MidCentral District Health Board

A Report by the

Health and Disability Commissioner

(Case 15HDC01036)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Table of contents

Executive summary

1. In 2014, Mrs A, a Type 1 diabetic aged in her thirties at the time of these events, was planning a further pregnancy. Due to suboptimal diabetes control during two previous pregnancies, Dr E of the MidCentral DHB referred Mrs A to a diabetic clinical nurse specialist and a diabetes specialist dietician for glycaemic management as part of pregnancy planning. However, at her first appointment, Mrs A was found to be pregnant already, at eight weeks' gestation.

2. Mrs A's pregnancy was managed through a joint multidisciplinary "high risk antenatal" service . Obstetrician Dr C was Mrs A's Lead Maternity Caregiver (LMC).

3. Mrs A told HDC that despite having been a diabetic for many years she had not been informed about the signs and symptoms of diabetic ketoacidosis (DKA), a serious complication of diabetes that occurs when the body produces high levels of blood acids (ketones). Endocrinologist Dr D stated that given Mrs A's long duration of diabetes, she would have expected it to have been covered as part of structured diabetes education, but there is no record of this having been done.

4. On 23 Month7[1], Mrs A (31 weeks pregnant) presented to the public hospital Emergency Department (ED) with a headache, nausea, and general illness. Mrs A was sent directly to the maternity unit without being triaged in ED.

5. When Mrs A arrived at the maternity unit she told staff that she had Type 1 diabetes mellitus, and that she was under specialist obstetric and endocrinologist care. Despite this, the joint multidisciplinary service was not notified of her admission.

6. Mrs A was administered IV fluids and analgesia for her headache. There is no record of her urine having been checked for ketones following the administration of the fluids. Mrs A's care was not handed over to, or discussed with, the overnight medical consultant. Her condition improved overnight with hydration, and she was discharged the following day (24 Month7) with a prescription for further analgesia and antiemetics if required. An appointment was made for Mrs A to be reviewed by the joint multidisciplinary service the following week.

7. On the way home, Mrs A became increasingly short of breath and nauseated. She began vomiting later in the day and, in the early hours of 25 Month7, Mrs A represented to the public hospital ED. She had shortness of breath, needed to urinate whenever she drank, and stated that she had noticed reduced baby movements.

8. Mrs A was seen by the ED registrar and the obstetric team.

9. A diagnosis of probable DKA was made and, given Mrs A's life-threatening condition at the time, the obstetric team performed an emergency Caesarean. A stillborn infant was delivered.

[1] Relevant months are referred to as Months 1-9 to protect privacy.

10. On 30 Month7, Mrs A was discharged from the public hospital, but the discharge summary contained no information about the reasons why Mrs A developed DKA, or information on how to reduce the risk of reoccurrence.

Findings

11. The MidCentral DHB team had sufficient information to provide Mrs A with appropriate care. However, a series of judgment and communication failures meant that it did not do so and, therefore, it failed to provide services to Mrs A with reasonable care and skill. Accordingly, MidCentral DHB breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[2]

Recommendations

12. It is recommended that MidCentral DHB provide an update to HDC on the following matters:

a) A review of the staffing of the joint multidisciplinary service.
b) A review of the physical layout and suitability of the clinic, and an audit of the documentation of the care provided by the clinic to pregnant women with diabetes.
c) A report on the national gestational diabetes guidelines, once implemented.
d) A copy to HDC of the patient information resource on diabetes management in pregnancy and the pregnancy-specific insulin infusion protocol, and any other relevant reviewed policies.
e) A report on the establishment of a preconception clinic and the outcome of the trial.

13. It is also recommended that MidCentral DHB undertake the following:

f) Consult with all other DHBs regarding the development of consistent glycaemic targets for pregnant women and report on the outcome.
g) Include in any protocols developed a requirement that, in circumstances where a patient is receiving multidisciplinary care and is admitted to hospital, all disciplines are informed and involved in treatment decisions, and provide a copy to HDC.
h) Review the training provided to RMOs on assessing patients, including a review of triaging, assessment, and supervision of junior doctors, and report on the outcome.
i) Consider the development of a protocol to provide that in cases where a woman's glycaemic control is poor, there is a regular review of the records by a doctor and limited contact by telephone and email.
j) Review the diabetes assessment/education checklist to include DKA, and provide HDC with a copy of the updated checklist.
k) Investigate the possibility of a system whereby the readings from BGL meters are downloaded electronically, and report on the outcome.

[2] Right 4(1) of the Code states: "Every consumer has the right to have services provided with reasonable care and skill."

l) Review the protocol regarding diabetic ketoacidosis in the clinic guideline, with a view to adding to the risks and precipitating causes, pregnancy-vomiting-hydration. Consider adding under 2.4 the recommendation that the blood sugar level is > 40mmol/L before referral to ICU, and report on the outcome.

Complaint and investigation

14. The Commissioner received a complaint from Mrs A about the services provided to her by MidCentral District Health Board. The following issue was identified for investigation:

- *Whether MidCentral District Health Board provided Mrs A with an appropriate standard of care.*

15. The parties directly involved in the investigation were:

Mrs A	Consumer
MidCentral District Health Board	Provider
Dr B	Intensive care specialist/Provider
Dr C	Obstetrician and gynaecologist/Provider
Dr D	Endocrinologist/Provider
Dr E	Diabetes physician/Provider
Ms F	Clinical nurse specialist diabetes/Provider
Ms H	Midwife
Ms G	Midwife

Also mentioned in this report:

Dr I	Medical registrar
Dr J	Consultant obstetrician
Dr K	Consultant obstetrician
Dr L	ED registrar

16. Independent expert advice was obtained from obstetrician and gynaecologist Professor Peter Stone (**Appendix A**).

Information gathered during investigation

Introduction

17. Mrs A (aged in her thirties at the time of these events) was diagnosed with Type 1 diabetes[3] when she was a child. She has a history of poorly controlled diabetes, and has had microvascular complications[4] with previous laser therapy for retinopathy.[5]

18. Mrs A has previously delivered a live baby by Caesarean section following a failed induction of labour. She has also experienced one miscarriage.

19. MidCentral DHB stated that Mrs A had achieved suboptimal diabetes control during these two previous pregnancies, and had required multiple reminders to provide her blood glucose levels (BGLs) to the Diabetes and Endocrinology Service team. This report addresses the care MidCentral DHB provided to Mrs A in relation to her pregnancy in 2014.

Diabetic ketoacidosis in pregnancy

20. Diabetic ketoacidosis (DKA) in pregnancy has the potential to compromise both the fetus and the mother. Usually DKA occurs in the later stages of pregnancy. DKA is a major clinical problem for pregnant women because it tends to occur at lower glucose levels, and more rapidly than in non-pregnant women, which often causes a delay in diagnosis.[6]

21. DKA occurs in approximately 1–3% of diabetic women who become pregnant, because pregnancy predisposes diabetic women to poor glycaemic control. The presentation of DKA is similar in both pregnant and non-pregnant women. The symptoms are nausea, vomiting, thirst, polyuria,[7] polydipsia,[8] abdominal pain and, when severe, a change in mental status.

22. During acute DKA the fetal heart rate often has minimal or absent variability and absent accelerations, as well as repetitive decelerations. DKA is managed by use of intravenous insulin, appropriate volume replacement, correction of electrolyte abnormalities, monitoring of acidosis, and a search for the precipitating causes.

[3] Diabetes mellitus (commonly referred to as "diabetes") is a chronic auto-immune condition in which the pancreas produces little or no insulin, a hormone needed to allow sugar (glucose) to enter cells to produce energy. People with Type 1 diabetes are insulin dependent.
[4] The damage caused by hyperglycaemia (high blood sugar) is separated into macrovascular complications (coronary artery disease, peripheral arterial disease, and stroke) and microvascular complications (diabetic nephropathy, neuropathy, and retinopathy).
[5] Retinopathy is persistent or acute damage to the retina of the eye. Frequently, retinopathy is an ocular manifestation of systemic disease in diabetes.
[6] See "Diabetes ketoacidosis in pregnancy, Seminars in Perinatology". Veciana M, 2013; 37:267–273.
[7] The passing of, and excessive quantity of, dilute urine, such as in diabetes mellitus.
[8] Constant, excessive drinking as a result of thirst. Polydipsia occurs in untreated or poorly controlled diabetes mellitus.

HbA1c testing

23. Haemoglobin A1c (HbA1c) is a form of haemoglobin (a blood pigment that carries oxygen) that is bound to glucose. The blood test for HbA1c level is performed routinely in people with diabetes. HbA1c levels are reflective of BGLs over the past six to eight weeks, and do not reflect daily variations of blood glucose.[9]

24. Blood HbA1c levels are a guide as to how well diabetes is controlled. High HbA1c levels indicate poorer control of diabetes than levels in the normal range. The normal range for HbA1c is less than 42mmol/mol (6%).

Pregnancy management

25. In 2014 Mrs A was planning a further pregnancy. At that time she was taking fluoxetine[10] to treat depression.

26. On 12 Month1, a specialist diabetes physician, Dr E, referred Mrs A to a diabetic clinical nurse specialist (CNS), Ms F, and a diabetes specialist dietician for glycaemic management[11] as part of pregnancy planning. Dr E noted in his clinical letter to Mrs A's general practitioner (GP) that he (Dr E) had suggested that Mrs A have a discussion with her GP about continuing to take fluoxetine in light of its possible risks during pregnancy.

27. Mrs A's clinical records contain an undated "Diabetes Assessment/Education Checklist". The line for "urine test for ketones" is blank, and the checklist has no space to record any discussion of DKA. On 13 Month2, Mrs A was reviewed by Ms F for pre-pregnancy glycaemic management, but was found to be pregnant already, at eight weeks' gestation. Mrs A's HbA1c was outside the normal range at 95mmol/mol (10.5–11%). Ms F recorded a BGL target of 7.0–8.0mmol/L. Mrs A was given education regarding carbohydrate counting.

28. Mrs A's pregnancy was managed through the joint multidisciplinary "high risk antenatal" service conducted by the MidCentral DHB. Obstetrician Dr C was Mrs A's Lead Maternity Carer (LMC).

29. MidCentral DHB stated that the joint multidisciplinary service has a weekly clinic in the Women's Health outpatient clinic. Women were seen by a doctor before being

[9] The aim of diabetes management is to keep blood glucose levels as close to the target range as possible, between 4–6mmol/L (fasting). Keeping the blood glucose level at the optimum range is a balance between what food is eaten, physical activity, and medication. Blood glucose levels that are too high can result in hyperglycaemia or ketoacidosis.

[10] Fluoxetine is an antidepressant of the selective serotonin reuptake inhibitor (SSRI) class.

[11] Glycaemic management or "glycaemic control" refers to the typical levels of blood sugar (glucose) in a person with diabetes mellitus. Evidence suggests that many of the long-term complications of diabetes, especially the microvascular complications, result from many years of hyperglycaemia (elevated levels of glucose in the blood). Good glycaemic control, in the sense of a "target" for treatment, has become an important goal of diabetes care, although recent research suggests that the complications of diabetes may be caused by genetic factors or, in Type 1 diabetics, by the continuing effects of the autoimmune disease that first caused the pancreas to lose its insulin-producing ability.

reviewed by the joint multidisciplinary team (MDT) consisting of an obstetrician, an endocrinologist, a diabetes CNS or nurse practitioner, a specialist dietician, and a midwife. MidCentral DHB said that the clinic provides oversight from maternity and diabetes specialties.

30. MidCentral DHB stated that historically the diabetes component of the team joined the clinic at 11am to see diabetic patients, and remained in the clinic until after 2pm. The obstetrician recorded the clinical documentation in the written obstetric notes, and the CNS recorded the clinical documentation in the diabetes notes. There were no dictated letters generated from the clinic.

31. MidCentral DHB stated that from Month2, as a result of a significant increase in patient numbers attending the high risk antenatal clinic, the obstetrician was unable to attend the joint MDT meeting, as he needed to be in the main clinic to supervise the junior obstetric doctors. The time spent on each consultation had increased, which resulted in very lengthy clinics. MidCentral DHB stated that Dr C was the sole obstetrician for the joint multidisciplinary services and, if he was unable to attend, the clinic was run by an obstetric registrar. Clinic midwives Ms H and Ms G provided midwifery care to women with pre-existing diabetes, facilitated the patient flow in the clinic, and performed CTG[12] readings.

32. Endocrinologist Dr D told HDC that women were asked to contact the diabetes service on Mondays and Thursdays to discuss their BGLs. If contact was not received, then the diabetes CNS assigned to the woman would attempt to contact her to review her BGLs and adjust her medication accordingly.

Monitoring of Mrs A during pregnancy

33. Dr D stated that Mrs A's glycaemic control during her early pregnancy was poor, with an initial HbA1c of 95mmol/mol, which had decreased to 71mmol/mol by 31 Month2. However, Mrs A self-reported that her BGLs during the latter part of her pregnancy were close to target. Dr D stated that there are limitations in interpreting HbA1c levels during pregnancy, and commented that Mrs A's BGL meter was not reviewed to verify the results she was providing, and the antenatal clinic did not have the software to download the data from the meter.

34. Mrs A told HDC that despite having been a diabetic for around 31 years she had not been informed about the signs and symptoms of DKA. She stated that she was "aware of [DKA] as she thought she had been told about it as a child (she thought her parents might have been educated about it) but as an adult she had never received any education on the signs and symptoms [of DKA] or how to recognise it".

