gave [Ms A] information on alternatives to valproate, assuming that she was treating bipolar disorder.

RESPONSE BY [DR G]

1 [Dr G's] documentation, and careful management of the withdrawal from valproate showed appropriate practice.

RESPONSE BY [DR F]

1 [Dr F] reports the nature of the information and discussions she had with [Ms A]. It is unfortunate that this was not documented at the time, as would be expected practice.

2 What she states that she discussed with [Ms A] is reasonable, especially given that the valproate had been started and was seen as of benefit by [Ms A].

FINAL COMMENT

The apparent practice in [the DHB] of there being no clinical notes made by psychiatrists, and the only record of their assessments, opinions and interventions being letters to the General Practitioner, is a practice which has in this case resulted in concerns that could have been prevented by good note keeping.

Allen Fraser
MB ChB, DPM, MRCPsych, FRANZCP, Dip Prof Ethics
PSYCHIATRIST"

Dr Fraser was asked to consider Dr C's response regarding her diagnosis. He made the following comments:

"[The Clinical Director Mental Health & Addictions] has provided references which support the argument that it can be difficult to distinguish between bipolar disorder and borderline personality disorder.

[Dr C] essentially recorded a differential diagnosis of either borderline personality disorder, or bipolar disorder. Her treatment choice was to give a mood stabiliser using NICE guidelines for the treatment of Borderline Personality Disorder.

While there is a lack of clear thinking in this, I accept the thrust of the argument from [the Clinical Director Mental Health & Addictions] that this is common practice, and would not be regarded by colleagues with disapproval.

Nga mihi

Allen Fraser
Psychiatrist"

Appendix D: In-house midwifery advice to Commissioner

The following in-house clinical advice was received from RM Isabelle Eadie:

> "Thank you for the request that I provide clinical advice in relation to the complaint from [Ms A] which was primarily focused upon the care and advice provided to her by Obstetrician [Dr E]. In preparing the advice on this case to the best of my knowledge I have no personal or professional conflict of interest. I agree to follow the Commissioner's Guidelines for Independent Advisors. The complaint made by [Ms A] is focused upon the care by [Dr E], however I have been asked to review the standard of midwifery care provided by [RM D] for completeness …
>
> 3) Did [RM D] comply with relevant midwifery ethical standards in altering her clinical records after receiving notice of the complaint from HDC?
>
> The New Zealand Midwifery Council published a document in 2018 entitled 'Be Safe — Documentation and Record Keeping' in which it is clearly stated 'Never amend or falsify records'. Correct practice would be to add a 'retrospective' note, such as [RM D] did in the entry dated 24th October 2020, alluding to additional information discussed (but not documented at the time) during specified visits rather than amending the original notes.
>
> [RM D] blatantly amended the antenatal notes following a meeting with [Ms A] whereby it was discussed what to add into the original antenatal record. It appears that [RM D] sought to embellish the original notes with a more in-depth description of what was discussed between herself and [Ms A] during their first few antenatal visits. In her response dated 15th December 2020, [RM D] defends her actions, claiming that her computer programme clearly shows the date when new entries were made to the record, but the printed format does not show this. However, [RM D] would have been very aware of this when she forwarded the printed notes to the NZCOM lawyer, yet her accompanying letter dated 29th October 2020 failed to draw attention to the fact that she had amended the original notes. Furthermore, in this letter she refers to these amended notes as 'contemporaneous'.
>
> Of concern here is that not only did [RM D] alter the antenatal record *per se*, she also added information which was not factually true. For example, the original notes dated 15th [Month18] record that [Ms A] was taking folic acid and iodine, but the dosages were not recorded. In the amended record, it is written that at this visit, [Ms A] was taking folic acid 5mg (the usual dose is 0.8mg/ daily, but women at increased risk of neural tube defects, such as [Ms A] are prescribed this higher dose), yet [Ms A] was not prescribed the higher dose until she saw her psychiatrist some ten days later on the 25th [Month18]. Therefore, [RM D] added to the clinical notes information which was not true at the time. Perhaps [RM D] amended the dosage of folic acid in fear that she might be adversely judged for not changing this prescription herself? The irony is that it is not expected that all midwives would know to ensure women taking sodium valproate should be taking 5mg folic acid, rather than the normal 0.8mg.

