Counties Manukau District Health Board

A Report by the
Deputy Health and Disability Commissioner

(Case 19HDC01222)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report relates to the care provided to a woman who underwent a planned Caesarean section (CS) at a public hospital in 2018 because she had major placenta praevia (meaning the placenta was lying in the lower part of the womb (uterus), completely covering the neck of the cervix). An ultrasound was carried out prior to the CS to recheck the position of the placenta. The report from this scan also included the comment: "Given history of … previous CS and placenta praevia, placenta accreta remains a high possibility." It was noted that the surgical team was aware of the findings from the scan, including the reference to placenta accreta. Tragically, the woman experienced significant blood loss during the procedure, had multiple cardiac arrests, and ultimately was unable to be resuscitated. In this report, the Deputy Commissioner highlights how multiple systemic issues affected the care provided to the woman.

Findings

2. The Deputy Commissioner found Counties Manukau District Health Board (CMDHB) in breach of Right 4(1) of the Code for a number of issues, including the following:

- An SMO obstetrician should have been present in the theatre at the time of the surgery. If no SMO was available, then the CS could have been delayed.
- At the time, CMDHB did not have in place a specific guideline for the management of placenta praevia or placenta accreta.
- The blood fridge in the theatre complex was out of operation, which in this case meant a slight delay in the woman receiving blood products.
- There were a number of issues with the clinical records.

3. However, the Deputy Commissioner emphasised that these findings were not intended to imply that the woman's death was caused by the actions of any one person. The Deputy Commissioner acknowledged that the woman's death in these circumstances was unexpected, and was felt strongly by the staff involved, who tried valiantly to save her.

Recommendations

4. The Deputy Commissioner recommended that CMDHB: a) provide a written apology to the woman's whānau; b) report to HDC on its processes for theatre equipment maintenance; c) consider introducing processes for ensuring that accurate and full documentation is completed following adverse events, and report back to HDC; d) report back on its compliance with the guideline for placenta praevia and placenta accreta introduced on 5 March 2020; and e) use the anonymised version of this report as a case study for training obstetrics and anaesthetics clinicians.

Complaint and investigation

5. The Health and Disability Commissioner (HDC) received a complaint from Mrs A[1] about the services provided to her late daughter, Mrs B, by Counties Manukau District Health Board (CMDHB). The following issue was identified for investigation:

- *Whether Counties Manukau District Health Board provided Mrs B with an appropriate standard of care in 2018.*

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

7. The parties directly involved in the investigation were:

Mrs A	Consumer's mother/complainant
CMDHB	Provider

8. Also mentioned in this report:

Dr C	Obstetric Fellow
Dr D	Obstetric registrar
Dr E	Consultant obstetrician

9. Further information was received from:

The New Zealand Blood Service
The Office of the Coroner

10. Independent expert advice was obtained from obstetrician Dr John Tait (Appendix A) and from anaesthetist Dr Paul Templer (Appendix B).

Information gathered during investigation

Introduction

11. This report focuses on the care provided to Mrs B (aged in her twenties at the time of events) during the Caesarean section delivery of her baby at CMDHB in 2018. Mrs B suffered a haemorrhage shortly after her baby's birth and had multiple cardiac arrests. Tragically, attempts to resuscitate Mrs B were ultimately unsuccessful.

Background

12. In 2017, Mrs B became pregnant. She had previously had babies delivered by Caesarean section (CS) and had had several miscarriages. She had a history of gestational diabetes

[1] The complaint was also referred to HDC by the Coroner.

mellitus (diabetes that is diagnosed in pregnancy), pre-eclampsia[2] (a potentially dangerous pregnancy complication characterised by high blood pressure that can lead to serious, and sometimes fatal, complications for both mother and baby), and a body mass index (BMI)[3] of 42.3 (a BMI of 30 or higher falls within the obese range).

Antenatal care

13. Mrs B received antenatal care from a self-employed registered midwife. Throughout her pregnancy, Mrs B had multiple episodes of bleeding (antepartum haemorrhage (APH)). She was admitted to CMDHB's Maternity Services for APH. During her admission, cardiotocography (CTG) monitoring showed that the baby's heartbeat remained normal.

14. A scan at 30 weeks' gestation confirmed[4] that Mrs B had "major placenta praevia completely covering the os" (ie, the placenta was lying in the lower part of the womb (uterus), completely covering the neck of the cervix (the cervical os)). The 30-week scan also identified that Mrs B's baby was, at the time, large for gestational age (LGA) ("well above the 90th [centile]").

15. Mrs B was admitted to the public hospital with vaginal bleeding. While in hospital, her bleeding settled and she was discharged. Part of the ongoing management plan was for her to undergo a lower segment CS at 37 weeks' gestation. This was booked.

Preoperative planning

16. Three days prior to the CS, Mrs B's management plan was reviewed by the obstetrics team and discussed with the anaesthetist who was rostered on for the day of the CS. Following this discussion, a cell saver (a device that collects and filters blood lost by a patient during surgery, which can then be returned to the patient if needed) and an additional anaesthetic technician to operate the cell saver were arranged for the procedure. A preoperative ultrasound by a fetal medicine specialist was also arranged for the day of the procedure to assess the location of the placenta in relation to the scar from Mrs B's previous CS.

Day of delivery

17. Mrs B presented to the public hospital at 6.45am. She signed a consent form for a "Caesarean section +/- management of PPH [postpartum haemorrhage — meaning post-birth bleeding]".

Ultrasound scan

18. As planned, prior to the CS an ultrasound scan was carried out at 8.30am to recheck the position of the placenta. The scan was reviewed by the fetal medicine expert.

19. The scan report noted that the placenta was difficult to visualise because of the position of the baby, but the report confirmed that the placenta was covering the cervical os. The report also noted that there was no ultrasound evidence of placenta accreta — a potentially life-

[2] Also referred to as pre-eclampsia toxaemia (PET).

[3] A measure of body fat based on height and weight. A BMI between 18.5 and 24.9 is classified as normal weight. A BMI between 25 and 25.9 is classified as overweight, and a BMI above 30 is classified as obese.

[4] An earlier scan, at 24 weeks' gestation, had reported a posterior placenta praevia.

threatening condition where the placenta attaches too deeply into the wall of the uterus. Placenta accreta is associated with major pregnancy complications such as massive blood loss and, depending on the circumstances, can necessitate a hysterectomy (surgical removal of the uterus). However, the report also included the comment: "Given history of … previous CS and placenta praevia, placenta accreta remains a high possibility." It was noted that the surgical team was aware of the findings.