[12] Cardiotocography (CTG) is a technical means of recording the fetal heartbeat and the uterine contractions during pregnancy. The machine used to perform the monitoring is called a cardiotocograph.

35. With regard to the education provided to Mrs A on urine ketone testing[13] and DKA, Dr D stated that "sick day" education,[14] including recognition of possible DKA, would be an expected part of a diabetes nursing review in early pregnancy. Dr D stated:

> "The prescription of urine ketone test strips would suggest that this was discussed, but there is no written documentation supporting this. Neither I nor [Dr E] recall discussing with [Mrs A] her understanding of sick day management or symptoms of DKA. I did discuss the use of additional correctional insulin to correct hyperglycaemia. Given her long duration of diabetes I expected it would have certainly been covered as part of structured education, but I was unable to find any documentation to support this."

36. MidCentral DHB provided HDC with Mrs A's pregnancy progress notes, which record the monitoring of her BGLs. On 5 Month5 (20 weeks' gestation) there is a record of an email having been sent to Mrs A requesting her BGLs for review. There is a gap in Mrs A's record between 7 and 19 Month5 and, on 22 Month5, a note that an email had been sent to her requesting her results immediately.

37. On 20 Month5 (22 weeks' gestation) a CNS emailed Mrs A stating that she (the CNS) had discussed the BGLs with Dr D and requested that Mrs A perform overnight tests for the following few days with a view to increasing her insulin[15] at night later in the week if the overnight BGLs were stable.

38. From 24 Month5 Mrs A's blood glucose control was deteriorating and, on 27 Month5, a nurse practitioner (NP) emailed Mrs A noting that her results were above target throughout the day. The NP recommended that Mrs A increase her insulin morning and night and do additional testing two hours after meals.

39. On 3 Month7, Mrs A was seen in the antenatal clinic and had 1+ proteinuria,[16] and she reported having had a few headaches. Mrs A's BGL results were generally stable until the week beginning 9 Month7 (29 weeks' gestation).

---

[13] Ketones are produced when the body burns fat for energy or fuel. They are also produced when a person loses weight or if there is not enough insulin to help the body use sugar for energy. Without enough insulin, glucose builds up in the blood. Since the body is unable to use glucose for energy, it breaks down fat instead. When this occurs, ketones form in the blood and spill into the urine. A urine test is used to test whether a person is making ketones.

[14] The stress of being unwell can increase basal insulin (background insulin) requirements in both Type 1 and Type 2 diabetes and result in higher than usual blood glucose levels. It is recommended that diabetics have a sick day management plan in place prior to becoming sick.

[15] Mrs A was prescribed Lantus (insulin glargine), a man-made form of a hormone insulin that works by lowering levels of glucose (sugar) in the blood. Insulin glargine is a long-acting insulin that starts to work several hours after injection and keeps working evenly for 24 hours. Lantus is used to improve blood sugar control in adults and children with diabetes mellitus.

[16] Urinary protein excretion is considered abnormal in pregnant women when it exceeds 300mg/24 hours at any time during gestation, a level that usually correlates with 1+ on urine dipstick.

17–23 Month7

40. On 17 Month7 Mrs A was seen in the joint multidisciplinary service. Increased fetal growth was recognised, and a plan was made to optimise glycaemic control in the middle of the accepted target range. Dr D said that Mrs A would have been asked to contact the CNS later in the week to review the effect of the increased Lantus doses, as is standard practice, and the contact would have been expected on Thursday or Friday as part of her usual weekly blood glucose reporting.

41. Dr D told HDC that the last contact the diabetes clinic had with Mrs A was on 17 Month7. From 19 Month7 there are no BGL results recorded.

42. Dr D said that all relevant staff from the service were attending in-service training on Friday 20 Month7, so follow-up of Mrs A's failure to make contact with the service took place on Monday, 23 Month7 when the CNS sent an email to Mrs A requesting her blood glucose records, but no BGL results were received.

23 Month7

43. On 23 Month7 at around 2pm Mrs A presented to the ED with a headache, nausea, and general illness. At that time, she was 31 weeks pregnant.

44. MidCentral DHB stated that all patients who arrive at the ED reception should be registered as per the Registration of an Emergency Department Patients' Policy. MidCentral DHB advised that, had Mrs A been assessed by a triage nurse initially, as required by the policy,[17] it would have been determined that she was not in labour but suffering from physical symptoms, and she would have been seen by the ED doctor as part of the usual process.

45. However, that did not occur. Mrs A was sent directly to the delivery suite. She told HDC that she informed the staff that she was under the care of Dr C and Dr D.

46. At 3.35pm Mrs A was reviewed by a registered midwife (RM). Blood tests were taken but no blood gases.[18] The RM noted, "[BGLs] were up a bit today", and that at 1pm the result had been 10mmol/L.

47. At 3.55pm the RM recorded that the outcome of the urinalysis was glucose+++[19] and ketones+++.[20] At 5.45pm Mrs A was given paracetamol[21] for her headache. Mrs A's

[17] Clinical Guideline for Women in Labour Presenting to ED, Appendix 1. "Triage assessment. Patient has abdominal pain/cramps indicative of labour → No → Assess and treat as clinically indicated."
[18] A blood gas test measures the amount of oxygen and carbon dioxide in the blood. It may also be used to determine the pH of the blood. Imbalances in the oxygen, carbon dioxide, and pH levels can indicate the presence of certain medical conditions such as uncontrolled diabetes.
[19] In normal states, urine contains no glucose, and a positive urine test for glucose indicates a level of sugar in the blood. In most urine strips the 3+ glucose correlates with 1,000mg/dL or 55.5mmol/L of sugar in the urine.
[20] In normal states, ketones will be completely metabolised so that very few, if any at all, will appear in the urine (< 150mg/day). If 3+ ketones are present (proteinuria) it indicates that proteinuria is at a 500mg/dL level. 4+ ketones indicates that proteinuria is equal to or more than 1,000 mg/dL.
[21] Paracetamol is a pain reliever and a fever reducer.

vital signs were normal. The RM recorded that there were good fetal movements and no concerns noted with regard to the CTG.

48. At 7.20pm Mrs A was seen by a registrar who noted that Mrs A had presented with a headache and feeling unwell, and that her BGLs were slightly high and, at highest, reaching 11mmol/L. An assessment was completed, which noted that Mrs A had no abdominal pain, vaginal bleeding, or discharge, she was eating and drinking well, and she had no issues with her bladder or bowel.

49. At 8.19pm Mrs A was seen by a senior house officer. The plan was for intravenous (IV) fluids (normal saline), analgesia,[22] and antiemetics.[23] Mrs A was given IV fluids and, at 8.45pm, codeine for her headache. Mrs A's urine was not checked for ketones following administration of the fluids.

50. MidCentral DHB told HDC that the registrar spoke to the on-call consultant, who was in theatre, and discussed the case with him. MidCentral DHB said that the registrar explained that Mrs A was a Type 1 diabetic, had headaches associated with vomiting, and some ketones in her urine, and that the consultant advised the registrar to arrange for the medical team to review Mrs A overnight.

24 Month7

51. On Tuesday, 24 Month7 at 12.23am, Mrs A requested further pain relief. She was seen by a senior house officer and was administered ondansetron[24] 8mg and tramadol 50mg. At 5.22am Mrs A was reviewed by medical registrar Dr I, whose impression was that Mrs A had a tension headache and was dehydrated owing to vomiting. The plan was to continue with simple analgesia and antiemetics if required. Mrs A's care was not handed over to, or discussed with, the overnight medical consultant.

52. At approximately 8.13am Mrs A was reviewed by consultant obstetricians Dr J and Dr K during the consultant ward round. It is recorded that Mrs A was feeling much better. Her BGL was 11.6mmol/L, fetal movements were good, and her vital signs were satisfactory. Mrs A's headache was again described as being like a tension headache.

53. Retrospective clinical notes state that the possibility of DKA was raised. MidCentral DHB told HDC that DKA was dismissed as a possible diagnosis at that time owing to the following factors:

- Mrs A's history was strongly suggestive of a musculoskeletal origin with shoulder pain, neck pain, and headache. Her shortness of breath was thought to be caused by the discomfort from her neck and shoulder.

- There was no obvious infectious cause, and Mrs A had vomited only once. Furthermore, she had been eating and drinking well. Her BGL at 9pm the previous

[22] Medication to relieve pain.
[23] Drugs to counteract vomiting and nausea.
[24] Ondansetron is a medication used to prevent nausea and vomiting.

evening had been normal, and in the morning it was 11.6mmol/L which, in light of Mrs A's poor blood sugar control, was considered acceptable.

- Mrs A's urinary ketones, near normal BGLs, slightly low sodium levels, and normal potassium levels were consistent with a diagnosis of dehydration.

- When Mrs A had been at her most unwell (the day of admission) her BGL was recorded at 10mmol/L, and later 7.2mmol/L. When feeling her best, Mrs A had a BGL of 11.6mmol/L. This was considered to be counterintuitive to her having DKA, when it was expected that her blood sugars would be at their worst when she was feeling her worst.

- Mrs A improved dramatically overnight with hydration.

54. Mrs A was cleared for discharge provided that a CTG and Partosure tests (to test for preterm labour) were satisfactory. An appointment was made for her to be reviewed by the joint multidisciplinary service the following week. There is no record that the joint multidisciplinary service was notified of the admission or had any involvement in Mrs A's management during the admission.

55. The Partosure test was negative, and a CTG at 9am showed reduced variability, but at 9.45am the tracing appeared normal. Mrs A was discharged home at 10.44am.

56. Mrs A stated that on her way home from hospital she became increasingly short of breath and nauseated. She said that she put the shortness of breath down to the baby sitting high and pushing up on her lungs, and the nausea down to the lasting effects of the tramadol she had been administered. She stated that during the day the shortness of breath did not go away and she also suffered from reflux and that, about 5.30pm, she started to vomit regularly and was still experiencing shortness of breath.

25 Month7

57. Mrs A told HDC that she slept intermittently until about 2.30am, at which time her husband called an ambulance and she was taken to the ED at the public hospital.

58. Mrs A arrived at the ED at 2.48am. The ambulance service Patient Report Form notes that Mrs A had shortness of breath onset at 2pm, which was exacerbated by any exertion. Mrs A had advised that she needed to urinate whenever she drank. The ambulance service records state: "[Patient] advises reduced baby movements."

59. At 2.57am Mrs A was seen by ED registrar Dr L. Dr L recorded that no fetal movements were felt. An abdominal ultrasound scan was performed to scan for a fetal heart, and a heart rate of 70 beats per minute (bpm) was seen. The obstetric team was paged urgently regarding the low fetal heart rate, and the team arrived within 10 minutes.

60. Dr L recorded: "At this point I was concerned about a pulmonary embolism or dehydration, but neither fit the clinical picture properly." The BGL was 15.5mmol/L. Dr J arrived and scanned Mrs A but, sadly, was unable to find a fetal heartbeat.

61. Dr L retrospectively recorded that while he considered a possible diagnosis of DKA, Mrs A's relatively low BGLs suggested otherwise. Dr L discussed the possible causes for Mrs A's condition with the ED consultant. They consulted "UpToDate"[25] and confirmed that DKA in pregnancy can occur with "high–normal" BGLs. A urine dipstick test was then conducted, which confirmed "4+ ketones", and a beta-hydroxybutyrate[26] scan came back at "5.7 (normal upper limit = 0.5)". The intensive care unit (ICU) was contacted immediately.

62. At 5.45am Mrs A was admitted to ICU. It is recorded in the clinical notes that the impression was that she most likely had DKA secondary to reduced oral intake and pregnancy.

63. Fluid resuscitation was commenced, and blood tests showed that Mrs A was severely acidotic. Urinalysis showed 4+ ketones, and her BGL was 15.5mmol/L.

Caesarean section

64. Dr C decided to perform an emergency Caesarean section. He told HDC that there were two reasons for performing a Caesarean section. The first was that although the baby was dead it was lying in a transverse lie with its back down and head towards the maternal left upper quadrant. In addition, Mrs A had previously had a Caesarean section and polyhydramnios.[27]

65. Dr C said that the second reason for the Caesarean section was Mrs A's DKA, systemic inflammatory response syndrome (SIRS),[28] and probable sepsis due to probable chorioamnionitis[29] with intact membranes. Dr C stated that Mrs A's severe acidosis and tachycardia (fast heart rate) were getting worse in spite of intensive insulin, fluid, and acid–base correction. He said that the teams were considering sepsis as an initiating cause of the severe ketoacidosis and the reason for her worsening condition.

66. Dr C stated that on examination of Mrs A he realised that she was in a dire, life-threatening condition, had a severe persistent tachycardia of 150–160bpm, which was getting worse, and her level of consciousness was deteriorating. Her white blood cell count and neutrophil count were increasing.