Similarly, in the amended record it is documented that [RM D] advised [Ms A] about the code of rights and making complaints, yet in the text messages, [Ms A] denies this was ever discussed.

Ultimately, [RM D's] actions involved amending the clinical notes, falsifying the information and failing to acknowledge this and consequently this reflects a severe departure from expected practice.

4) In the event that [RM D] asked [Ms A] to destroy the contemporaneous notes, to what extent would this be a departure from accepted midwifery standards?

The implication from the text messages is that [RM D] asked [Ms A] to throw away *her* copy of the original antenatal record, presumably [Ms A] had been given a copy of her antenatal notes as this is quite common practice. Although, as noted by [RM D], the electronic record would remain, this would be the amended version. In the event that [RM D] did make this request, this represents a moderate to severe departure from expected practice. Maternity records need to be kept for a minimum of ten years following the last dated entry (Midwifery Council 2018), although it is not written, the presumption is that this refers to the *original* records.

5) Any additional matters that you consider warrant comment.

None.

Summary

[Ms A's] complaint was not focused upon the care provided to her by [RM D], and [Ms A's] willingness to meet with [RM D] in October 2020, and the nature of their text messages suggests they had a positive midwife–client relationship that suggests [Ms A] found an ally in [RM D] with regards to a health professional who shared her concerns about taking sodium valproate.

Based upon the *original* antenatal notes, I do not find that the care provided by [RM D] failed to meet expected standards of midwifery care towards a woman with a medicated mental health condition, albeit arguably [RM D] could have requested a more urgent obstetric review. The greater concern is the way in which [RM D] has amended and falsified the antenatal record in light of the HDC investigation.

Recommendations

I note that the NZCOM lawyer has already recommended [RM D] undertake a documentation course and I strongly reinforce this. NZCOM facilitate such a course and dates throughout the year are advertised on their website.

I hope that my report addresses concerns pertaining to [RM D's] midwifery practice and conduct.

Isabelle Eadie BHSc Midwifery
Midwifery Advisor
Health and Disability Commissioner

References

Midwifery Council of New Zealand (2018). Be Safe — Documentation and Record Keeping. https://www.midwiferycouncil.health.nz/common/Uploaded%20files/Be%20series/Be%20Safe%204%20Documentation%20and%20record%20keeping%20F.pdf accessed 1/3/21

Ministry of Health (2012). Guidelines for Consultation with Obstetric and Related Medical Services (Referral Guidelines). Wellington: Ministry of Health. https://www.health.govt.nz/system/files/documents/publications/referral-glines-jan12.pdf accessed 24/9/20"

Appendix E: In-house clinical advice to Commissioner

The following in-house clinical advice was received from GP Dr David Maplesden:

> "1. The events in question occurred about the same time there was an ACC[1] and Medsafe[2] push to raise awareness amongst prescribers of the risks of Epilim (sodium valproate) in pregnancy. The ACC leaflet for professionals was first published in 2017 but I am unable to confirm what changes were made in the 2019 revision. However, in 2015 Medsafe had published warnings regarding the risks of Epilim in pregnancy[3] which included the following information and recommendations for health professionals:
>
> *Ensure that all other treatments have been tried and failed before using Epilim (sodium valproate) in female children or women of childbearing age.*
>
> *Discuss the risks to the fetus of exposure to Epilim in pregnancy before use with all female patients and regularly during use with women of childbearing age.*
>
> *Discuss the need to use effective contraception with women of childbearing age taking Epilim.*
>
> *Ensure that your patient and her caregivers (if appropriate) have understood the potential consequences of pregnancy whilst taking Epilim.*
>
> *Advise women considering trying for a baby that they should discuss this with you.*
>
> *Consider referring women thinking of becoming pregnant for specialist pre-conception advice.*
>
> *Advise women trying for a baby to take recommended supplements such as folic acid prior to becoming pregnant.*
>
> *Advise women that if they think they might be pregnant they should contact you immediately.*
>
> *Ensure that any pregnant women taking sodium valproate receive appropriate pregnancy monitoring and tests to detect neural tube defects and other malformations.*
>
> 2. In 2018 the GP orientated publisher BPAC produced an article on balancing benefits and risks of prescribing antiepileptic medication to women[4] which included similar recommendations including the need to ensure women of childbearing potential being commenced on Epilim are provided with appropriate contraception, and specific advice regarding folic acid supplementation as: *Folic acid supplementation is recommended*