Surgical team

20. The surgeons who carried out Mrs B's elective CS were obstetric Fellow (meaning a trainee in the last year of specialist training) Dr C, and obstetric registrar Dr D. CMDHB told HDC that there had been a consultant obstetrician (ie, a senior obstetrician) rostered on to manage the elective obstetric surgery list. However, that morning, the consultant was unwell. CMDHB said that it then contacted obstetricians/fellows to ask whether they could be reassigned to cover the elective list. Dr C was the "most accessible person", and she agreed to attend.

21. CMDHB also told HDC that when the service was notified that the consultant rostered to manage the elective obstetric surgery list was unwell, the consultant obstetrician assigned to cover acute surgery that morning (Dr E) was already in theatre performing an emergency CS, and therefore he was not informed of the women on the elective surgery list. Dr E wrote in the operation note for Mrs B's CS that he was unaware that an elective CS with major placenta praevia was taking place until he was called into the theatre to assist (as noted in paragraph 29 below).

22. In addition, a consultant anaesthetist was present at the start of the surgery. Another consultant anaesthetist was in the back-up role,[5] which meant that she was immediately available if extra anaesthetic support was needed.

Preparation for surgery

23. In anticipation of possible blood loss during the procedure, as well as the cell saver, two intravenous (IV) lines were in place (to enable faster administration of medications and resuscitation fluid). In addition, four units of red blood cells were cross-matched with Mrs B's blood prior to surgery.

Caesarean section

24. Mrs B was given a routine combined spinal epidural anaesthetic prior to the surgery commencing. The operation note recorded that the initial entry (incision) into Mrs B's abdomen was straightforward, and there was no sign of placenta accreta. However, "brisk bleeding" was noted upon surgical entry into Mrs B's uterus. Her baby was delivered in a good condition at 12.15pm, and the umbilical cord was clamped and cut.

25. The anaesthetics team administered IV Syntocinon (a medication that stimulates the muscles of the uterus to contract — it is used to bring about labour, and, after birth, to help the placenta to separate from the wall of the uterus and be delivered, and to treat bleeding

[5] CMDHB told HDC that it is not usual to have a second back-up anaesthetist. A second back-up anaesthetist had been assigned specifically because of Mrs B's case.

(postpartum haemorrhage)). However, Mrs B continued to bleed, and was described as having a "rapid haemorrhage". Mrs B's systolic blood pressure (BP) (one of two measures of BP — systolic BP measures the force exerted against the arteries as the heart pumps) dropped to around 85mmHg (normal systolic BP is between 110–130mmHg). The anaesthetics team administered IV resuscitation fluids (Plasmalyte, which contains potassium) and medication to increase blood pressure[6] and treat the massive blood loss.[7]

26. Blood products were requested from the blood bank at the same time. The operating theatre's blood fridge (which is used to store cross-matched units of blood products for patients who are undergoing surgery) was not working at the time. CMDHB told HDC that the fridge was unavailable for nearly two months. As a result, the blood products requested for Mrs B (including the four units that had been cross-matched prior to surgery) were retrieved from the blood bank, which is located on a different floor within the hospital, a five-minute walk from the operating theatre. While waiting for the blood products to arrive, the anaesthetics team administered further Plasmalyte to maintain circulating blood volume.

27. In response to the provisional opinion, CMDHB noted that although the blood fridge was unavailable, its effective emergency back-up plan to store cross-matched blood units in the blood bank was implemented. It also stated that there was no requirement to have a blood fridge near an obstetric theatre, and its opinion is that the unavailability of the blood fridge near the obstetric theatre had no impact on the care provided to Mrs B.

Removal of placenta

28. Because of the ongoing bleeding, the decision was made to remove the placenta manually. The placenta separated easily from the back (posterior) lower segment of the uterus; however, it was described in the operation record as being "moderately adherent" to the front (anterior) lower segment and "required manual separation bluntly with finger". Following removal of the placenta, "brisk bleeding" was noted.

Massive Transfusion Protocol initiated

29. At approximately 12.22pm, the decision was made to commence CMDHB's Massive Transfusion Protocol (MTP).[8] The MTP is a process to aid in the clinical management of massive ongoing bleeding. Additional senior clinicians were called in, and Dr E and the back-up consultant anaesthetist arrived at approximately 12.25pm. At this point, Mrs B's estimated blood loss was two litres (severe postpartum haemorrhage is defined[9] as blood loss of one litre or more). She was noted to be looking very pale and reported feeling sleepy.

30. To try to control the bleeding, the obstetric team decided to use a Bakri balloon (a device used to help to control postpartum bleeding — the balloon is inserted into the uterus and filled with saline to compress the uterus) and perform a B-lynch suture (a type of surgical

[6] Phenylephrine.
[7] Tranexamic acid.
[8] Relevant extracts of the MTP are set out in Appendix D.
[9] In the Royal Australian and New Zealand College of Obstetricians and Gynaecologists publication "Management of Postpartum Haemorrhage" (July 2017).

stitch used to compress the uterus and help to control postpartum bleeding). The decision was made to convert to general anaesthesia due to Mrs B's ongoing haemorrhage, haemodynamic instability (broadly speaking, instability of a person's blood pressure, which can lead to inadequate blood flow to organs) and worsening conscious level.

31. Between 12.35pm and 12.45pm, Mrs B was given a Massive Transfusion Box of blood products (two units each of red blood cells and fresh frozen plasma) from the blood bank. At approximately 12.40pm, Mrs B's oxygen saturation suddenly dropped to 88%. She was given ventilation with 100% oxygen but this caused "little change" to her oxygen saturation level.

32. Following placement of the Bakri balloon and completion of the B-lynch suture, it was noted that Mrs B had "good uterine tone" (meaning that the uterus was contracting well), and no significant ongoing bleeding occurred when downward traction was applied to the Bakri balloon. Mrs B's estimated blood loss at that point was 3.7 litres.

33. However, at 12.41pm, it was noted that there was further ongoing bleeding when pressure was released on the Bakri balloon. Two other obstetric consultants were called in to provide advice and assistance. A blood gas sample was taken at approximately 12.50pm and was received by the laboratory for testing at 1.01pm. Blood gas testing determines the level of oxygen and carbon dioxide in a person's blood, as well as the acidity (pH) of the blood. It can help to indicate whether a person's lungs, heart, and kidneys are functioning correctly. CMDHB added that an arterial line was also present – as is standard of care in actively bleeding patients.

34. At approximately 12.55pm, Mrs B's uterine tone deteriorated and blood loss was noted to be watery. The decision was made for surgical removal of the uterus and cervix (a total abdominal hysterectomy), to be performed by Dr E and an obstetric consultant.

35. Mrs B continued to receive boxes of blood products "back to back" via a rapid infusion device as soon as the blood products became available from the blood bank. She also received further fluid (Plasmalyte) resuscitation.