67. The Caesarean section was performed by a registrar with Dr C as the assistant. A stillborn infant was delivered.

[25] UpToDate is an evidence-based, electronic clinical decision support resource covering a number of speciality fields and designed to be used at point of care.
[26] Beta-hydroxybutyrate accounts for about 75 percent of the ketones in ketoacidosis, and is the preferred test for monitoring DKA.
[27] Polyhydramnios is an excess of amniotic fluid in the amniotic sac.
[28] SIRS is defined as two or more of the following variables: Fever of more than 38°C or less than 36°C; heart rate of more than 90bpm; respiratory rate of more than 20 breaths per minute or arterial carbon dioxide tension ($PaCO_2$) of less than 32mmHg; abnormal white blood cell count (>12,000/µL or < 4,000/µL or >10% immature [band] forms). SIRS is nonspecific and can be caused by ischaemia, inflammation, trauma, infection, or several insults combined. SIRS is not always related to infection.
[29] Chorioamnionitis is an inflammation of the fetal membranes due to a bacterial infection.

Discharge

68. On 27 Month7, Mrs A was discharged from ICU to the maternity unit. She was discharged on 30 Month7. The discharge summary contains no advice to Mrs A, her GP, or her LMC, about the reasons why Mrs A developed DKA, or information on how to reduce the risk of recurrence.

Root cause analysis

69. MidCentral DHB conducted a root cause analysis (RCA). The findings included the following.

70. With regard to information provided to Mrs A about DKA, as part of the assessment of women with Type 1 diabetes, the joint multidisciplinary service uses a checklist to document education provided to women when they are pregnant. The checklist also discusses "sick days", which helps the patient to understand the illness and how this can affect other common illnesses such as cold or flu, hypoglycaemia, or hyperglycaemia. The RCA states:

> "[W]hilst the diabetes clinician can remember having had these discussions with [Mrs A], the checklist does not indicate what was discussed at each session. Education around DKA is also on the checklist but it was not ticked as having been discussed during any of [Mrs A's] pregnancies. The clinician could not remember if it had been discussed at any time."

71. The RCA also states that the HbA1c blood test performed at the high risk antenatal clinic looks at the average glucose control for the last three months. That test is less reliable in pregnancy, but can act as a second check to the weekly results patients send into the diabetes team. There is no guideline within the diabetes team as to how often HbA1c testing should be performed on pregnant women, as that is dependent on the lead clinician.

72. There is no national or international consensus on the frequency of HbA1c monitoring, but the National Institute for Health and Care Excellence (NICE) guidance suggests three monthly. Mrs A had an HbA1c test done in Month2 (95mmol/mol) when she was eight weeks pregnant. The next HbA1c test was done in Month7 (72mmol/mol).

73. The RCA also notes that the DHB has no electronic system in which to record blood glucose results. They cannot be recorded in Éclair[30] or any other system.

74. The RCA states that there are differing practices between clinicians regarding checking whether their patients have presented to ED and/or whether they have been admitted. The process relies on the wards referring on to the Diabetes Service, and there is little proactive action by the Diabetes Service to check whether there have been admissions that require its support.

[30] An electronic clinical information system enabling doctors to see all investigations relating to that patient, including community and hospital laboratory tests, radiology reports, etc.

75. There is limited MDT discussion about women who attend the high risk antenatal clinic, and case-by-case discussion occurs if there are concerns. The RCA states:

> "[W]omen are seen by both services and interaction occurs through the written notes and discussions between the [joint multidisciplinary] team and the obstetric registrars, consultants and diabetes midwives around areas of concern. It is also of note that whilst clinic letters are placed on the clinical portal site from both services, diabetes general notes and recordings of blood glucose levels/changes to medications sit within the file which are held physically in the service. Current systems do not support the sharing of notes between services."

76. The RCA identified three causal factors:

- Failure to triage Mrs A in the ED on the first admission.
- During Mrs A's first admission to the delivery suite no contact was made with any diabetic clinician or her high risk obstetric and gynaecologist consultant.
- Failure to diagnose DKA.

77. As a result of a review of this event, a pregnancy clinical data record checklist was introduced. The checklist shows the type of diabetes, other medical conditions, other medications, gestation, fetal growth, weight, blood pressure, HbA1c mmol/mol, eye screening, ACR, creatinine, smoking status, hypo or hyper glycaemia, DKA, mode of delivery, gestation, complications, and neonatal outcomes.

78. The RCA recommended the development of:

- A robust MidCentral DHB health-wide system for advising specialist services when one of their patients is admitted under another team.
- Appropriate guidelines for clinicians to support assessment and diagnosis of patients with Type 1 diabetes at risk of DKA, and detailed information pamphlets for patients.
- A project team to look at the redesign of the paper-based paperwork used by the Diabetes Service to include the collection of information, storage, and access for other services for all diabetes patients.

79. The RCA also recommended that diagnostic test results, such as blood, glucose, and HbA1c be available through Éclair. MidCentral DHB advised that clinicians are now able to access blood glucose results (polycose and glucose tolerance tests) and HbA1c results via Éclair.

80. MidCentral DHB also advised HDC that the Maternity Service has agreed an approach to the development of a model of care for gestational diabetes mellitus (GDM). The role of a specialty midwife is central to this model, as a liaison with the woman and her LMC. Implementation will see a strengthening of GDM

management within the service, providing education and support for the woman, her partner/support person, whānau, LMC, and clinicians. Agreement was reached on this model in late 2016, with implementation currently being planned over 2017.

Policies and guidelines

Women in labour presenting to ED

81. This policy guides staff in the most appropriate process to follow when a pregnant woman of 17 weeks plus six days' gestation or more presents to the ED. It applies when the patient has been assessed at triage and is presenting with abdominal pains/cramps and the patient is haemodynamically stable.

82. The appendix to the policy states that if the woman does not have abdominal pain/cramps indicative of labour then the process is:

- Assess and treat as clinically indicated.
- Document if LMC aware of patient's presentation and attempt to contact if required.
- Refer O&G registrar/other specialty as appropriate.

Diabetic Ketoacidosis and Hyperglycaemic Hyperosmolar non-Ketotic Syndrome: Management in Adults

83. This guideline states that DKA is an emergency characterised by hyperglycaemia and metabolic acidosis due to ketone body accumulation. The guideline states that dehydration is more life-threatening than any hyperglycaemia, so its correction takes precedence. The choice of rehydration fluid is "hypotensive or serum sodium concentration of less than a 140mmol/l equals 0.9% sodium chloride".

MidCentral DHB — other information

84. MidCentral DHB stated that blood gases were not obtained at the time of Mrs A's initial assessment on 23 Month7, because no one had considered a diagnosis of DKA.

85. MidCentral DHB advised that currently work is being undertaken by a steering group to implement the national guidelines for management of diabetes in pregnancy. An additional obstetrician has been recruited.

86. It has been reinforced to ED clinical staff that pregnant women are to be registered in triage in the same way as any other patient presenting to the ED.

Dr D — other information

87. Dr D stated that she accepts that the joint multidisciplinary service's clinical records are suboptimal, and said that it would be ideal to have more staff time available to follow up patients like Mrs A whose engagement with the service is not ideal.

88. Dr D said that the joint multidisciplinary service is limited by a lack of staff, and also noted that clinics during this period were significantly overloaded. She stated that there was a lack of physical space in the clinic and an inability to check point of care HbA1c, and a lack of capacity to maintain high quality documentation.

89. Dr D stated that the joint multidisciplinary service has been compelled to ration care, and said that she had raised concerns in that regard with the DHB on numerous occasions since 2013.

90. Dr D stated that in response to these events the following steps have been undertaken:

- She has provided two education sessions about pregnancy management.
- The joint multidisciplinary service has reviewed adult sick day management/diabetic ketoacidosis and published a new patient education handout. A pregnancy specific handout is under development.
- A steering group is reviewing the implementation of the national gestational diabetes guidelines. As part of this work a review of staffing levels has been promised.
- In 2015 a project commenced to look at the provision of diabetes care by the secondary diabetes service.
- A pregnancy clinical data record sheet has been introduced within the diabetes notes to ensure that fetal growth and HbA1c are considered.
- Development of a preconception clinic has been discussed and a trial is underway.
- In 2016 there was a plan to develop a pregnancy specific insulin infusion protocol and review of relevant policies.

91. MidCentral DHB has since advised:

- Clinicians are now able to access blood glucose results (polycose and glucose tolerance tests) and HbA1c via Éclair.
- The development of a pregnancy-specific insulin infusion protocol has now started, with relevant guidelines from a number of other DHBs obtained, and work is in progress to redevelop local guidelines.

92. Adult sick day management patient information has been developed, and is now in use throughout the service. A pregnancy-specific sick day management plan has also been developed and shown to patients for feedback, with further revisions underway before the document is finalised. MidCentral DHB also advised that the diabetes pregnancy guidelines and infusion policy will take several months to write, and will then need extensive consultation with Women's Health, General Medicine, Pharmacy, and other services, and is likely to take until the end of 2017.

Response to provisional opinion

MidCentral DHB

93. MidCentral DHB provided a response to the provisional opinion. This has been incorporated into the report where appropriate. MidCentral DHB also advised that representatives met with Mr and Mrs A in March 2016 to discuss the outcome of the external review of maternity services and to apologise for the shortcomings in the care that was provided to Mrs A. MidCentral DHB advised that it has accepted the Commissioner's recommendations as outlined below.

Mrs A

94. Mrs A was provided with an opportunity to respond to the "information gathered" section of the provisional opinion. She advised that she did not wish to make any comment on the information presented.

Opinion: MidCentral District Health Board — Breach

Introduction

95. District health boards are responsible for the operation of the clinical services they provide, and are responsible for any service failures. In my view, it was the responsibility of MidCentral DHB to have adequate systems in place and appropriate oversight of staff to ensure that Mrs A received appropriate care. I consider that there were service failures that are directly attributable to MidCentral DHB as the service operator. The failures by MidCentral DHB, outlined below, exhibit a pattern of suboptimal care.

DKA education

96. Mrs A told HDC that, despite having had Type 1 diabetes for over 30 years, she had not been educated about the symptoms and signs of DKA to enable her to recognise the seriousness of the condition she had developed. Dr D stated that "sick day" education, including DKA, would be an expected part of a diabetes nursing review in early pregnancy. She noted that the prescription of urine ketone test strips suggests that DKA was discussed with Mrs A, but Dr D said that there is no written documentation supporting that such a discussion took place. Dr D said that given Mrs A's long duration of diabetes, she expected that DKA would have been covered as part of her structured education, but was unable to find any documentation of that having occurred.

97. Neither Dr D nor Dr E recall discussing with Mrs A her understanding of sick day management or the symptoms of DKA. There is no record of Mrs A having been provided with such education. The "Diabetes Assessment/Education Checklist" completed in 2014 has the line "urine test for ketones" blank, and there is no space on the checklist to record any discussion of DKA.

98. I accept Mrs A's account that the signs and symptoms that she might expect, should she be suffering from DKA, were not communicated to her sufficiently. Consequently, Mrs A was not in a position to recognise the seriousness of her condition on 23–25 Month7.

Monitoring of diabetes during pregnancy

99. Mrs A tested her BGLs on a daily basis, and her hypoglycaemic control gradually improved during early pregnancy and was stable by the week of 10 Month3 (12 weeks' gestation). Patients of the diabetes clinic are asked to contact the Service twice weekly on Mondays and Thursdays via telephone or email. When Mrs A did not report her BGLs, the clinic staff contacted her by telephone or email and asked her to email her results.

100. On 24 Month5, in response to Mrs A's deteriorating BGLs, her insulin dosages were adjusted. However, there is no record of any urinary ketone testing have been undertaken. I note that my expert advisor, obstetrician and gynaecologist Professor Peter Stone, advised that as Mrs A's hypoglycaemic control was improving, the requirement for urinary ketone testing would not be absolute. Taking into account Professor Stone's advice, I am not critical of the lack of urinary ketone testing at that time.

101. There are no BGL results recorded after 17 Month7. Dr D said that Mrs A would have been asked to contact the CNS later that week to review the effect of the increase in her Lantus doses, as is standard practice, and contact would have been expected on Thursday or Friday as part of her usual weekly BGL reporting. Dr D said that all relevant staff from the joint multidisciplinary service were attending in-service training on Friday, 20 Month7, so follow-up of Mrs A's failure to make contact with the service took place on Monday, 23 Month7, when the CNS sent an email to Mrs A requesting her BGLs.

102. Professor Stone advised that there are a number of concerns about the monitoring of Mrs A's diabetes during the pregnancy. He stated:

> "[I]t appears that much of the care was done by telephone or email, which may be appropriate where control is good but this pregnancy began with very poor control. It is not clear how often a doctor reviewed the notes and at the time when there seemed to be concerns about hypos there were periods subsequent to that when the control was poor."

103. Professor Stone stated that he was concerned that the very high HbA1c level suggested that Mrs A had much poorer glycaemic control than was indicated by her BGL records that were available at the start of her pregnancy.

104. In my view, in light of the high-risk nature of Mrs A's pregnancy, closer monitoring of Mrs A's diabetes during the pregnancy was required. In particular, I consider that increased personal contact, for example by way of telephone contact by clinicians, was warranted.

23 Month7

105. On 23 Month7, Mrs A (31 weeks' gestation) presented to the public hospital ED and was sent directly to the delivery unit from the ED, contrary to MidCentral DHB's policy that pregnant women are to be registered and triaged in exactly the same way as for any other patient presenting at ED.