[1] https://www.acc.co.nz/assets/provider/f7db32f429/antiepileptic-medicine-females-healthcare-providers.pdf Accessed 19 May 2020
[2] https://www.medsafe.govt.nz/safety/Alerts/Epilim.asp Accessed 19 May 2020
[3] https://www.medsafe.govt.nz/safety/ews/2015/sodiumvalproate.asp Accessed 19 May 2020
[4] https://bpac.org.nz/2018/antiepileptic.aspx Accessed 19 May 2020

from a minimum of four weeks before to at least 12 weeks after conception to reduce the risk of neural tube defects. A higher than usual dose of folic acid (5 mg per day) [usual prescribed dose is 0.8mg daily] *is recommended for females taking antiepileptic medicines. Folic acid supplementation reduces the background risk of spontaneous neural tube defects, however, it does not reduce the teratogenic effects of antiepileptic medicines.*

3. As far as I can gather from the available information, [Ms A] was referred to Adult Community Mental Health Services (AMHS) by her GP [Dr H] on 15 Month1. Reason for referral was recorded as *low mood, anxiety, stress of being a […] mother.* On 28 [Month4] she was seen by [Dr C]. Diagnosis was recorded as *Fits Borderline vs BPAD spectrum.* [Ms A] was commenced on Epilim 200mg mane, 500mg nocte with concurrent weaning of quetiapine which she had been taking as 150mg nocte. It is not possible to determine from the clinic letter to what degree there was discussion of risks and benefits of the medication in women of reproductive age. There is no reference to [Ms A's] current contraceptive use although the assessment appears quite comprehensive otherwise. On 12 Month5 [Dr C] reviewed [Ms A] noting a good response to Epilim with dose increased to 900mg nocte. Again, there is no reference to discussion regarding contraception or pregnancy planning. On 13 [Month8] and 15 [Month11] psychiatrist [Dr F] reviewed [Ms A] and increased her Epilim dose to 1000mg then 1200mg nocte. There is no reference in the clinic letters to discussion regarding pregnancy of contraception. At further reviews on 14 [Month14] and 14 [Month16] [Ms A's] Epilim dose was maintained at 1200mg nocte and there is no reference to discussion regarding contraception or partner status.

The DHB response dated [2019] states [Dr F] discussed at each appointment with [Ms A] the risks of Epilim use in pregnancy, the need for reliable contraception and the need to discuss with mental health services if she was contemplating pregnancy at any stage.

4. On 31 Month17 [Ms A] attended [Dr I] at [the urgent care clinic] having had a positive pregnancy test at home. Her LMP was unsure but felt to be around early [Month16] placing her around 7/40 gestation based on those dates (later scans gave an EDD of 9 [Month26] meaning gestational age at this time was closer to 4/40. [Dr I] requested an urgent review by Perinatal Specialist Nurse in relation to [Ms A's] Epilim prescription (via e-referral) requesting: *to follow-up re tapering of Epilim and if new meds should be started in place. Pts GP closed until 07 [Month18] and issue would need to be addressed sooner.* [Ms A] was advised to continue with her current Epilim dose until contacted by the nurse. It does not appear folic acid was prescribed.

5. The e-referral appears to have been actioned on 8 [Month18] (unclear why the delay) with communication between the referral assessor and [Ms A's] case worker and psychiatrist. However, [Ms A] had already contacted her case worker by phone on 7 [Month18] prior to a scheduled appointment with [Dr H] and an e-mail was sent to both [Dr I] and [Dr H] at 1616hrs on 8 [Month18] noting [Dr H] had already started reducing the Epilim dose the previous day which was appropriate, and advising him to organise

an urgent pregnancy scan (which he had already done) and to commence [Ms A] on folic acid (dose not advised).