36. At 1.08pm, the laboratory reported the results of the blood gas tests. A number of Mrs B's results were abnormal,[10] and in particular her blood pH was low (7.15 — the normal pH for blood is between 7.36 and 7.44. Abnormally acidic blood (acidosis — as measured by a lower pH) can be caused by haemorrhage). The laboratory report also noted that the blood sample size was insufficient to give reliable results for a number of other tests.[11] The anaesthetics team sent a second urgent arterial blood gas sample to the laboratory at 1.15pm.

[10] The blood gases showed increased carbon dioxide; decreased partial pressure of oxygen; decreased bicarbonate; decreased oxygen saturation; and decreased base excess.
[11] Specifically, tests for levels of sodium, potassium, chloride, glucose, anion gap, calcium (ionised), blood lactate, and haemoglobin.

First cardiac arrest

37. At 1.04pm, just before the hysterectomy began, the anaesthetics team noted that Mrs B had a haemoglobin (a protein found in red blood cells that contains iron and carries oxygen in the body) of 63 (significantly low), as well as an unstable and slowing heartbeat.[12] Mrs B's heart then stopped beating (cardiac arrest) and the anaesthetics team stepped in to perform cardiopulmonary resuscitation (CPR). Five rounds of CPR were performed, and Mrs B was given two doses of adrenaline (a medication used in emergency resuscitation as it increases the chance of restoring the heartbeat).

Second cardiac arrest

38. At approximately 1.15pm, Mrs B's cardiac output was restored. Dr E and the obstetric consultant then began performing a surgical incision. No ongoing blood loss was noted at that time. However, at approximately 1.22pm, Mrs B experienced a second cardiac arrest. Again, the anaesthetics team stepped in and performed one cycle of CPR, administered two doses of adrenaline, and delivered one defibrillator shock.

39. Mrs B's cardiac output was again restored. The obstetrics team began the hysterectomy and clamped the uterine arteries. A vascular surgeon was also called in to provide advice.

40. At 1.25pm, the results from the second blood sample were reported from the laboratory. It was noted that Mrs B had a high level of potassium,[13] and her acidosis had increased (i.e., her blood pH had dropped further to 7.01), among other abnormal results. High potassium can be caused by massive haemorrhage (and the resulting rapid administration of blood products) and can cause irregular heartbeats (arrhythmias). The anaesthetics team administered medications to lower the potassium level and prevent cardiac arrhythmias.

Third and fourth cardiac arrests

41. At approximately 1.32pm, Mrs B experienced another cardiac arrest. The anaesthetics team performed one cycle of CPR and administered one dose of adrenaline, and Mrs B's cardiac function was again restored.

42. Tragically, Mrs B experienced a fourth cardiac arrest at 1.38pm and, this time, after a prolonged and intensive effort, was unable to be resuscitated. She passed away at approximately 1.55pm. A post mortem determined Mrs B's cause of death to be postpartum haemorrhage. The post mortem also confirmed that Mrs B did have placenta accreta.

Clinical records

Blood loss and blood products administered

43. Mrs B's total estimated blood loss was documented as 3.7 litres; however, CMDHB's Adverse Event Review (AER) (a summary of the AER is included as Appendix C) noted that there was no accurate measure of blood loss in theatre, because although swabs were counted after the surgery, they were not weighed (which would have indicated the volume of blood they were holding).

[12] Specifically, it was noted that the electrocardiogram (ECG) was showing "widening complexes".
[13] 8.2mmol/L; normal range 3.5–5.2mmol/L.

44. CMDHB also told HDC that commonly during an MTP event, the empty IV and blood product bags would be collected for counting. However, CMDHB noted that in this case the operating room was cleared following Mrs B's death so that her whānau could visit, and the bags of resuscitation fluid were not accounted for. CMDHB said that the anaesthetics team estimated that Mrs B received about six litres of crystalloid resuscitation fluid.

45. In addition, based on the anaesthetics team's count of empty blood product bags, Mrs B received a total of 14 units of red blood cells, 14 units of fresh frozen plasma, 6 units of cryoprecipitate (a blood product used to prevent or control bleeding), and 2 units of platelets. However, according to the blood bank records, 18 units of red blood cells were issued (the blood bank's records for the other products matched the anaesthetic count). CMDHB noted that four blood product bags therefore may have been lost.

Cell saver documentation

46. There was no record of the volume of cell saver blood given back to Mrs B during the surgery. CMDHB told HDC that usually after a procedure that involves a cell saver is completed, the cell saver technician will complete a form that includes a written record of cell saver blood volumes processed. In this case, the form was not completed. CMDHB told HDC that it was "extremely unusual for cell saver paperwork to have not been fully completed and is most likely attributable to the emotional distress experienced by the theatre team after the unexpected death of [Mrs B]".

47. The anaesthetics team retrospectively analysed the electronic record from the cell saver, and estimated that 1,383ml of Mrs B's fluids was collected, and 144ml of concentrated red cells was reinfused into Mrs B. The anaesthetics team told HDC that the volume of cells that was reinfused into Mrs B was "disappointingly low". It explained that possible reasons for this are because the cell saver does not collect any blood lost vaginally, and when blood loss is very rapid, as was the case for Mrs B, additional suction systems must be used that are not connected to the cell saver, which means that the cell saver is less effective than when the rate of cell saver suction matches the rate of blood loss.

CMDHB policy for managing placenta praevia and placenta accreta

48. At the time of events, CMDHB did not have a dedicated policy in place for the management of placenta praevia and placenta accreta. CMDHB told HDC that management of placenta praevia and postpartum haemorrhage is a "fundamental part of training for all obstetricians". In response to the provisional opinion, CMDHB highlighted that it had an antepartum haemorrhage guideline in place at the time, and this document referenced management of these conditions (and also included reference to the UK's Royal College of Obstetricians and Gynaecologists Green-top Guideline No. 27a (September 2018) "Placenta Praevia and Placenta Accreta: Diagnosis and Management" (the RCOG Guideline)). CMDHB said that as part of its internal review of Mrs B's management, it identified an opportunity to improve its guidance on the management of these conditions by instituting a separate dedicated guideline.

49. Subsequently, the CMDHB "Guideline for Placenta Praevia and Placenta Accreta" was introduced on 5 March 2020. The guideline states that for women with placenta praevia, at

the time of surgery an "SMO Obstetrician and SMO Anaesthetist must be in theatre for delivery".[14] However, notwithstanding CMDHB recognising the importance of having an SMO obstetrician present in the theatre when a CS is being performed on a woman with a diagnosed placenta praevia and with a high possibility of placenta accreta, CMDHB does not accept that a lack of dedicated guideline at the time constituted a departure from the required standard of care.