106. Professor Stone advised that whether that was appropriate would depend on how the unit best functions. He said that, in general, he supports the practice of women going to a women focussed area, especially when an ED does not have such a focus or if it is physically distant from the women's area. Professor Stone stated: "It is actually better for women to be seen by the obstetric rather than the emergency department … however, it would be predicated on the ability of the Obstetric service to be able to attend to the patient expeditiously."

107. Mrs A was reviewed by an RM. Urinalysis showed glucose +++ and ketones +++. Mrs A's BGL was 15mmol/L. However, she was not seen by the senior house officer until approximately four hours later. Professor Stone advised that there are no absolute rules in New Zealand about timeliness of medical review.

108. The senior house officer's plan was for IV fluids (normal saline), analgesia, and anti-emetics. Mrs A was administered IV fluids and analgesia for her headache. There is no record of her urine having been checked for ketones following the administration of the fluids. MidCentral DHB stated that the maternity unit protocol states that a urine analysis for ketones should be done on all Type 1 diabetic pregnant women, but that process was never completed in this case.

109. When Mrs A arrived at the delivery suite she told staff that she had Type 1 diabetes mellitus and that she was under the specialist care of obstetrician Dr C and endocrinologist Dr D. Despite this, none of the staff who reviewed Mrs A (a midwife, senior house officer, registrars, and two consultants) contacted the joint multidisciplinary service during this admission.

110. Professor Stone also advised that a diabetic patient with ketones needs to be investigated, and that either a venous gas test or serum hydroxybutyrate test should have been done. I note that Professor Stone stated that MidCentral DHB should have a policy that if a pregnant woman with established diabetes presents with ketonuria, then the risk of DKA must be considered and appropriately investigated.

111. On the morning of 24 Month7 Mrs A had a moderately high BGL of 11.6mmol/L. Professor Stone said that moderate hyperglycaemia DKA is uncommon. However, he said that Mrs A's BGL of 11.6mmol/L after rehydration was not a satisfactory level for a pregnant woman, and that at that time there was an opportunity to reassess Mrs A's management of her diabetes and for the joint multidisciplinary service to engage with her. Professor Stone advised that it was of concern that, following the ward round on the morning of 24 Month7, Mrs A was discharged with clearly poor glycaemic control and no inpatient assessment by the joint multidisciplinary service.

112. I am critical that the joint multidisciplinary service was not advised of Mrs A's admission and did not review her prior to her discharge, particularly in light of her poor diabetic control and high BGL. I agree with Professor Stone that Mrs A needed a full review prior to her discharge.

Second admission — 25 Month7

113. After Mrs A was discharged from hospital on 24 Month7 she became increasingly short of breath and nauseated. At about 5.30pm she started to vomit regularly, and at 2.30am on 25 Month7 her husband called an ambulance and she was taken to the public hospital.

114. Mrs A was seen by Dr L, who paged the obstetric team urgently because of the low fetal heart rate of 70bpm. Dr L retrospectively recorded that the working diagnosis became possible DKA, but there was some concern regarding Mrs A's relatively low BGLs. The urinalysis showed 4+ ketones and the beta hydroxybutyrate scan came back at 5.7.

115. At 5.45am Mrs A was admitted to the ICU. The impression was that she most likely had DKA, secondary to reduced oral intake and pregnancy. Fluid resuscitation was commenced, and blood tests showed that she was severely acidotic. Her BGL was 15.5mmol/L

116. Dr C decided to perform an emergency Caesarean section. Professor Stone advised that, as the fetus was in the transverse lie, a Caesarean section was appropriate. The registrar delivered a stillborn infant by Caesarean section.

117. On 27 Month7 Mrs A was discharged from ICU to the maternity unit. She was discharged from the public hospital on 30 Month7.

118. Professor Stone noted that there is no record of consideration of the reasons why Mrs A developed DKA, and no guidance was provided at discharge on how to reduce the risk of recurrence. Professor Stone stated:

> "I believe this is below the standards expected. Apart from wanting to get the baby delivered by Caesarean section to improve the recovery, there does not seem to have been an analysis as to why this had happened in the first place. Given all the history and what has been said, this is a serious omission. Most peers, at least physician peers would agree with that."

Conclusion

119. MidCentral DHB failed to provide Mrs A with care of an appropriate standard in the following respects:

- The signs and symptoms that she might expect to experience should she be suffering from DKA were not communicated to her adequately.

- Mrs A's diabetes was not monitored sufficiently closely during the pregnancy, particularly through personal contact with clinicians.

- Despite telling hospital staff that she was a patient under specialist diabetes care, the joint multidisciplinary service was not contacted during Mrs A's hospital admission on 23/24 Month7.

- During Mrs A's hospital admission on 23/24 Month7, no venous gas test or serum hydroxybutyrate test were performed. Mrs A's urine was not checked for ketones following her rehydration. Her BGL was 11.6mmol/L, but the management of her diabetes was not reviewed.

- On 24 Month7 Mrs A's risk profile did not result in an assessment by a diabetes clinician before discharge.

- The discharge summary does not state why Mrs A developed DKA, and gives no guidance on how to reduce the risk of recurrence of DKA.

120. These factors paint a cumulative picture of poor care. I consider that the MidCentral DHB team had sufficient information to provide Mrs A with appropriate care. However, a series of judgement and communication failures meant that it did not do so. In my view, MidCentral DHB failed to provide services to Mrs A with reasonable care and skill and, accordingly, breached Right 4(1) of the Code.

Recommendations

121. I recommend that within three months of the date of this report MidCentral DHB provide an update to HDC on the following matters:

a) A review of the staffing of the joint multidisciplinary service.
b) A review of the physical layout and suitability of the clinic, and an audit of the documentation of the care provided by the clinic to pregnant women with diabetes.
c) A report on the national gestational diabetes guidelines, once implemented.
d) A copy to HDC of the patient information resource on diabetes management in pregnancy and the pregnancy-specific insulin infusion protocol, and any other relevant reviewed policies.
e) A report on the establishment of a preconception clinic and the outcome of the trial.

122. I also recommend that within three months of the date of this report MidCentral DHB undertake the following:

f) Consult with all other DHBs regarding the development of consistent glycaemic targets for pregnant women, and report on the outcome.
g) Include in any protocols developed a requirement that, in circumstances where a patient is receiving multidisciplinary care and is admitted to hospital, all

disciplines are informed and involved in treatment decisions, and provide a copy to HDC.

h) Review the training provided to RMOs on assessing patients, including a review of triaging, assessment, and supervision of junior doctors, and report on the outcome.

i) Consider the development of a protocol to provide that in cases where a woman's glycaemic control is poor, there is a regular review of the records by a doctor and limited contact by telephone and email.

j) Review the diabetes assessment/education checklist to include DKA, and provide HDC with a copy of the updated checklist.

k) Investigate the possibility of a system whereby the readings from BGL meters are downloaded electronically, and report on the outcome.

l) Review the protocol regarding diabetic ketoacidosis in the clinic guideline, with a view to adding to the risks and precipitating causes, pregnancy-vomiting-hydration. Consider adding under 2.4 the recommendation that the blood sugar level is > 40mmol/L before referral to ICU, and report on the outcome.

Follow-up actions

123. A copy of this report with details identifying the parties removed, except the expert who advised on this case and MidCentral DHB, will be sent to the Midwifery Council of New Zealand.

124. A copy of this report with details identifying the parties removed, except the expert who advised on this case and MidCentral DHB, will be sent to the New Zealand College of Midwives, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, and Diabetes New Zealand.

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

Appendix A: Independent advice to the Commissioner

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

"**Ref: C15HDC01036**

Please find enclosed my report to HDC on this complaint. For reasons that you and I discussed, please view this as preliminary in case you are able to obtain more DHB information. The full file about the patient from the Diabetes service would also be of value in the HDC assessing how much education had been offered to her.

The way the DHB has provided notes with electronic screen dumps and sheets of notes in non chronological order has been a particular problem and has not helped this investigation.

Due to poor documentation I have struggled at times to ascertain what was happening and to get an insight into the impressions of the clinicians and the workings of the Unit.

There was a missed diagnosis; I believe that this must be accepted. The issue is why and could this be prevented in future. The brief histories, not obtaining all the necessary information, including symptoms that the patient may down play, meant that the clinician was not led in the right direction. There were ketones and nurse in ED obtained a history of vomiting, both risk factors for Diabetic Ketoacidosis (see table in references) that were either missed later or not acted upon. The need to be assiduous in the clinical process becomes obvious.

Please accept this report with the limitations I have outlined and should more information come to light I will need to revise as appropriate.

I confirm that there is no conflict of interest.

In preparing this report I have read all the documentation supplied and have searched the literature for definitions, guidelines and current knowledge about diabetic ketoacidosis in pregnancy. Also I can confirm to the Commissioner that I have over 35 years experience in general, high risk and practical obstetrics.

In preparing this report it became obvious to me that some of the notes were missing and I made contact with the Health and Disability Commission who also confirmed that there had been some delays and difficulty obtaining the notes from the Mid Central District Health Board (MCDHB). At the time of writing, the requested notes had not arrived. Thus should further information become available, I may be in a position to add to or modify this report. In particular the booking letter from the obstetrician and the Physician who saw [Mrs A] is not in the bundle supplied to me. This is relevant, because in the booking notation of [Mrs A's] health conditions and risk factors for the index pregnancy may have

been highlighted. These would have then been expected to alert all carers should there have arisen subsequent complications which indeed was the case. The first detailed letter about [Mrs A], after her referral from the general practitioner was from a Diabetes Nurse Specialist and as far as I can gather this was written subsequent to that first booking appointment.

If there has not been a letter from the booking (or if it cannot be retrieved) then these are issues that the DHB needs to rectify for the safe care of future patients. There needs to be an accurate risk or alert sheet as part of every pregnant woman's booking. This is what is done at National Women's in Auckland so that whenever the woman presents at least the risk information is available.

In addition, the absence of notes from the Diabetes service at Mid Central DHB, makes it impossible to comment on the assertions from the patient-complainant, that there had not been education about risks of ketoacidosis. (This may not be the case as in the bundle of notes given to me there was a prescription for urine Ketostix with the instruction to test once daily, — thus at some point there had at least been some effort made to have the patient test for ketones. One can only assume that some explanation for the prescription would have been given.) Also, given that the complainant had had Type I diabetes for many years, it is surprising that she entered this pregnancy with poor diabetic control and was markedly overweight. Planning pregnancy and achieving as good a control of the diabetes as possible are critical points in having a successful outcome.

It is unclear, in the absence of documentation, how much of this outcome relates to patient issues — including compliance with medication and how much relates to clinic factors. In fairness to all parties, this issue needs to be resolved (it is possible that [the GP] could provide some independent comment by way of elucidation of these matters).

Case Summary:

[Mrs A] was a [Gravida 3 Parity 1 woman in her thirties] whose medical history was complicated by obesity and Type I diabetes and depression. Her obstetric history was complicated by a fetal loss at […] weeks gestation (for which no other notes were available — but are relevant) and a previous caesarean section after a failed induction of labour. (The records of that pregnancy and delivery were also not available and these could also have been relevant.)

She was referred by her GP to the 'High Needs Clinic' at [the public hospital] when she was 6 weeks pregnant and it was intended by the GP that the Clinic provide the 'ongoing cares'.

She had had Type I diabetes [for] over 20 years. (A case summary written after her discharge in [Month7] noted that she had previously had diabetic ketoacidosis.) (Not only is that a risk factor for DKA, but one would have imagined that there would have been some discussion and counselling with her

after that previous event. It is impossible for me to ascertain whether or not that was the case.)

The first record I can find of antenatal care is [dated] when she was 9 weeks gestation. The blood pressure was 149/70 — the systolic is high for a woman and pregnancy. She was seen by a person signed as [first name] who was most likely one of the junior medical staff. Her case was discussed with [Dr C], Obstetric Specialist and also the diabetic team (uncertain who in that team) and the dietician. It was noted that the 'BSL 13–16 mane feels low~5mmol'.

That level of blood sugar control is very inadequate and required a rapid response and assessment, but she was given an appointment for 2 weeks.

There is a letter dated 13 [Month2] to [Dr E], Physician from the Diabetes Nurse specialist [Ms F], in which she states 'As you have recently seen [Mrs A] in clinic you will be aware that she is up to date with her annual screening …'. It is not clear if this refers to an appointment [Mrs A] had in pregnancy or before pregnancy. In that letter, the latest HbA1c (an important marker of diabetes control) was 95 mmol/mol which is very high. Also the targets for blood glucose control set by the Nurse Specialist (of 7–8mmol/L) would not be the accepted practice in most centres and certainly would not be at National Women's in Auckland. *([a] Diabetes Physician at National Women's would be able to confirm that.)* (At National Women's and indeed in most places in New Zealand we would aim to have the range between 4 and 7mmol/L — depending on the time of day of testing, because, the better the control (especially in Type I diabetes), the better the outcome.)

There is no sense of urgency in the letter and seemingly no realisation that at that level of HbA1c there is a significant risk of fetal abnormality in addition to the very poor diabetic control and something needed to be done rather than the focus on her so called hypoglycaemia. Thus, [Mrs A] entered the pregnancy with truly very poor control for which there would be a collective responsibility between the patient and the carers. It would be hoped that women with long standing diabetes and having had a previous child, would have some knowledge of the importance of planning a pregnancy and entering pregnancy with as good control as possible. On the information available, it is not possible to comment further on pregnancy education and/or patient compliance or other difficulties.