6. [Dr H] saw [Ms A] on 7 [Month18] and GP notes have been provided from that date. Notes include: *current pregnancy, bipolar disorder, we discussed the pros and cons of taking Epilim while pregnant, she is already mostly through her first trimester now and I hesitate to stop this medication as we have to balance mom's mental health with the risks of her medication. I will refer her urgently to the hospital to get some input going forward. Will get antenatal bloods, start folate, iodine and organise her dating scan.* [Ms A] was prescribed folic acid 0.8mg daily and iodine 150mcg daily and reduction made in Epilim dose to 1000mg nocte. An urgent referral was sent to [the DHB] obstetric service for review of [Ms A] and advice regarding management. I have assumed [Ms A] informed [Dr H] she had been in touch with her case manager and information from the AHMS would be forthcoming.

7. [Ms A] was reviewed by psychiatrist [Dr G] on 25 [Month18] at which stage it was noted she was taking Epilim 1000mg nocte and folic acid 0.8mg daily. Further weaning of the valproate was advised *to find the lowest effective dose as she is midway through her first trimester, and the risk for congenital abnormality with valproate is dose dependent. I will add high dose folic acid per RANZCOG recommendations.* The dose of folic acid was increased to 5mg daily. [Ms A] was seen regularly for follow-up and eventually weaned off her Epilim completely during the pregnancy. I am not commenting on the obstetric aspect of the complaint.

8. [Ms A's] Epilim was initiated by the AMHS. The degree of information provided to her regarding the risks and benefits of the medication and need to avoid pregnancy is not apparent in the AMHS reports to the GP, although [the DHB] maintains such advice was provided. The prescriber of Epilim has primary responsibility for ensuring the prescription is appropriate and that the consumer has been adequately informed of risks, benefits etc[5]. I recommend [expert advice] is obtained from a psychiatrist regarding the following:

(i) Given [Ms A's] age and psychiatric diagnostic formulation, was it clinically appropriate to trial treatment with Epilim (in preference to any other treatment) from Month4 and to continue to prescribe it at increasing doses subsequently?

(ii) Are you able to comment on the adequacy of the information provided to [Ms A] regarding risks and benefits of Epilim and need to avoid pregnancy based on:

The complainant's recollection

The DHB response

The content of the relevant clinical documentation

[5] https://www.mcnz.org.nz/assets/standards/ceae513c85/Statement-on-good-prescribing practice.pdf Accessed 19 May 2020

(iii) Do you have any comment on the actions taken by [the DHB] following this complaint in relation to use of Epilim for psychiatric diagnoses in women of child-bearing age.

9. [Dr I] did not prescribe [Ms A] folic acid supplementation on 31 [Month17] although it is unclear what his expectation was in terms of response to the urgent referral he had provided to mental health services. It is also unclear why there was an apparent one week delay before the referral was reviewed (DHB issue). Best practice would have been to prescribe [Ms A] folic acid 5mg as soon as possible following diagnosis of her pregnancy, but ideally prior to her falling pregnant if it was known she was contemplating a pregnancy.

10. I believe [Dr H's] management of [Ms A] on 7 [Month18] was reasonable although as noted above, best practice would have been to prescribe 5mg folic acid rather than 0.8mg. I am not able to ascertain if [Ms A] was prescribed contraception by [Dr H] while she was taking Epilim. I recommend further information is obtained from [Dr H] as:

(i) A copy of GP notes from [2017] to [Month18]

(ii) Comment on the following issues:

At any time while [Ms A] was taking Epilim did she discuss that her psychiatrists had recommended she be on contraception?

At any time while [Ms A] was taking Epilim did you receive any verbal or written recommendation from her psychiatrists that she should avoid pregnancy?

Did you consider proactively discussing with [Ms A] the need to avoid pregnancy and to discuss any planned pregnancy, while taking Epilim?

What process do you have in place for ensuring your female patients of child-bearing age who are prescribed Epilim, whether initiated by yourself or another provider, are aware of the risks of the drug during pregnancy and the advice to avoid pregnancy or discuss with a clinician prior to planned pregnancy?"