Communication with Mrs B's whānau

50. Mrs A told HDC that she was also concerned by how CMDHB offered support to her and her whānau following Mrs B's death. She said that CMDHB kept telling them that they could share information only with Mrs B's husband, but Mrs A commented that "[Mrs B] was more than just her husband", and that her whānau was wider than him. Mrs A added that Mrs B's husband was so young and grieving, and had to take care of the children, which meant that he was not able to handle liaising with CMDHB. Mrs A acknowledged that CMDHB had to maintain patient privacy, but said that she and her whānau did not feel supported after Mrs B's death.

51. CMDHB told HDC that on the day of Mrs B's death, a number of clinicians involved in the care provided to Mrs B spoke with Mrs B's husband and other members of her whānau, and CMDHB's Perinatal Loss Midwife also spoke to the whānau. The Perinatal Loss Midwife was the primary contact for Mrs B's whānau after the events. CMDHB stated that the Perinatal Loss Midwife saw Mrs B's husband several times prior to the baby being discharged. She also followed up with calls and emails to Mrs B's husband on a number of occasions, including to offer counselling support. However, between November 2018 and June 2019, all attempted contact with Mrs B's husband went unanswered.

52. In response to the provisional opinion, CMDHB added that following receipt of the post-mortem report, unsuccessful attempts were made to contact Mrs B's husband to arrange a family meeting to discuss the findings.

53. In June 2019, the Perinatal Loss Midwife was contacted by Mrs A, who expressed concerns about the lack of contact from CMDHB. CMDHB said that this was the first time it was alerted to Mrs A's disappointment that the hospital had not been in direct contact with her. It said that as soon as it was made aware of this, communications were solely with Mrs A.

54. On November 2019, a meeting between CMDHB and Mrs B's whānau was held. After the meeting, in December 2019, a letter outlining the results of the AER was sent to Mrs B's whānau. In addition, the letter noted that following the whānau's feedback, CMDHB would review its processes to ensure that following a similar event, and where appropriate, two primary contacts would be identified, and ongoing communication from CDMHB would be in a manner agreed with whānau.

[14] In cases where placenta accreta is confirmed or highly suspected, the guideline states that two obstetric SMOs must perform the operation together, with an anaesthetist SMO present.

Further information — age of blood products and resuscitation fluid

Age of blood products

55. In its initial response to the Coroner about Mrs B's case, on the subject of Mrs B's raised potassium levels prior to her death, CMDHB commented:

> "The National Blood Transfusion Service's national policy is to give the oldest available blood first (which has higher potassium levels due to a slow but constant leakage of potassium from the cells during storage). Due to the amount and speed of blood transfused, it is possible that [Mrs B] would have received a high potassium load which may explain her hyperkalaemia (high level of potassium in her blood). Therefore this is a possible contributor to [Mrs B's] cardiac arrest."

NZ Blood Service

56. HDC obtained comments from the New Zealand Blood Service (NZBS). NZBS considered that there was no evidence that the age of the red blood cells contributed to Mrs B's death, but acknowledged: "[T]here will always be a potassium load associated with high volumes of [red blood cells] in any massive transfusion event." It also acknowledged that the potassium levels increase in stored red blood cells. NZBS pointed out that the likelihood of hyperkalaemia developing in a massive transfusion event can be affected by a number of things, including the total volume of red blood cells transfused, the transmission rate, the storage age of the red blood cells, and the presence of patient factors such as hypovolaemia (loss of more than 20% of the body's blood or fluid supply) and circulatory failure.

57. NZBS's national policy states that generally blood products will be supplied on a "first in first out basis",[15] and notes that generally NZBS will aim to provide hospital blood banks with red blood cells that are less than 15 days old. The policy also notes that most patients will not benefit from the use of fresher blood cells. NZBS told HDC that its national policy is in line with similar guidance from the UK and Australia. It also said that death or poor outcomes in massive transfusion events are generally driven by blood components arriving too late and not being given in sufficient quantities. NZBS commented that additional barriers to the provision of red blood cells (such as having to choose the freshest blood products) would therefore likely result in additional patient risk. Accordingly, NZBS's view is that there is no evidence to support changing its current policy.

Resuscitation fluid

58. NZBS also commented to HDC:

> "The choice of a resuscitation fluid that contained potassium is unusual in the setting of a massive haemorrhage. The initial 2 litres … may have been given based upon a need to respond to the impact of spinal anaesthesia on blood pressure. The next 4–6 litres … in the context of massive haemorrhage would be unusual given the known risk of hyperkalaemia from high volumes of [red blood cells] and a non-potassium containing

[15] Except where there is a clear clinical indication for the use of "fresh" red blood cells (i.e., the red blood cells that have been stored for the shortest time) for a particular patient.

> crystalloid would generally be the treatment of choice if fluid boluses were considered essential."

59. CMDHB's anaesthetics team told HDC that it strongly refutes the criticisms of the choice of Plasmalyte resuscitation fluid. It said that although Plasmalyte contains potassium, it does not raise plasma potassium levels. The team added that resuscitation with normal saline (usually the only available resuscitation fluid alternative to Plasmalyte) causes plasma acidosis (an increase in the blood's acidity), which itself would increase potassium levels more than Plasmalyte. It said: "Plasmalyte is therefore widely recognised internationally as a better choice for use during large volume fluid resuscitation than normal saline."

Responses to provisional opinion

60. Mrs B's whānau (via Mrs A), CMDHB, and NZBS were all given the opportunity to respond to relevant sections of my provisional opinion. Where appropriate, their responses have been incorporated into this report. In addition, I note the following.

Mrs A

61. Mrs A highlighted a number of areas in the "Information gathered" section that were of much concern to the whānau. In particular, Mrs A told HDC:

> "A few of the initial specialists team assigned to our daughter's procedure on the day were apparently absent. Our concern here is the staff that were assigned were trainee doctors. Were they being supervised by the appropriate Lead Specialist Doctor."

62. Mrs A also highlighted their concern about what they interpreted as a lack of availability of equipment for the team. Lastly, she reiterated their concerns about "supports for grieving family".

CMDHB

63. CMDHB told HDC:

> "The loss of [Mrs B] was keenly felt by all those involved in her care. For the team, knowing that they did all that they could for [Mrs B], was little consolation given the tragic outcome. For [Mrs B's] family, her loss would have likely been unfathomable so we would again like to take this opportunity to offer our deepest and sincerest condolences to her family."

64. However, CMDHB told HDC that it disagrees that its systems did not work to ensure that Mrs B received an appropriate standard of care, and it does not consider that it breached the Code of Health and Disability Services Consumers' Rights (the Code).