Thus this pregnancy did not get off to a good start, but the outcome was not directly related to this, however, for future women, it would seem that there needs to be improvements in the care of women with diabetes in pregnancy and this should be made known to the team involved.

After the booking, there were a number of visits to the antenatal clinic with seemingly satisfactory progress and comments that the diabetes control was improving. It would seem that the diabetes service did not do a combined clinic but saw [Mrs A] separate from the obstetric care.

If this is indeed true, then there is much to be gained by having a combined clinic not the least saving the patient time which is obvious, but also getting a more consistent care plan with clear messages to the patient. It would be a standard of care in most places now to have combined clinics.

At clinic on 3 [Month6] (the dates on the Multistix urine dip stick are probably in North American format), there were ketones in the urine but no comment apart from 'to see the diabetic team'. A note on 17 [Month6] said that she had been seen by the diabetic team.

On 3 [Month7] when seen in the antenatal clinic she had 1+ proteinuria and a 'few headaches', the blood pressure was 125/64, she was to see the diabetes team and return in 2 days for a scan. Blood tests were arranged as they were again at the next visit 17 [Month7]. (I have not been able to find all these results however the HbA1c was 70 on 26 [Month7].) She again had 1+ proteinuria which had not been present at the beginning of pregnancy — thus it was not likely to be diabetic related microalbuminuria, but a pregnancy complication. Otherwise, it appeared as though the care givers were satisfied as she was given an appointment for 2 weeks. It was noted that the scan had shown a large baby above the 90th percentile in estimated fetal weight.

The evidence must be that the diabetes control remained poor. There are no other clinic notes or letters supplied. Maybe the DHB has these, maybe the diabetes service has separate notes, but these should all be filed together. Somehow there seems to have been a lack of an overview as an HbA1c at 33 weeks of 70 is indicative that diabetic control has not been achieved. Also the new proteinuria required at least some minimal investigation, such as a mid stream urine for infection and/or to ensure a true reading. Also a protein (or albumin)/creatinine ratio could have been done to exclude significant proteinuria. There were no further antenatal notes after this as the patient became unwell and was admitted acutely.

The next entry in the notes relates to an admission on 23 [Month7] at 31 completed weeks gestation. **The entry is untimed and unsigned** and although there is a clinical plan the impression marked as an 'I' is not filled in, that is it would appear that the person doing this admission was unclear as to what the problem was (or may have forgotten to fill it in which seems less likely).

The presenting complaint was entered as 'presented with headache and unwell' (yet the ED nurse had noted vomiting). The examination seemed unremarkable and an antiemetic and codeine were prescribed. The blood tests showed heavy proteinuria (PCR 240 n=<30mmol/L), a lowish Na+ at 133.

From the electronic notes it would appear that [Mrs A] was admitted at 1535 hours on 23 [Month7] to the Delivery Unit from the Emergency Department where she had presented with the symptoms. The recorded note was of 'persistent headache felt in the back of her head' … with nausea and vomiting BSLs up a bit today 13.00 BSL was 10 …'

It is actually better for women to be seen by the obstetric rather than the Emergency Department (for many reasons too copious for this report) and that was the policy at the public hospital. However, it would be predicated on the ability of the Obstetric service to be able to attend to the patient expeditiously.

It was noted that she had symptoms of PET (this means preeclampsia) she also had 3+ ketones. It was noted that her booking BMI was 37.3 (obese).

It appears as though the assessment was done by a midwife and the Senior House Officer saw her at 2019 hours according to the electronic notes. The handwritten hard copy was unsigned and untimed. This SHO states that 'controlling fine' referring to the diabetes.

Thus there was no consideration at this point that any of the symptoms or signs could be related to diabetes.

At some stage after this the patient was seen by a [registrar] who was more senior and the plan of pain relief and antiemetics was agreed with intravenous fluids being given. The urinary PCR was now 24mmol/L (in the normal range). No comment was made about the ketosis. (Again, there was no thought that any of the symptoms or signs could be related to the diabetes.) The HbA1c was 72mmol/mol. During the early hours of 24 [Month7], [Mrs A] seemed to be unsettled and asked for pain relief though it states 'feels a bit better'. At 0522 on 24 [Month7] the Medical Registrar, [Dr I], saw [Mrs A] with respect to the headaches. [Dr I] stated that the diabetes was poorly controlled. [Dr I's] impression was of Tension headache and dehydration due to vomiting and prescribed simple analgesia, eat and drink and antiemetics as already charted. (There was no thought about the implications of dehydration and vomiting on the diabetes.)

There do not appear to be any further handwritten or contemporaneously written notes after [Dr I's] assessment and the further events of the 24th [Month7] are from the electronic Notes Print. A midwife had performed fetal monitoring and the CTG was reactive.

There was a consultant obstetric ward round at 0813 with [Drs J and K] as specialists. The BSL was 11.6mmol/L. The impression was 'headache' … 'atypical history for preterm labour but to rule out'. This was done by the use of the vaginal swab 'Partosure' which was negative. At 10:43 the IV luer was removed and [Mrs A] was discharged home with the comment 'knows to return if any signs of preterm labour, continued unwellness'.

Thus she went home without a diagnosis, no thought of investigation of the ketosis and as far as can be gathered, despite a BSL of 11.6 and the HbA1c of 72, no discussion with the diabetes service. The impression gained (and written by medical staff such as 'controlling well') was that all carers thought that the diabetic control was satisfactory; there was no overview of risk factors including her weight, previous […] week loss, previous C/S, evidence of a large fetus and

the other evidence of poor control, then the admission with symptomatology which was not worked out. This is hardly an adequate assessment.

On the following morning 25 [Month7], she was admitted via ambulance to the Emergency Department of the public hospital at 0255hrs with nausea, vomiting, increasing shortness of breath and decreased fetal movements.

The contemporaneously written notes are difficult to follow and assess but it would appear she was critically unwell although this was not stated as such by ambulance or 1st person to see her in ED. However, the initial nursing assessment says BBA (brought in by ambulance) SOB (short of breath). The respiratory rate was 22 breaths per minute which is very rapid, she was flushed, the heart rate was ~140 beats per minute, she was vomiting and as an intravenous fluid line was inserted with fluids to be given 1Litre 'stat' there were clearly concerns. It was difficult to hear the fetal heart and subsequently an ultrasound scan confirmed that the heart rate was very low — 'preterminal' and fetal demise was confirmed soon after.

There is a typed note which appears to be by [Dr L] the ED registrar timed at 0545 hours with the comment 'notes written in retrospect'. (There is a well recognised condition of euglycaemic ketoacidosis, which has also been reported in pregnancy, but this does not seem to have been realised initially. This will be commented upon later.)

There were problems with intravenous access for which help was sought. [Dr L] was concerned about the small peripheral venous access and had a discussion about this but in the doctor's own words 'met with a terse and somewhat rude response'.

At 0430 [Dr I], the medical registrar who had seen [Mrs A] the night before, was called down to see her and review results. [Dr I] wrote DKA (diabetic ketoacidosis). She did state (in my view and the evidence speaks for itself against the comments) that 'Patient seen by myself yesterday … BSLs controlled … symptoms had resolved completely by time of review and d/c by O&G'. Nevertheless, [Dr I] recognised the severe metabolic acidosis.

After further discussion, given her severe acidosis it was decided to admit her to the Intensive Care Unit and this occurred at 0600hours (Ketoacidosis generally is managed on the wards so I assume that the patient was extremely unwell, unwell enough to warrant admission to intensive care). Here the diagnosis of diabetic ketoacidosis was clearly stated along with the fetal death.

It is concerning how long it took to come to the diagnosis and maybe even more concerning that there appears to have been discord or dissention over the management of this critically ill patient. Given the time it took to treat the diabetic ketosis, it would appear that she was much more unwell than was appreciated.

The diagnosis of fetal death was made by [Dr J], Obstetrician, on ultrasound. The CTG was of poor quality (I would consider not interpretable) and because of the very high maternal heart rate there had been the valid concern that it was not certain that the fetal heart rate could be distinguished from that of the mother.

There had been difficulty recording the fetal heart noted before 0355. In the 'Notes Print' page 41 of 164 there is an entry at 0506 whereby it is stated that [Dr J] was called at 0415 and attended by 0430 and scanned at 0440 confirming a fetal bradycardia of 60 beats per minute and fetal death at 0500. The entry also confirms the difficulty getting intravenous access. There is a comment that there had been 'no idea how long this terminal [fetal] bradycardia had been occurring for, I elected to stabilise [Mrs A] first …'. The family were informed of the gravity of the prognosis for the baby.

This is a difficult situation to be in and to do what [Dr J] did is a courageous plan but not unreasonable especially if the mother was so unstable that an emergency caesarean section under general anaesthesia could have been life threatening for her. It is not possible to comment further on the actual appearance of the fetal heart (which may have had almost no ejection and therefore a high risk of fetal damage if the baby had survived an emergency delivery or suffer a neonatal death from profound asphyxia damage) and the state of the mother except that from the biochemical results, she would be critically ill herself. We have to accept the comment that fetal heart appearance was that of a preterminal rhythm and ejection — such as barely moving or fasciculating).

In the Intensive Care Unit, definitive treatment for the diabetic ketoacidosis (DKA) was instituted (for some reason the O&G specialist said that there were no signs of DIC (disseminated intravascular coagulation) so not for C Section at present). *DIC is very rare in DKA and would not be expected after intrauterine death for some time*.

The patient had been given 2 litres of IV fluids and insulin and the comment was that she 'looked better'.

At 0820 on 25th [Month7], there was a combined ward round in the ICU where the impression stated was

> Severe DKS ?trigger pregnancy with IUFD 0 sign of infection
>
> Intrauterine fetal demise
>
> Acidosis not improving despite treatment

after which there was a plan.

The 'impression' seems difficult to understand. Intrauterine death would not trigger DKA (more likely to be the other way around) and there were no symptoms nor signs of infection). Also, it is well recognised in the management of

DKA, that the acidosis may take a very long time to clear, much longer than achieving euglycaemia and general improvement in the patient's condition.

From the fluid charting on 25 [Month7] she was given Hartmann's solution at around 0330 and again at 0430 and 0530 hours. It appears that after this 'plasmalyte' was used at least on the 27th [Month7]. These two intravenous fluids are not recommended now as the primary treatments in this condition (see attached guidelines and also Medsafe sheet regarding plasmalyte. It is beyond the scope of this report to go into the details of fluid management in DKA but it would appear that the management given is not consistent with current published guidelines both internationally and from the Auckland District Health Board).

(The Health and Disability Commissioner may wish to ascertain if MCDHB has a protocol for DKA and if it was followed in this case and also, if it is not consistent with the current guidelines why this is the case.)

(In the references, I provide further evidence to support these comments.)

During the morning of the 25th [Month7] it was decided to perform a caesarean section, on the basis it would appear that the acidosis was not correcting and that delivery of the fetus and placenta would improve the mother's condition.

Given the literature around the time it may take to clear the acidosis (up to 38 hours in some cases or longer — see Montoro reference) plus the fact that in the notes it had been written that she seemed 'better' after some fluid replacement, the reason for the caesarean is unclear. Delivery could have been effected (or at least attempted to be effected) vaginally and a very reasonable option — and probably safer —, would have been to prescribe the antiprogestagen Mifepristone — registered in New Zealand for the management of intrauterine death and/or then prescribe misoprostol and induce labour. This would have given the patient the option of avoiding a repeat caesarean section and its morbidity, both immediate and long term.

During the ensuing 5 days, the patient made a gradual but good recovery. Appropriate management with lactation suppression and thromboprophylaxis was given and there was a follow up plan. A post-mortem was performed on the baby which in effect confirmed (due to lack of other findings) that the baby had died a metabolic death, that is from the maternal ketoacidosis.

[Mrs A] was discharged on 30 [Month7]. Despite inaccuracies in the postnatal discharge summary computer generated by a hospital midwife, there was a follow up plan. The community midwife follow up note stated that she was first seen at home on 3 [Month8], that is, 4 days after the discharge. This is tending to be the pattern now in New Zealand with no fixed appointments made to see the woman with telephone communication being used. It is unclear when she was next physically seen as there are few entries in the Postnatal Mother assessment form. In this case given all that had happened more actual face to face assessments with a formal psychological as well as physical examination would seem appropriate.

In answer to the specific questions and Issues

(In italics are responses to standards of care and possible departures as well as likely peer opinion.)

Question 1.

As stated, it is impossible to comment on the adequacy or otherwise of the antenatal education given as there are no records provided about this. I have tried to highlight the situation as I see it, particularly the issue of having a combined diabetes in pregnancy clinic and also given the patient's longstanding diabetes, the planning and advice that all women are given prepregnancy. It does not appear to me that there has been an assiduous overview of her whole case and a clear list of all the risk factors that she brought into the pregnancy. The assessment on 16 [Month4] was incomplete and there did not appear to be an awareness of the possibility that such a patient could be at risk of DKA or simply slipping into very poor control.

Whether there have been any departures from standards of care depends on whether the DHB can confirm what it does generally and also provide you documentary evidence of what was provided to [Mrs A].