The following further advice was received from Dr Maplesden:

"The following advice should be read in conjunction with my original advice dated 19 May 2020. I have reviewed further information obtained in a response from [Dr H] dated 21 September 2020 and I have reviewed additional GP notes from [2017] to [Month18]. [Dr H's] responses to specific questions outlined in my original advice are summarised below.

1. *At any time while [Ms A] was taking Epilim did she discuss that her psychiatrists had recommended she be on contraception? At any time while [Ms A] was taking Epilim did you receive any verbal or written recommendation from her psychiatrists that she should avoid pregnancy?*

[Dr H] does not recall any discussion with [Ms A] regarding advice received from her psychiatrist about contraception and he did not receive any direct advice from the psychiatric service regarding [Ms A] requiring contraception. He believes this might be because [Ms A] was regularly using a combined oral contraceptive (Ava) since 2013. On review of GP notes, a six-month supply of Ava was prescribed on 15 [Month1] and again on 2 [Month7]. A further supply would have been due in [Month13] but there is no reference to [Ms A] requesting a prescription around that time. [Dr H] had prescribed [Ms A's] usual Epilim on 3 [Month12] but did not see [Ms A] again until 7 [Month18]. On 18 [Month17] [Ms A] had been seen by provider […] for [an] injury. Assuming [Ms A] had been informed of the importance of contraception by the clinician initiating her Epilim, I think it was a reasonable expectation she would request further supplies of Ava when needed. It would not be common or expected practice to 'track' the patient's request for contraception to ensure continuity as the patient is expected to make appropriately informed but autonomous decisions regarding use of prescribed medications. The main issue here I believe is whether or not [Ms A] had been appropriately and adequately informed of the risks associated with Epilim use in early pregnancy, the need for contraception and the need to plan any pregnancy in conjunction with her clinicians to enable such autonomous decisions. As stated previously, I believe the primary responsibility for such discussion lay with the clinician initiating the prescribing.

2. *Did you consider proactively discussing with [Ms A] the need to avoid pregnancy and to discuss any planned pregnancy, while taking Epilim?*

[Dr H] states that had he initiated the medication, he would certainly have had such a discussion. However, [Ms A] had been taking Ava regularly for several years and continued to request prescriptions for Ava while on Epilim (see above). [Dr H] assumed [Ms A] had been given adequate information regarding the need for contraception from the psychiatric service. I believe this was a reasonable assumption, reinforced by the fact [Ms A] continued to request, and was provided with, repeats of her oral contraceptive during the first year of her treatment with Epilim. In the absence of formal tracking of due or overdue prescription requests (which is not common or expected practice), until [Ms A] attended [Dr H] on 7 [Month18] having had a positive pregnancy test, there was no way for him to know [Ms A] had apparently stopped taking her oral contraceptive and was planning a pregnancy.

3. *What process do you have in place for ensuring your female patients of child-bearing age who are prescribed Epilim, whether initiated by yourself or another provider, are aware of the risks of the drug during pregnancy and the advice to avoid pregnancy or discuss with a clinician prior to planned pregnancy?*

[Dr H] states he is very aware of the risks of many medications in early pregnancy and is generally proactive about this issue for women of childbearing age, particularly in ensuring there is adequate discussion prior to initiating any treatment. [Dr H] states he was unaware of the recommendation of a higher dose of folic acid for women on Epilim but he now incorporates this into his practice.

4. As stated in my original advice, I believe [Dr H's] management of [Ms A] on 7 [Month18] was reasonable although best practice would have been to prescribe 5mg folic acid rather than 0.8mg. I think it was a reasonable assumption by [Dr H] that [Ms A] would continue to request prescriptions for the oral contraceptive she had taken regularly since 2013, and continued to take for the first year of her Epilim treatment, as required while she was using Epilim. This comment is based on the equally reasonable assumption that the clinician initiating the Epilim had adequately informed [Ms A] of the need for regular contraception. However, noting the possible failure of accepted practice on this occasion, I recommend [Dr H] consider undertaking an audit of all of his female patients of childbearing age who are taking Epilim (the number will be small) to ensure they are being prescribed contraception and/or that they have been provided with adequate information (perhaps using the ACC information pamphlets available) regarding the need to avoid or at least carefully plan pregnancy while taking Epilim."