65. CMDHB stated that Mrs B's CS could not have been delayed, because despite it being an "elective" CS, it was not truly elective as her history and presentation made her need for a CS more acute. CMDHB said that delaying Mrs B's CS beyond 37 weeks' gestation would have put Mrs B at further risk of her going into labour and/or bleeding acutely, given her known placenta praevia and history of previous Caesarean sections. It said that this would have increased the chance of Mrs B having a life-threatening haemorrhage or uterine

rupture, with associated fetal distress and potentially fetal demise, as well as possible impacts on the availability of the anaesthetics team, theatre space, and cell saver equipment.

66. CMDHB also told HDC that Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) trainees (which includes advanced trainees, ie, Fellows, such as Dr C) are required to have learning opportunities that reflect the situations they will have to manage when they complete their qualifications. It said that Dr C had regularly performed CS for high-risk women, including those with placenta praevia. Initially, this was with direct supervision, and then indirect with the duty obstetrician. CMDHB submitted that Dr C was appropriately trained to manage this type of complex case, and ably provided the appropriate standard of care. CMDHB believes that it is appropriate for a Fellow or senior registrar in their last year of specialist training to perform a CS in these circumstances, knowing that an SMO is immediately available to assist if required.

67. CMDHB also noted that because of the high volume of women with complex presentations who birth at CMDHB, it frequently manages women who experience significant postpartum haemorrhage. It noted that since January 2019, it had dealt with 94 cases of severe postpartum haemorrhage.[16]

NZBS

68. NZBS told HDC that it had no comments to make on the provisional opinion.

Opinion: Counties Manukau District Health Board — breach

Introduction

69. This case involves the tragic death of a young woman during the birth of her child. The devastation her loss has caused to her extended whānau, and in particular her partner and young children, cannot be overstated, and I extend my sincere condolences to them.

70. It is important to note at the outset that it is not my role to determine cause of death. Any findings made in this report about the standard of care provided are not intended to imply that Mrs B's death was caused by the actions of any one person. I would also like to acknowledge that Mrs B's death in these circumstances was unexpected, and was felt strongly by the staff involved, who tried valiantly to save her.

71. I note the comments from both my expert obstetrics advisor, Dr John Tait, and my expert anaesthetics advisor, Dr Paul Templer, about the standard of the preoperative planning and the response to Mrs B's haemorrhage, including the resuscitation. Dr Tait commented that the preoperative planning was of an acceptable standard of care. He also commented:

[16] CMDHB told HDC that there will always be some SMO involvement in cases of severe PPH (as in the 94 cases referred to here).

> "I believe that the obstetric team responded appropriately to [Mrs B's] post-partum haemorrhage and deterioration. … The standard of communication and co-ordination between the anaesthetics and obstetrics team was very good."

72. Similarly, Dr Templer commented:

> "Once things started to go wrong there seems to have been a team based approach to do everything possible to save [Mrs B] and I can't think of anything else they could have done."

73. However, I have some concerns about the care that was provided to Mrs B by CMDHB. In particular, I am concerned that in light of the high-risk nature of Mrs B's CS, CMDHB's systems did not work to ensure that Mrs B received an appropriate standard of care. I discuss these issues in further detail below.

Surgical team performing procedure

74. On the morning of Mrs B's CS, the consultant obstetrician who was rostered to manage the elective obstetric surgery list (which included Mrs B's elective CS procedure) was unwell. CMDHB asked surgical Fellow Dr C to perform the surgery. She was assisted by registrar Dr D. Consultant Dr E, who was covering the acute surgical list, was already in theatre performing an emergency CS, and therefore was not informed of the women on the elective surgery list. He was unaware that the procedure for Mrs B, who had major placenta praevia, and where placenta accreta remained a high possibility given her history of previous Caesarean sections and placenta praevia, was taking place until he was called in to assist. CMDHB's AER found that there was no specific SMO named as back-up for Dr C for the elective surgery list.

75. Dr Tait acknowledged that Dr C was credentialled for complex Caesarean sections including placenta praevia. However, he advised:

> "[Mrs B] had significant risk factors with a BMI 42.3, … previous caesareans, gestational diabetes and a posterior placenta praevia. In my view the expectation would be that a senior SMO would have been at the caesarean section. I understand the difficulties of staffing with the SMO calling in sick, but the procedure was elective and could have been delayed until a senior SMO was available. …
>
> I am not criticizing the Senior Registrar and registrar on the obstetric team. I remain, however, concerned about a system that enabled a Senior Registrar to perform an elective procedure on such a high risk patient without [an SMO] being scrubbed in theatre. If a[n] SMO 'was always available to assist should they be required', why was there not a[n] SMO available to perform the surgery. I still believe that the majority of my peers would agree that in this case a Senior SMO would be expected to perform this surgery."

76. In respect of Mrs B's risk factors, I also note that the pre-CS ultrasound report noted that while there was no ultrasound evidence of placenta accreta, placenta accreta nonetheless "remain[ed] a high possibility".

77. Dr Tait considered that CMDHB's failure to ensure that Mrs B's procedure was carried out by an SMO was a moderate departure from accepted practice.

78. CMDHB disagrees with this advice, and has submitted that trainees (including Fellows such as Dr C) are required to have learning opportunities that reflect the situations they will have to manage when they complete their qualifications. CMDHB believes that it is appropriate for a Fellow or senior registrar in their last year of specialist training to perform Caesarean sections in these circumstances, knowing that an SMO is immediately available to assist if required. CMDHB added that Dr C was appropriately trained to manage this type of complex case, and ably provided the appropriate standard of care. CMDHB also submitted that Mrs B's CS could not have been delayed beyond 37 weeks' gestation, because this would have put her at further risk of going into labour and/or bleeding acutely.

79. RANZCOG does not currently have a guideline specifically on placenta praevia. However, the RCOG Guideline (referred to in paragraph 48 above) states that for placenta praevia, a senior obstetrician (usually a consultant) should be present within the delivery or theatre suite where the surgery is occurring. The RCOG Guideline also referenced a care bundle for placenta accreta developed by an expert working group. The care bundle contains six "elements of good care", including: "Consultant obstetrician planning and directly supervising delivery." However, the RANZCOG guideline on placenta accreta (November 2015)[17] does not include this recommendation.

80. I acknowledge that there is no clear recommendation from RCOG or RANZCOG for a senior obstetrician to be present in the room for a CS for known placenta praevia. I also acknowledge that there were increased risks in delaying Mrs B's CS beyond 37 weeks, and that Dr C was credentialled to perform the surgery, and that, once called, senior clinicians arrived promptly to assist.