Question 2

Point 1

The issue of the use of Delivery Unit vis a vis the ED area relates to how best to serve women and how the Unit best functions. In general, I would support women going to a woman focussed area especially when an ED does not have such a focus or if it is physically distant from the women's area. However, it is incumbent upon the Women's Health Service to ensure that they provide timely expert care and should they need ancillary diagnostics such as laboratory services or imaging, that they can get these expeditiously — it is obvious that many times, pregnancy emergencies cannot wait and there are two patients, mother and fetus. So the Mid Central DHB needs to look at its processes and decide what will best serve women.

There are mixed views in Delivery Unit assessment vis a vis ED. Different DHBs have different processes. Generally however, for women who are stable and/or have obviously a pregnancy related problem eg antepartum haemorrhage, then immediate admission to the Women's Health Service is best. This is what happens in Auckland DHB. Where the issues may be of a more general nature such as a severe road accident with multiple trauma, then ED is best.

Point 2

RMO review was not timely (the handwritten notes were not timed). Unfortunately, the impact of the timeliness depended on the triaging midwifery assessment and also the assessment and knowledge of the RMO when that person did arrive. If the triaging midwife had no knowledge of the potential issues that

the patient could have had, she would not impart any urgency or sense of severity. Thus, part of timeliness would be to having the most appropriate person act as the initial 'diagnostician' at the door. So, as part of the MCDHB review of the triage process, the breadth of experience of the person doing the triaging needs to be considered. However, in this case, the time from admission to RMO was too long as it was around 4 hours.

There are no absolute rules in New Zealand about timeliness and in this era of LMC midwives being placed in positions of diagnostic responsibility it may depend on each DHB how the triaging is performed. It would seem a good plan that where there is any diagnostic dilemma, a serious problem or a woman with comorbidities, that there be medical review as expeditiously as possible and in any case within the hour. The Commissioner may wish to consider a recommendation about this.

Point 3

The standard of the RMO assessment needs to be considered in terms of all the RMOs who assessed [Mrs A]. Unfortunately, none considered that any part of the symptom complex could be related to diabetes (prior to the last admission to the ED at 0255 hrs), and what history was documented is superficial and not in enough depth nor breadth to have encompassed alternative possibilities. From my years of experience in hospital medicine, I would have to say that what has been written by the RMOs in this case would be similar to what could be found in many institutions, however, that is not to say it is adequate.

There were missed opportunities. A review of all the risk factors such as the diabetic control, the obesity, the fetal size, the patient's being unwell and then the ketones should have alerted the RMOs to potential for DKA or at least consider more than 'tension headache'. This is in my view a reflection of lack of depth in assessment even if the problem of euglycaemic DKA had not been known. I would think that many peers would consider that the assessments missed key points. One of the problems with this case has been that the notes do not reflect the thought processes of the staff concerned so it has been difficult to ascertain whether the problems were lack of knowledge, or lack of care and consideration of differing diagnoses. Handbooks on how to assess patients such as the RMO handbook for juniors in Auckland DHB or even the Oxford Handbook of Medicine — any modern pocket book could be referred to if there is a diagnostic dilemma. There may also be issues of teaching or supervision in this DHB and it may be that the Commissioner could ask the DHB to review how triaging, assessment and supervision is done in Mid Central.

Point 4

This follows from the above. The 'diagnostic formulation' was incomplete and as I noted above in my case summary, at least one RMO felt that the symptoms and signs did not fit. It is correct therefore that the cues such as the ketonuria did not trigger further investigation and it seems that either the RMOs took [Mrs A's]

comments about her control at face value and/or with a lack of awareness that there is such a possibility of euglycaemic DKA, it took a long time (2 admissions) to reach the definitive diagnosis. Perhaps of more concern was that on the ward round the following morning, 24 [Month7], she was allowed to go home with clearly poor control and with no inpatient assessment by the diabetes service. Thus even if the RMOs had missed a number of points, the overall check and balance — one of the purposes of a specialist round — did not occur.

I believe that O&G peers would be critical of the specialist review, because there does not seem to have been an holistic view of the case and it was very unfortunate that the whole issue of the diabetes did not feature in the plans. I suspect that there were medical and system factors of importance. If there is not an expectation of a combined diabetes service with in patient and outpatient commitments then patients are at risk of being missed. There is a question as to whether there is a diabetes physician dedicated to pregnancy given the prevalence of diabetes in general and in pregnancy; the DHB needs to have a service and staff dedicated to pregnancy diabetes.

Point 5

The consideration of DKA would have hinged upon being alerted to the ketonuria and stepping back and taking stock of the whole case. It would probably be fairer to say that she was at risk of DKA and that this risk should have been considered. That is, if she had been unwell, if a history had teased this out and her obviously poor control (for whatever reason — compliance or medical difficulty) had been noted then there hopefully would have been less desire to get her discharged. I just don't think anything apart from 'tension headache', preterm labour or preeclampsia was considered and that is inadequate.

Point 6

The question of whether blood gases should have been done really hinges on being on top of the case, how unwell and so on. However, specifically, a diabetic with ketones needs to be investigated and either a venous gas or serum hydroxy butyrate should be done. There is a condition called 'euglycaemic' DKA where the blood sugar is not very high, but the point really is, if the diabetic has ketones, then the question has to be asked — why — what is the cause and this must be investigated. I could not ascertain for sure in this case, whether the midwife (or someone else such as a health care assistant) tested the urine on the admission but this did not get passed on or whether it was disregarded by the RMO. In any case, all DHBs in New Zealand should have a policy that if a pregnant woman with established diabetes presents with ketonuria, then risk of DKA must be considered and appropriately investigated. This is very simple and involves simply a venous blood test for hydroxybutyrate and gases.

My advice from those working directly in the field of acute medicine would be that a basic workup such as gases and serum hydroxybutyrate should be done. This was a missed diagnostic opportunity and if these investigations had been a protocol, then it is almost certain that she would have had the diagnosis made at

the first admission, and the baby would most likely have survived! Medical physician peers would be critical of the care, obstetricians may be less so but would most likely have referred for expert advice.

Point 7

The short answer here is no and this relates to all the comments above, so on the first admission, at the very least the discharge the following day was done without a clear diagnosis.

As mentioned in the report, the review on the specialist ward round was not holistic. I believe many but not all peers would consider that the outcome of the round was inadequate in that it did not address important issues such as the diabetes.

Point 8

Following from the above point, noting the poor control and the high blood sugar levels, the Diabetes service needed to see her before discharge. If this is not currently standard practice in MCDHB, then this needs to be reviewed. Also, the inpatient review of the patient, in such a circumstance, needs to be by a physician, not a diabetes nurse specialist who is trained to adjust insulin and provide patient advice, but is not trained to a level to manage the complexities of diabetes.

This I believe was not up to a standard needed [at the time]. Where there is supposed to be multidisciplinary care, then the various disciplines need to be involved. I believe that nowadays, with the complexity that this patient brought into the pregnancy and in particular the current admission, she needed to have a full review. Most peers would agree with this. In very small centres where multidisciplinary teams are not available at least telephone communication could be had. In centres such as [this], which is a large secondary maternity hospital serving a large hinterland, there needs to be dedicated maternity teams to look after the special medical and high acuity problems. Failing that, there would need to be referrals of such patients to tertiary hospitals and for many women that would not be necessary so the local institution needs to ensure that good care can be provided.

Point 9

This point is really based on what the care team thought the diagnosis might be. I was surprised that they did not consider an atypical presentation of preeclampsia — or if they did this was not documented. For some reason there seemed to be a focus on excluding preterm labour. It is not possible to comment further as the standard of monitoring and observation at the first admission was focussed on different issues from revisiting a diagnostic process.

Similar comments to previous points.

Question 3

Point 1

It seemed that it took some time to finally reach the diagnosis of DKA — at least that is how the notes read, although the ED officer did consider it and aggressive IV fluids were commenced by 0330. Thus, although the care team was somewhat put off by the blood sugar levels, they did eventually accept that DKA was the diagnosis. I suspect given what would seem to be some of the dynamics going on in the ED area, (alluded to above in my report from the verbatim comments of the ED officer), the actual diagnosis and getting on with treatment probably occurred as quickly as it would in many such Departments.

I believe that peers would view with concern the comments from the ED officer about rude and terse responses. There is no place for such behaviours and these can lead to harm to patients. I would expect all peers to agree with that.

Point 2

I have included in this report what I would consider to be the current management of DKA. It is of concern that these recommendations differ from the treatment that the patient received. The treatment was begun by 0330, but it was not how DKA would be managed in many other centres nowadays.

The standard of care and the documentation is less than best practice now. Most people working in the area would be aware of current guidelines and the literature on fluid replacement and the course of recovery. If the ICU staff advised the obstetric service to perform a caesarean section, I believe this was based on an incorrect appreciation of the effect of a fetal death on the course of the disease.

Point 3

The management of the fetal bradycardia, by not expediting delivery at 0430hrs was probably appropriate and I have commented upon that. The reason being is that the clinician involved felt that the baby was in such a state that serious neurological damage was inevitable and hence there was no prospect that urgent delivery would lead to a good outcome. It is assumed that some sort of brief but traumatic discussion was held with the husband even if [Mrs A] was in no state to comprehend. The notes are brief on this point.

Many peers would struggle with the documentation but most would support the decisions made not to expedite delivery.

Point 4

It was certainly reasonable to defer delivery until [Mrs A] was stabilised. In fact as I have commented in my report, there was no need to expedite delivery later in the morning as the patient condition had improved despite the laboratory results. (The entries in the notes are brief in fact there is an entry at the combined ward round and one at 1335 hours 25 [Month7].)

I have commented previously. There is little evidence to suggest that delivery was needed and the notes do not reflect whether the patient was getting clinically better. All there is, is the comment about no improvement in the acidosis. This in my view is problematic but it has been difficult to form an absolutely firm opinion. However, in the service in which I have worked for many years, the aim would have been to achieve a vaginal birth if at all possible for now and the future. There may not be peer consensus on this point, but both in the developing world and in those places where there is an incisive examination of indications for caesarean section, it would have been considered reasonable to try to avoid caesarean section.

Point 5

The cause of DKA was most likely due to non compliance–poor control with the insulin and the gastrointestinal upsets and other problems that were associated with the first admission. There was no evidence of infection and the white blood cell count and the CRP would be consistent with the DKA and the severe pathophysiological disturbance the patient underwent. In retrospect of course there was no sign of infection anyway, neither in the pregnancy (amniotic fluid, placenta or fetus) nor in any of the maternal specimens. Infection is a possible cause of DKA and does need to be considered, but if it was it was not well documented but there were not strong symptoms or signs of infection in this case.

Data from New Zealand and overseas suggests that non compliance with insulin requirements is the biggest single reason now for DKA. The problem in this case has been lack of the documentation, (which may still be forthcoming). There is no real analysis in the notes, once DKA was diagnosed to tease out why this might have occurred — and nothing also at discharge to provide guidance on how to reduce risk of recurrence. (She had had DKA previously.) I believe this is below the standards expected. Apart from wanting to get the baby delivered by caesarean section to improve the recovery, there does not seem to have been an analysis as to why this had happened in the first place. Given all the history and what has been said, this is a serious omission. Most peers, at least physician peers would agree with that.

References:

In these references, I have written in italics my description of the reference and its relevance to the case. (I can provide these in hard copy should the Commissioner require these.) They are of interest and provide context from which I have been able to base some of my comments.

1. **DKA guideline Auckland DHB RMO handbook**

Clinical presentation:
Thirst, polyuria, weakness, abdominal pain (30%), nausea and vomiting (50–80%), shortness of breath (Kussmaul respiration), drowsiness and coma

Diagnosis of DKA
The following must be present and documented:

- Hyperglycaemia (usually but not always >14mmol/L)
- Evidence of ketosis as raised serum β hydroxybutyrate or at least (2+) ketonuria
- Metabolic acidosis (bicarbonate (HCO3) ≤18mmol/L, pH ≤7.3)

Biochemical severity of DKA can be graded as follows:

- Mild: pH 7.25–7.30, HCO3 15–18mmol/L
- Moderate: pH 7.0–7.24, HCO3 10–15mmol/L
- Severe: pH <7.0, HCO3 <10mmol/L

Potentially serious errors to avoid

- Not seeking senior help early
- Striving for rapid control of hyperglycaemia and acidosis: the morbidity and mortality of DKA is related to hypovolaemia, electrolyte disturbance, coma, lack of airway protection and precipitating events e.g. sepsis. It is treatment of these aspects that is most important
- Not monitoring K+ frequently or commencing K+ too late. (K+ should be monitored at least 2-hourly initially, minimum 3 measurements in the first 24 hours)
- Use of insulin. In DKA use IV insulin
- Underestimating fluid deficit

11. Fluids and insulin:

- The first litre of hydrating solution should be sodium chloride 0.9% given as quickly as possible in the first hour and followed by 500–1000mL/h of sodium chloride 0.45% or 0.9% (depending on the state of hydration and serum sodium) during the next 2h
- The type and rate of continued fluid replacement will depend on assessment of clinical and biochemical factors
- If hypernatraemic (>146mmol/L) consider sodium chloride 0.45%
- Repeat electrolytes regularly as above. K+ may be required in large amounts (often >20mmol/L). Do not begin to replace until K+ <5.0mmol/L and urine output >30mL/h. When K+ <5.0mmol/L begin replacement at 20mmol/hour — don't wait until K+ is low
- Insulin: do not strive for rapid control as glucose will often fall significantly with rehydration alone. Thereafter commence an IV insulin infusion according to table 1

2. Maria Grazia Dalfrà, Silvia Burlina, Giovanni Sartore & Annunziata Lapolla. Ketoacidosis in diabetic pregnancy, J Maternal-Fetal Neonat Med. 2015;DOI: 10.3109/14767058.2015.1107903

A very useful review and detailed explanation of the physiology as well as treatments.