81. Nonetheless, in light of Mrs B's risk factors, and most notably the high possibility of placenta accreta as indicated by the ultrasound scan, and noting Dr Tait's advice, I remain of the view that the most senior clinician available should have, at the very least, been present in theatre to supervise the procedure and to provide immediate guidance or assistance as necessary. While I acknowledge CMDHB's submission that Mrs B's CS could not have been delayed beyond 37 weeks, owing to the increased risk of her going into labour and/or bleeding acutely, I share Dr Tait's view that Mrs B's elective CS could have been delayed, at least by a day, until a senior clinician became available.

82. In making these comments, I note with approval that CMDHB's new guideline for placenta praevia and placenta accreta (introduced on 5 March 2020) requires that for women with

[17] Currently under review.

placenta praevia, at the time of surgery an SMO obstetrician and SMO anaesthetist are to be in theatre for delivery.

Lack of placenta praevia and placenta accreta guidelines

83. At the time of events, CMDHB did not have a specific guideline for the management of placenta praevia and placenta accreta.

84. Dr Tait advised:

> "A guideline should have been in place for the management of placenta praevia and placenta accreta. Although there are guidelines from RANZCOG it would be considered normal practice in a large hospital for there to be their own guidelines, in particular as to who should be in attendance."

85. In Dr Tait's view, this lack of a dedicated guideline at the time represented a minor departure from accepted practice. In response to the provisional opinion, CMDHB noted that it had an antepartum haemorrhage guideline, which referenced management of placenta praevia and placenta accreta, as well as the RCOG Guideline. CMDHB does not accept that not having a dedicated guideline for management of these conditions was a departure from the required standard of care.

86. Dr Tait acknowledged that there were external guidelines in place for the management of placenta praevia and placenta accreta, but commented: "[I]t would be considered normal practice in a large hospital for there to be their own guidelines, in particular as to who should be in attendance."

87. I therefore accept Dr Tait's advice. It is concerning that at the time, CMDHB did not have specific guidelines in place to provide guidance for staff as to the best management of such cases, including the seniority of clinicians who should be performing such procedures.

88. However, I also note Dr Tait's further comments:

> "I commend [CMDHB] on the changes they have made with the development of the new protocols for Primary Postpartum Haemorrhage, Secondary Postpartum Haemorrhage and placenta praevia and placenta accreta, and would suggest they audit against the key steps of the protocols."

89. I agree with Dr Tait, and I recognise and endorse the work that has occurred in the meantime to offer the clarity such risky cases warrant. As noted above, on 5 March 2020 CMDHB introduced a guideline for placenta praevia and placenta accreta. The guideline states that "SMO Obstetrician and SMO Anaesthetist must be in theatre for delivery". I welcome the new guidelines introduced by CMDHB.

Lack of working blood fridge

90. At the time of events, the blood fridge in CMDHB's theatre complex was not working, and had been unavailable for 26 days (the blood fridge was unavailable for nearly two months

in total). As a result, and as noted by CMDHB's AER, the administration of the first four units of red blood cells to Mrs B was delayed by about 10 minutes.

91. Dr Tait commented: "[I]t is unacceptable for the 'blood fridge' to be unavailable for that period of time." I agree. As noted by Dr Templer, "[m]assive transfusion protocols (MTP) are an attempt to save time and avoid error in a crisis". Again, I agree. The unavailability of the blood fridge worked against the goal of saving time in what was an emergency situation. It is not possible to determine (and it is not my role to determine) whether the slight delay in Mrs B receiving blood products contributed to the outcome. Nonetheless, it is concerning that the lack of a fairly basic item of theatre equipment delayed the administration of critically important blood products to Mrs B.

Clinical records

92. There were a number of issues with the clinical records in this case. In particular:

- The total volume of blood loss was inaccurate, because a count of the swabs was documented, but the weight of the swabs (which would have given an indication of how much blood each swab was holding) was not.
- The total number of blood products administered to Mrs B, as counted by the anaesthetics team, did not completely match the records of products delivered by the blood bank.
- The cell saver documentation was not completed, which meant that there was no record of the volume of Mrs B's blood that was returned to her.

93. These issues are concerning. However, as noted by CMDHB and acknowledged earlier in this report, the tragic outcome would have been traumatic for the staff involved, and this may explain some of the shortcomings in the records. In addition, I note Dr Templer's comment: "The [cell saver] paperwork was apparently not fully completed but, in the circumstances, this is not unexpected …"

94. I acknowledge that the events of Mrs B's CS were understandably extremely distressing for the staff involved. However, notwithstanding this, it remains my expectation that providers ensure that documentation is carried out adequately. Where a serious event has occurred, arguably the need for accurate and complete documentation is even greater, in order to understand events as they unfolded, and to fully interrogate all the factors and issues that may have contributed and impacted on the eventual outcome, and perhaps most importantly to ensure that all learnings are fully realised.

Conclusion

95. As detailed above, I have a number of concerns about the services that were provided to Mrs B during her CS. In particular:

- The most senior clinician available should have been present in the theatre for delivery. If no SMO was available, then Mrs B's elective CS could have been delayed.

- At the time, CMDHB did not have in place a specific guideline for the management of placenta praevia or placenta accreta.
- The blood fridge in the theatre complex was out of operation for nearly two months, which in this case meant a slight delay in Mrs B receiving blood products.
- There were a number of issues with the clinical records.

96. Dr Tait identified a series of mild and moderate departures from accepted practice, and I consider that cumulatively they present a picture of systemic failures. I consider that the above deficiencies amount to a failure to provide services with reasonable care and skill, for which ultimately CMDHB is responsible. Accordingly, I find that CMDHB breached Right 4(1) of the Code.

97. In making this finding, I reiterate that I am not making a finding about the cause of Mrs B's death, nor am I holding individual clinicians responsible. As the events unfolded, the clinicians involved worked valiantly to try to stem the blood loss and preserve Mrs B's life. It is impossible to know whether the tragic outcome could have been averted had these issues not occurred.

Communication with Mrs B's whānau following death — other comment

98. I note concerns from Mrs B's whānau about the way in which CMDHB communicated with them following Mrs B's death. In particular, the whānau were concerned that CMDHB said that it could share information only with Mrs B's husband. However, as Mrs A pointed out, Mrs B's husband was not in a position to liaise with CMDHB owing to his grief and need to look after his other young children. Mrs A also commented that Mrs B's whānau were wider than just her husband.

99. CMDHB has commented that between November 2018 and June 2019, all attempted contact with Mrs B's husband was unanswered. As a grieving young man confronted with the loss of his partner in such traumatic circumstances, any lack of engagement with the DHB over this time is completely understandable.

100. I also note that CMDHB met with Mrs B's whānau in late 2019. CMDHB also sent a letter to the whānau in December 2019, which reflected on the feedback that Mrs A had provided about CMDHB's communication with them after Mrs B's death, and outlined some steps it is taking to address those concerns. I consider that these steps were appropriate; however, I suggest that CMDHB reflect further on the comments made by Mrs A and consider whether any further improvements can be made to the way it communicates with, and provides support to, whānau following serious adverse events.

Resuscitation fluid — other comment

101. NZBS questioned the use of Plasmalyte, which contains potassium, as a resuscitation fluid, given that massive haemorrhage comes with a known risk of hyperkalaemia from high volumes of red blood cells. CMDHB's anaesthetics team, however, refuted the criticism. It considers that Plasmalyte does not increase blood potassium levels, and that the other

resuscitation fluid option (saline), despite not containing potassium, would actually cause potassium levels to rise more.

102. Dr Templer agreed with the comments from the anaesthetics team. He advised:

> "The amount of potassium in the fluid makes little or no difference to serum potassium and has significant advantages. The use of this fluid in this situation would be regarded as correct by all anaesthetists."

103. I accept Dr Templer's advice and, accordingly, accept that the use of Plasmalyte was appropriate.

New Zealand Blood Service — other comment

104. CMDHB suggested that the age of the blood products administered to Mrs B from the blood bank may have caused increased potassium levels and, as such, may have contributed to her cardiac arrest. NZBS, on the other hand, considers that there was no evidence that the age of the blood products contributed to Mrs B's death. However, it acknowledged that potassium levels do increase in stored blood products, and that a potassium load is associated with large volumes of blood products being administered in a massive transfusion event. NZBS also noted that its policy about the order of delivery of blood products is consistent with international guidelines.

105. Dr Templer advised:

> "As blood is stored potassium levels rise and can raise the potassium in the recipient. However, there is no evidence that this causes harm as the vast majority of potassium in the body is intracellular and extracellular potassium is rapidly taken up by the cells. The volumes of blood administered in this case are large (12+ units) but transfusions of 20, 40, or more units can occur in acute haemorrhage and do not usually result in such high potassium values or cardiac arrest — even if the potassium was elevated the treatment for raised potassium — calcium, insulin/dextrose, and salbutamol was administered with no benefit. This implies other processes had caused/were causing the cardiac arrest(s)."

106. I accept Dr Templer's advice, and I am not critical of the age of blood products administered to Mrs B.

Changes made

107. CMDHB told HDC that since these events it has made the following changes, being the implementation of the recommendations arising from its AER:

- It has put in place contingency plans to store theatre blood units in the blood bank, in case of unexpected blood refrigeration failure within the theatre complex at the public hospital.
- As a direct result of this case, the theatre complex now has its own blood gas machine, which means that results can be presented rapidly to the anaesthetics team.
- A process has been put in place to weigh swabs in theatre, and a new Intraoperative Major Blood Loss Record has been developed and is in use.
- It has developed new placenta praevia and placenta accreta guidelines.
- A back-up SMO is now always rostered to support any Fellow who is rostered to the elective Caesarean theatre list.
- The MTP (for both the public hospital and CMDHB's Surgery Centre) has been reviewed and updated by CMDHB's Transfusion Committee.
- Its cell saver guideline was reviewed and updated by the anaesthetics team in both 2019 and 2020.
- It has established a new group to further develop innovations originally put in place during the initial COVID-19 pandemic, with the goal of creating a comprehensive staff support system that will respond to situations such as adverse events for individuals and teams.

Recommendations

108. Bearing in mind the above changes already made by CMDHB, I recommend that CMDHB:

a) Provide a written apology to Mrs B's whānau for the failures identified in this report. The letter should include an offer to meet again with the whānau to discuss the contents of this report. CMDHB is to provide this apology to HDC within three weeks of the date of this report, for forwarding to the whānau.

b) Report back to HDC on its processes for reviewing its theatre equipment to ensure that it is functional, and for ensuring timely maintenance of equipment that is non-functional. CMDHB is to provide this information to HDC within three months of the date of this report.

c) Report back on compliance with its guideline for placenta praevia and placenta accreta introduced on 5 March 2020. Specifically, CMDHB is to report back on compliance with

the following factors (from the guideline) for a random selection of 30 cases of women with placenta praevia or placenta accreta:

i. antenatal haemoglobin optimisation;

ii. appropriate timing of repeat ultrasound scans (including transvaginal scans as appropriate);

iii. urgent referral to see an obstetrician in an antenatal clinic when placenta praevia or a low-lying placenta is identified;

iv. referral to the Maternal Fetal Medicine Unit for all women who have placenta praevia or a low-lying placenta and a history of previous CS or uterine surgery; and

v. planned delivery via CS at 34 to 36 weeks' gestation.

CMDHB is to provide HDC with the results of this audit, including details of any improvement measures identified as a result, within six months of the date of this report.

d) Consider how, in light of my comments about documentation in this case, it can incorporate into the new staff support system it is developing, processes for ensuring that accurate and full documentation is completed following adverse events. CMDHB is to report back to HDC on the results of its consideration, and any initiatives to be introduced as a result, within six months of the date of this report.

e) Use the anonymised version of this report as a case study for training obstetrics and anaesthetics clinicians. Evidence of the training is to be provided to HDC within six months of the date of this report.

Follow-up actions

109. A copy of this report will be sent to the Coroner.

110. A copy of this report with details identifying the parties removed, except CMDHB and the experts who advised on this case, will be sent to the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, the Australian and New Zealand College of Anaesthetists, the Ministry of Health, the Health Quality & Safety Commission, and the Perinatal and Maternal Mortality Review Committee, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent clinical advice to Commissioner

The following expert advice was obtained from obstetrician Dr John Tait:

"**Complaint Counties Manukau District Health Board (Your Ref. 19HDC01222)**

My name is John David TAIT. I have the qualifications of MBBS FRCOG FRANZCOG. I have been a consultant obstetrician and gynaecologist in Wellington since 1986. At present I am the Chief Medical Officer at Capital and Coast District Health Board (CCDHB). I am the Chair of the PMMRC, an ex officio member of the National Maternal Monitoring Group, a member of the NE Taskforce, the Vice President of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZOG), and the Vice President of Asia-Oceanic Federation of Obstetrics and Gynaecologists (AOFOG). I have received and read the documents forwarded to me.

Question 1:

The adequacy of preoperative planning between the obstetrics and anaesthetics team.

[Mrs B had had a number of previous pregnancies.] She had had … previous caesarean sections and … miscarriages. She also had a history of gestational diabetes and had a BMI of 42.3.

At 24 weeks she was diagnosed, on ultrasound, with a major posterior placenta praevia.

At 30 weeks [Mrs B] attended an ante-natal clinic where she was counselled about the risks of placenta praevia and started on insulin to control her blood sugars. She also received advice to present to hospital if she had any onset of abdominal pain, vaginal bleeding or reduced fetal movement.