'In pregnancy complicated by type 1 diabetes, the total absence of endogenous insulin hinders the achievement of an appropriate balance between the accelerated starvation and facilitated anabolism characteristic of pregnancy. This explains

why it is difficult to keep glucose levels within the normal range and, when hyperglycemia is not treated promptly, the pregnancy-induced lipolysis makes patients more susceptible to ketoacidosis'. (Dalfra et al 2015)

Table 2. Management of DKA in pregnancy.

Fluids
Use isotonic saline solution for a total replacement in the first 12 h with 4–6 l (1 l in the first hour; 500–1000 ml/h for 2–4 h; 250 ml/h up to 80% fluid replacement).
In cases of hypernatremia, use 0.45% saline solution.
Use glucose infusion, starting with a 5% dextrose, when glucose levels drop <250 mg/dl (14 mmol/l).
Electrolytes
Potassium: if normal or low, begin with 15–20 mEq/h; if high, wait until it drops to within normal range, then 20–30 mEq/l.
Bicarbonate: infusion of 44 mEq only if pH < 7.
Insulin
An initial bolus of 10–15 U of regular insulin (0.2–0.4 U/kg).
Intravenous infusion with 2–10 U/h.

Table from Dalfra et al 2015.

3. Dhatariya KK, Nunney I, Higgins K, Sampson MJ, Iceton G. National survey of the management of Diabetic Ketoacidosis (DKA) in the UK in 2014. Diabetes Med. 2015; DOI: 10.1111/dme.12875.

This review showed that despite national guidelines, results were less than optimal. This survey was not specifically about pregnancy, but gives some insight into issues of units adopting and achieving best practice guidelines. Of particular relevance is the time to commence fluid therapy. In this case, it was similar. It would be generally accepted in internal medicine in New Zealand, that the admitting team should be able to institute initial management so it would not be considered necessary for the diabetes team to see right at the admission (where the diagnosis is clearly DKA and treatment is what is needed) — but the team should see the patient before discharge.

'The results showed that 7.8% of cases occurred in existing inpatients, 6.1% of admissions were newly diagnosed diabetes and 33.7% of patients had had at least one episode of DKA in the preceding year. **The median times to starting 0.9% sodium chloride and intravenous insulin were 41.5 and 60 min**, respectively. The median time to resolution was 18.7 h and the median length of hospital stay was 2.6 days. There were also significant issues with care processes. Initial nurse-led observations were carried out well, but subsequent patient monitoring remained suboptimal. **Most patients were not seen by a member of the diabetes specialist team during the first 6 h, but 95% were seen before discharge**. A

significant minority of discharge letters to primary care did not contain necessary information'.

4. Gosmanov AR, Kitabchi AE. Diabetic Ketoacidosis. In: De Groot LJ, Beck-Peccoz P, Chrousos G, Dungan K, Grossman A, Hershman JM, Koch C, McLachlan R, New M, Rebar R, Singer F, Vinik A, Weickert MO, editors. 2015.

Useful comments

'Omission of insulin and infection are the two most common precipitants of DKA. Noncompliance may account for up to 44% of DKA presentations; while infection is less frequently observed in DKA patients.'

5. Karpate SJ, Morsi H, Shehmar M, Dale J, Patel C. Euglycemic ketoacidosis in pregnancy and its management: case report and review of literature. Europ J Obstet Gynecol Reprod Biol 2013;171:386–387.

This article described the entity with a useful literature review of reported cases.

6. Kitabchi AE, Umpierrez GE, Miles JM, Fisher JN. Hyperglycemic Crises in Adult Patients With Diabetes. Diabetes Care. 2009; 32:1335–1343.

This extensive review article detailed fluid therapy. Like all contemporary articles it was consistent with its use of normal saline and the overall care plan. The [MCDHB] therapy seemed to differ from these guidelines.

'Fluid therapy
Initial fluid therapy is directed toward expansion of the intravascular, interstitial, and intracellular volume, all of which are reduced in hyperglycemic crises and restoration of renal perfusion. In the absence of cardiac compromise, isotonic saline (0.9% NaCl) is infused at a rate of 15–20 ml/kg body wt per hr or 1–1.5 litre during the first hour. Subsequent choice for fluid replacement depends on hemodynamics, the state of hydration, serum electrolyte levels, and urinary output. In general, 0.45% NaCl infused at 250–500 ml/h is appropriate if the corrected serum sodium is normal or elevated; 0.9% NaCl at a similar rate is appropriate if corrected serum sodium is low. Successful progress with fluid replacement is judged by hemodynamic monitoring (improvement in blood pressure), measurement of fluid input/output, laboratory values, and clinical examination. Fluid replacement should correct estimated deficits within the first 24 h.'

7. Montoro MN, Myers VP, Mestman JH, Xu Y, Anderson BG, Golde SH. Outcome of pregnancy in diabetic ketoacidosis. Am J Perinatol 1993; 10:17–20.

A useful review of outcomes. It would be fair to say that to have DKA and fetal loss in pregnancy nowadays is rare and in a patient having hospital care would suggest a breakdown or failure somewhere in the system.

(In type I diabetics) … Patients with a fetal death presented later (after 24 weeks), the DKA took longer to resolve — 38 hours as opposed to 28 hours in the early presentations with live fetal outcomes — and in this group 2/20 had severe ketoacidosis with lowish sugars. Precipitating factors were poor compliance, infection unrecognised diabetes (not relevant in this case) and in these there was a high fetal mortality.

8. NZ Medsafe Datasheet Plasmalyte 148 pH 7.4.12 June 2014

Local guidance on fluids

'PRECAUTIONS
Plasmalyte 148, pH 7.4 infusion solution is not indicated for:

- The treatment of hypochloremic hypokalaemic alkalosis and should be used with caution, in patients with hypochloremic hypokalaemic alkalosis.
- The primary treatment of severe metabolic acidosis.
- Hypomagnesaemia'

9. Veciana M. Diabetes ketoacidosis in pregnancy. Seminars in Perinatol. 2013;37:267–273.

A very good review article explaining why pregnant women are at greater risk of DKA than non pregnant subjects. Also a detailed discussion of treatments with N/Saline being the fluid replacement of choice. Veciana's table of clinical features of DKA is table 1 here. The case in question had some of the features.

Table 1 – Clinical features of DKA.

Nausea/vomiting	Hyperventilation/fruity breath
Polydipsia	Dry mucous membranes
Polyuria→Oliguria	Tachycardia
Weakness	Hypotension
Weight loss	Mental status changes
Abdominal pain	Coma

10. Yong KW, Moore MP, Lunt H. Medically facilitated discharge of adult diabetic ketoacidosis admissions: precipitants and average length of stay. N Z Med J. 2014 Apr 11; 127(1392):86–94.

A local summary describing the common causes of admission with DKA in New Zealand:

'The majority of DKA admissions were of short duration. Achieving further reduction in LOS is therefore difficult. Insulin omission was the commonest DKA precipitant. Diabetes clinical resources may be best allocated on preventing DKA admissions, rather than facilitating early discharge.'"

Further advice 18 January 2016

"I am now in receipt of records from the MidCentral DHB Diabetes Service and some antenatal records — these latter being copies of what I had already received. Given that this must be the totality of records available I will now complete my report.

The new documents have enabled me to clarify some issues and also form an opinion. However, I do not need to modify the substance of my 'preliminary' report and the comments regarding the inpatient cares remain.

The comments included are based on ~70 pages of notes supplied from the MCDHB Diabetes Service dated from 12 [Month1] through to 23 [Month7] with a comment on the sheet dated 23 [Month7] on 26 [Month9] about the stillbirth and that she was seen by [Dr D] on that day with a plan to recommence subcutaneous insulin when ready to stop IV. There are no further notes supplied about the consultation and it is not clear therefore if [Dr D] wrote a separate letter that day.

The first record I have is a detailed summary on 12 [Month1] when she was seen by [Dr E] (Diabetes Physician) who stated 'she is actively trying to become pregnant again and obviously her HbA1c is suboptimal … She admits to not infrequent miscalculations in regards to carbohydrate estimation and I wonder if a refresher in carbohydrate counting might help bring down her HbA1c …'

[Dr E] also wrote a letter to [her GP] and referred her to the Diabetes nurse specialist as well as to [a psychology service] because '… she was actively trying for pregnancy and … she was a poor attender at previous appointments and not measuring glucose levels …'

The [psychology service] stated that their aim was to 'explore barriers to her management of diabetes and perhaps … (word illegible) …'.

It is clear that she **must have been very early pregnant** at the time of this appointment [in Month1], because when seen in the antenatal clinic after referral from [her GP] on 21 [Month2], she was already 9 weeks pregnant. It would seem that a menstrual or pregnancy history was not taken or not documented by [Dr E].

One of the benefits of having combined pregnancy and diabetes clinics is that physicians think of pregnancy as well as diabetes. Although, it was not thought that she was pregnant on 12 [Month1], a history of menstruation and a pregnancy test if pregnancy was possible, would have clarified the issue at that time. Whilst this does not impact directly on the outcome which has led to the complaint, it is an example of how compartmentalised care can fail to detect issues such as pregnancy (by my calculations a serum BHCG test would have been positive on 12 [Month1].

Similarly, it was known by the GP and [Dr E] that she was taking Fluoxetine which is an SSRI type of antidepressant which does have a small but significant risk of fetal anomalies especially fetal cardiac and skull bone defects. Thus early specific

counselling and/or referral to the Obstetric Specialists at the public hospital would be appropriate should she have wished that.

It is also clear from [Dr E's] letter and [the psychology service] report, that [Mrs A] was not a good clinic attender and outside of pregnancy, did not care for her diabetes particularly well. For much of her pregnancy in 2014–15, she did however email through results on a regular basis.

Close to [Dr E's] letter of 12 [Month1], there was an undated Diabetes Assessment/Education Checklist which had been filled in and it would appear to me that this was done on 12 [Month1] as it fits with the outcomes of the consultation that day. The checklist is that used by the clinic and appears very full indeed but although it has a line for urinary ketones, it does NOT specifically mention Diabetic Ketoacidosis (DKA) anywhere on the sheet.

In the case of [Mrs A], the sheet did not have the urine test for ketones ticked, but it did have ticked 'when to contact Health Professional'.

Thus, as part of the complaint, it has not been possible to confirm or refute whether or not [Mrs A] ever received education on urinary ketone testing or information about DKA. I made the point in my first report that she had been prescribed urinary ketostix so at some point, the need to test for ketones must have been raised with her. Whilst I can date the prescription, I cannot find any reference in any notes to the ketostix nor what she may have been told. This would have to be clarified by the HDC interviewing the staff and the complainant.

On 13 [Month2] [Mrs A] saw [Ms F], the Clinical Nurse Specialist Diabetes. The consultation seems to be have been focussed more on hypoglycaemia, but nevertheless the documentation and presumably the consultation appears to be very full. There was no documentation about DKA neither was the row in the Diabetes and Endocrinology Service Pregnancy Progress notes sheet labelled UK (which means urinary ketones) ever filled from 6 [Month2] through to 23 [Month7].

The Pregnancy Progress Notes have been provided and in general [Mrs A] was testing on a daily basis and the sheets document the blood glucose levels with sometimes comments also. As a summary, control gradually improved and was more stable by the week of 10 [Month3]. When there was a break in reporting, it appears that the clinic staff contacted [Mrs A] and asked her to email in results which she did. There is a gap in the record between 7 [Month5] and 19 [Month5] and there was an email on 20 [Month5]. At that time the Nurse wrote that she had discussed the results with [Dr D]. On 24 [Month5] there was some deterioration in control of the blood glucose and emails around 27 [Month5] suggest that the poor control was recognised and adjustments to the insulin dosages were made. At no time can I see any record of urinary ketone testing, however, as the control was improving after this, the requirement for this would not be absolute.

The week beginning 2 [Month6] showed better control and the weeks 9 and 16 [Month6] seemed stable, though either the clinic or the patient seemed to run the blood glucose levels higher than some clinics would consider optimal.

On the week beginning 3 [Month7] there is the comment that 'has cold' and the note 'increase nocte Lantus' was made by the nurse.

On the week beginning ~9 [Month7] in the 29th week of the pregnancy, results seemed unchanged.

On 16 [Month7] at week 30 in the pregnancy, the record becomes incomplete. There is a comment that a scan has shown the baby to be big ('increased baby growth') and a further comment increase Lantus BD. That is the last record I have received and I believe it is probably the last outpatient record available of the blood glucose levels.

There are a number of concerns about this care. It appears that much of the care was done by telephone or email, which may be appropriate where control is good but this pregnancy began with very poor control. It is not clear how often a doctor reviewed the notes and at the time when there seemed to be concerns about hypos there were periods subsequent to that when the control was poor. This may reflect poor management of the hypos or that because the patient usually runs high, even being brought to a 'normal' level of blood glucose may precipitate feelings of hypo even when the blood levels are in the normal range. Taking treatment for a 'hypo' in such circumstances may make matters worse. It is not possible to say if this sequence of events was occurring. It is unclear whether medical help was sought. There may be an element of patient factors in this as well as people who have had diabetes for a long time usually are able to make minor adjustments. For example, when it was reported that [Mrs A] had a cold, many patients would have looked at their blood glucose levels and made a 2–4 U adjustment of the insulin to cover the stress of the infection. I have no sense of how well or otherwise she understood and managed her diabetes on her own. I also have a concern that the very high HBA1c indicated much poorer control than was reflected in the records of the blood glucose that were available at the start of the pregnancy.

After this date there are no more records, so there is nothing to provide help in understanding what precipitated the sequence of events which finally led to the first admission to hospital in [Month7]. That is, the development of DKA (even euglycaemic DKA) usually has a gradual or insidious onset, but in the absence of failing to take insulin (a common cause — see references already provided) infection, dehydration such as from vomiting or diarrhoea are likely causes. There are no records about this, so it is not clear to me why from 17 [Month7] to 23 [Month7] there is nothing in the medical record. **The HDC would need to interview the complainant and the hospital staff to find out whether the patient lost contact for some reason, whether there are missing or more notes elsewhere or whether there is some other explanation.**

This is relevant in ultimately ascribing responsibilities related to the outcome in this case. As previously discussed in my first report, pregnant women are at increased risk

of DKA compared to non pregnant and males, and in a case where control is poor and there may be issues of compliance or understanding, there would be extra concerns. In such circumstances, the risk of DKA is higher and the need to test for ketones, especially during periods of being unwell or when control is poor becomes particularly important.

Summary — Opinion:

This complaint to the HDC was from a patient with longstanding poorly controlled diabetes.

Some of the issues of control could be attributed to patient factors as stated in the notes and by comments in the notes from the patient herself.

She was at risk of diabetic ketoacidosis especially when pregnant. Whether or not she and the physicians and obstetricians looking after her were aware of this is difficult to define from the case records provided. Evidence about that is difficult to find and I am unable to determine what the patient knew (longstanding diabetes and she had had DKA before), what the diabetes service had told her and what alerts the clinicians were aware of.

There were a number of obstetric risk factors in addition to the diabetes including her obesity (high BMI), previous caesarean section, anxiety-depression, previous late miscarriage.

During the index pregnancy, in the early periconceptual period, diabetes control was very poor which increased the risks of a fetal problem as did the use of Fluoxetine, but fortunately, no structural fetal abnormalities occurred.

It appeared that for the most of the pregnancy up until mid [Month7], there was close surveillance of blood glucose levels with improving control. From the Diabetes monitoring records there are no notes about any event which may have precipitated the admissions to hospital and information about that has to be retrieved entirely from the inpatient hospital records.

It is highly likely that the baby died as a result of the severe maternal diabetic ketoacidosis.

There was delay in diagnosis of the DKA. On the first hospital admission in [Month7] there was no diabetes service overview and the reason for admission and readiness for discharge were not viewed in great depth by the team with, for some reason which is not explained clearly, a focus of preterm labour rather than other issues.

At the second admission there again was some delay in appreciating the DKA and the acuity of her illness and given some comments in the case notes, there may have been some discord in the communications between staff caring for her.

The treatment used to treat the DKA was different from that published and used in other centres nowadays.

The decision to perform a post-mortem caesarean section based on progress in correcting the DKA is not in my view justified (for that reason) as the DKA was improving and was progressing along what are expected time courses, it being known that the acidosis takes longer to resolve than the abnormal glucose levels — in this case pregnancy related 'euglycaemic' DKA was likely.

Documentation was a problem in reviewing this case. At times the notes were brief, at other times whilst there were entries, the reasons for decisions were not clear.

Follow up did occur, but the documentation about the outcomes of the follow up discussions are not available. I have had to ask for records that were not supplied and it is unfortunate that obtaining information from the DHB has proven to be difficult. The notes as given are not easy to follow.

The lack of a combined diabetes and obstetric clinic with in and outpatient commitments may have contributed to the lack of holistic care and oversight in this case.

The patient presented a very difficult and challenging clinical situation and the staff have tried hard but a mix of system issues and not considering a wide range of possibilities for her presentation at the first admission misled the staff. It would appear (though it is not specifically stated in the notes) that she was readmitted extremely unwell — but it did take some time before definitive treatment was established and effective. Everyone involved has an opportunity to learn from the events in this case and also there is an opportunity to review systems generally, both in the obstetric service and in the Emergency-Intensive Care Departments."

Further advice 9 June 2016

"1. Having read the letter from the complainant, it would seem that she is grateful for the debriefing and would look to finding out in due course what changes MidCentral DHB (MCDHB) finally make. Based on her letter which I think all parties accept, it would seem that had the ketones been rechecked on the morning after the first admission, the course of the subsequent events would have been different. Heavy ketonuria in this situation would be unlikely to have resolved that quickly with the 'fluids' as given. (I do not think I have the fluid chart for that evening to see the volume and nature of the fluid infused.)

2. The Letter from the CEO is helpful and some changes have been put in place.

With regard to the comments around question 2c, all I can reiterate is that the team of people assessing the patient (excluding the locum consultant obstetrician) did not fully consider the possible diagnoses. Whether the ketosis was due to diabetic ketoacidosis (DKA) or dehydration — these are along a spectrum anyway, the fact that that information and a recheck were not considered was an omission. I do accept that euglycaemic DKA is a complex diagnosis but had the locum's suggestion been followed up and had the medical-diabetic team seen her prior to discharge events may have bene different.

As far as 2d in the CEO letter is concerned, again I will beg to differ, but acknowledge that I was not there. However, I did provide referenced evidence that a different course was a possibility and the comments from the ICU specialist that the patient became better after the delivery is really a self fulfilling prophecy and there is no way of knowing whether or not this would have happened anyway. However, in terms of the complaint and the comments from myself, I think the caesarean section issue is a small point. I was not convinced that there was sufficient evidence for uterine sepsis to be a very likely problem, but if the clinicians felt that was the case then maybe their decision to perform the Caesarean could be justified. However, there was no evidence of intrauterine sepsis at operation, so the reason for her improvement could not have been due to removing a septic focus. Also, I do note that those comments as well as comments about fluid management were not offered to the HDC at the original request for comment. I also am concerned that whilst respecting [Dr B's] opinion about fluid management, if what he states is the case, he should really have ensured that the whole hospital was following his evidence and practice. He states 'they deviate …' well then if this is done for the good reasons he states, they need to change hospital policy. Also, it is possible that [Dr B] may have overstated the case for the advantages of Plasmalyte over Normal Saline and some studies have shown that the expected alkalinising effects of the acetate and gluconate in Plasmalyte is more theoretical that real in practice. Thus whilst again, not a major point, the whole hospital needs to determine the best fluid on the best evidence and note that in women in pregnancy, the normal run with a respiratory alkalosis and they are at risk of developing a metabolic acidosis quite quickly when dehydrated due to the physiology of pregnancy. Gluconate is excreted largely unchanged and may act as an osmotic diuretic, so may have few advantages in the situation of DKA. I made enquires of the ICU in Auckland and they do not have a protocol but they now also tend to use Plasmalyte in the DKA situation. Thus despite all the publications in the literature about the management of euglycaemic DKA, it would seem that there has been an 'informal' shift in IV fluid management. It would be beneficial therefore if this has become established practice for it to be embedded in protocols and placed in ICUs EDs as well as on medical wards.

If I read the CEO letter correctly, it appeared that there was a policy for Emergency Department assessment prior to this case and it would appear that that was not followed. As non Obstetric registrar arrived to assess [Mrs A], the policy stated that the ED registrar would see her and treat. This did not occur, rather the nurses had her sent to the Obstetric Department and Delivery suite.

In question 10, the point about placing blood tests such as the HbA1c and blood sugar on the computerised system available to all staff is a good one. It will be important to ensure that this does in fact happen.

3. [Dr C's] letter also brings in new material not offered before such as the SIRS concept. However, obstetrically, as the fetus had been in the transverse lie there is no question that a caesarean was appropriate as stabilising induction was shown many years ago not to be effective. (I wonder if these notes were missing from the bundle.) The time lag between offering mifepristone and performing an induction does not

have to be greater than 24 hours and indeed there is evidence of efficacy of the drug is used and then the induction is commenced so afterwards. I did not find anywhere in the notes that the ICU thought that she had the SIRS condition. However, again, I think these are secondary points and also are not the substance of [Mrs A's] complaint. As such, whether she had SIRS or not, if she had a transverse lie, on balance it would be safer to perform a planned caesarean section.

4. The letter of [Dr D] provides important insights into a service which was under resourced and poorly organised, in part due to resourcing but also due to longstanding practices or issues that clearly [Dr D] […] was trying to revise. It is clear that the midwife on the ward on 24 [Month7] would have been expected to notify the Diabetes service of the patient's admission, this is hospital policy. It is also clear as I wrote in my original report that the patient (for whatever reason) has some responsibility for poor control of her diabetes and it is noted that in 30 occasions during the pregnancy, she had to be contacted or prompted to send in her results. Of concern to [Dr D] and me (given the difficulty with the ultimate diagnosis) is the veracity of the blood sugar levels that [Mrs A] sent in, because the HbA1c levels would suggest much higher blood sugar levels than were reported. The DHB needs to make moves to ensure that the equipment for home monitoring is up to date and can download results such that these may be confirmed as accurate. I have little further to add to the full and incisive letter from [Dr D], except that this and all DHBs need to recognise that diabetes is an increasing problem and to avoid adverse outcomes, adequate resourcing — of staff and time — needs to be given to run safe services.

5. As a final comment about the information provided by the CEO letter; the guideline or protocol from MCDHB regarding Diabetic Ketoacidosis Clinical Guideline DOC CODE II — E 35; I would like to see added to the risks and precipitating causes under 2.2 the words pregnancy-vomiting-dehydration. Also under 2.4 the recommendation that the blood sugar level is >40mmol/L before referral to ICU seems very high and especially so in pregnancy.

In summary, with my comments above, I feel that the basis of my original report still stands. I acknowledge that euglycaemic (or moderate hyperglycaemia) DKA is uncommon, but I maintain that there were opportunities to potentially alter the course of events. I would not accept a blood sugar level of 11.6mmol/L (after [Mrs A's] rehydration) as a satisfactory level in pregnancy and notwithstanding her possible noncompliant behaviours, it was an opportunity to take stock and endeavour to get better control and re-engage with the diabetes service. This fact and the fact that we do not know if the ketosis was ever cleared compromised the situation on her readmission. What happened afterwards on the second admission is really secondary to the main issues in my view, but I have discussed areas where I believe some improvements are possible.

It would seem that the follow up meeting with [Mrs A] was well received and all parties can take credit for that."

Further advice 18 October 2016

"From my report and my supplementary report, I can state that I believe that the fetal death and aspects of the morbidity that the patient suffered were avoidable, so overall the outcome was potentially avoidable.

As you know this was a very complex case and there were provider, system and patient factors which all contributed to the outcome.

Thus there is learning for all from the above.

My specific responses to the issue of how serious or significant were the departures vary somewhat depending on the issues in question, the retrospective nature of the enquiry and the reliance on what was sent to me (though I know the HDC may have had further separate contact with the complainant).

I felt that the fragmentation of care, the failure to follow up on the initial ketosis and the associated discharge from hospital when the blood sugars were still poorly controlled and there had been no diabetes service input, and also the stated disagreements between staff when the patient was admitted on the second admission to the Emergency Department and the problems getting ICU involvement are serious issues. — Provider and system.

(Included in the fragmentation of care were my comments about the early pregnancy visit to [Dr E]. In my comments, there are issues of seeing the patient in isolation and also reflecting upon the impacts of poor glycaemic control as well as the use of Fluoxetine on a pregnancy. I certainly believe that the situation as described in the records is less than optimal and not best practice.)

The issue of the actual diagnosis of the euglycaemic ketosis is a difficult one (despite some clues) and as such I would not see this as necessarily a departure from standards of care as supportive therapy was given. The second admission was probably a consequence of the previous discharge when the patient was unstable, but either due to poor documentation or poor clinical assessment it is not possible to determine reason for the earlier discharge.

There does remain an element of patient involvement in her illness which I feel has not been resolved and as I don't know if the Commissioner has interviewed the complainant, I do not have sufficient information to understand why her compliance with aspects of her care seemed poor. So there appear to be patient factors involved here. Having said that, had this been more clearly apparent to the Obstetricians on her first admission, it may have led them to be less inclined to discharge her as it is possible that they thought her blood glucose monitoring at home would be better. I can only surmise this as I do not have any evidence in the reports on which to make further comment. In my report I raised an issue about the caesarean section and I still maintain those comments but as I was not there, I have to accept that the specialists

involved believed it was in the patient's interests to deliver by caesarean section. Thus I would not consider that a departure for standards of care.

Overall, I feel that the standard of diabetes care (the system as much as any thing else) was not as well organised as it could have been and this is at least moderately serious. As my report stated, all pregnant women are more at risk of diabetic complications such as ketoacidosis, than the non pregnant or males and also when control starts to deteriorate as happened here for reasons that are not fully clear, the situation is serious and requires close and detailed attention. I feel from what I can glean, that this did not occur to the level that was needed. I would hope that all concerned can learn from this.

Please let me know if I can be of any further assistance."