At 32 weeks [Mrs B] presented with vaginal bleeding, she was hospitalised, steroids to mature the fetal lungs were commenced and she was booked for an elective LUSCS at 37 weeks.

On the Friday, prior to her LUSCS, a plan was initiated by the obstetrician. The anaesthetist was notified, the cell saver was organized, four units of red blood cells were cross matched and a Maternal Fetal medicine specialist was organized to perform an ultrasound prior to commencing the LUSCS to assess the placental edge and to look for any signs of a placenta accreta (where the placenta has invaded the muscle of the uterus).

From the anaesthetic point of view a second anaesthetist was organised who would be immediately available. A second anaesthetic technician was rostered on to ensure that the cell saver would also be immediately available.

I believe that the pre-operative planning was of an accepted standard of care, and that would be the view of my peers.

Question 2:

Whether the obstetrics team, which carried out the caesarean section procedure, had the appropriate level of experience.

The elective caesarean was performed by an obstetric fellow with an obstetric registrar. The obstetric fellow was in the final year of training and had the RANZCOG fellowship. The fellow was credentialed for complex caesarean sections including placenta praevia.

[Mrs B] had significant risk factors with a BMI 42.3, … previous caesareans, gestational diabetes and a posterior placenta praevia. In my view the expectation would be that a senior SMO would have been at the caesarean section. I understand the difficulties of staffing with the SMO calling in sick, but the procedure was elective and could have been delayed until a senior SMO was available. I believe this is a moderate departure from accepted practice and I believe that this view would also be held by the majority of my peers.

Question 3:

The overall standard of the caesarean section procedure including:

a. Whether the obstetrics team responded appropriately to [Mrs B's] postpartum haemorrhage and deterioration.

b. The standard of communication and co-ordination between the anaesthetics and obstetrics team.

a. The caesarean section began at 12:06. The baby was delivered at 12:15. Rapid large blood loss occurred, estimated at 2,000mls. Further 51U Oxytocin was given IV as was Tranexamic Acid. At 12:20 the obstetric fellow called for obstetrician B. Blood was asked for. Unfortunately, the dedicated 'blood fridge' was unavailable due to a fault and the blood had to be retrieved from the Blood Bank, a five minute walk.

At 12:22 the Massive Transfusion Protocol was activated. Seven minutes after delivery.

12:24 Obstetrician B arrived and a decision was made to insert a Bakri Balloon and a B-Lynch suture was also recommended. Obstetrician B called for Obstetrician C.

12:28 A general anaesthetic was administered. The Bakri Balloon was positioned and a B-Lynch Suture was placed.

The Belmont rapid infuser was brought into theatre and set up, the four cross-matched units of red blood cells were rapidly administered.

12:29 The first massive transfusion box was issued. Obstetrician C arrived. [Mrs B] was relatively haemodynamically stable so the obstetrician left theatre and planned to return in 10 minutes.

12:47 Blood loss was noted to be watery, and as there was no improvement in uterine tone a decision was made to do a hysterectomy.

13:00 The hysterectomy began.

13:04 [Mrs B] had an asystolic cardiac arrest. At that time in theatre there were seven senior anaesthetists, and an anaesthetic registrar, five obstetricians, two obstetric registrars, seven senior anaesthetic technicians, eight nurses and two midwives.

Aortic compression was commenced.

13:15 Surgery recommenced.

13:22 A second cardiac arrest occurred. The operative field was enlarged by using a vertical incision and a vascular surgeon was called.

13:32 A third cardiac arrest occurred.

13:38 A fourth cardiac arrest occurred.

13:56 Time of death was recorded.

I believe that the obstetric team responded appropriately to [Mrs B's] post-partum haemorrhage and deterioration.

(b) The standard of communication and co-ordination between the anaesthetics and obstetrics team was very good.

Question 4:

The lack of a specific guideline on managing placenta praevia at the time of events.

A guideline should have been in place for the management of placenta praevia and placenta accreta. Although there are guidelines from RANZOG it would be considered normal practice in a large hospital for there to be their own guidelines, in particular as to who should be in attendance. I consider this to be a moderate departure from accepted practice and I believe that this view would also be held by the majority of my peers.

Question 5:

Any systems issues that you consider contributed to the events.

The two system issues that are identified are:

1. The lack of a functioning 'blood fridge' in the theatre complex where cross matched blood for [Mrs B] would have been stored. This 'fridge' was unavailable [for nearly two months].
2. Although obstetricians came quickly when called there did appear to be staffing difficulties in finding a SMO obstetrician to cover the elective caesarean section list.

Although these system issues may not have affected the outcome for [Mrs B] it is unacceptable for the 'blood fridge' to be unavailable for that period of time.

Question 6:

Any other matters in this case that you consider warrant comment.

I commend Counties Manukau on the changes they have made with the development of the new protocols for Primary Postpartum Haemorrhage, Secondary Postpartum Haemorrhage and placenta praevia and placenta accreta, and would suggest they audit against the key steps of the protocols.

I would also offer my condolences to the family of [Mrs B]."

The following further advice was obtained from Dr Tait:

"**Complaint Counties Manukau District Health Board (Your Ref. 19HDC01222)**

Thank you for giving me the opportunity to respond to [the] letter of the 28th October 2020.

I wish to make it clear that I am not criticizing the Senior Registrar and registrar on the obstetric team. I remain, however, concerned about a system that enabled a Senior Registrar to perform an elective procedure on such a high risk patient without a Senior Medical Officer (SMO) being scrubbed in theatre. If a SMO 'was always available to assist should they be required', why was there not a SMO available to perform the surgery. I still believe that the majority of my peers would agree that in this case a Senior SMO would be expected to perform this surgery, and in my opinion this is a moderate departure from accepted practice.

A further comment would be that although the outcome may have been the same, a Senior Registrar should not have been put in the situation which subsequently ensued.

Regarding the question of the theatre 'blood fridge', I still find it difficult to believe that it could be unavailable for two months.

With regards to not having guidelines for the management of placenta praevia/accreta, I may have been harsh but still believe that this was a departure from accepted practice but more on a minor scale."

Appendix B: Independent clinical advice to Commissioner

The following expert advice was obtained from anaesthetist Dr Paul Templer:

"I am Dr Paul Templer BHB, MBChB, FANZCA a consultant anaesthetist and pain physician. I have been a consultant for 20 years and work in a tertiary public hospital (Dunedin); my work includes acute and elective obstetrics.

I do not personally know any of the staff primarily involved in the case and wasn't previously aware of the case or the outcome.

Introduction:

This is a tragic case — a [woman in her twenties] has died on what should have been a joyous day. A family and whānau have been left to mourn the death of a mother/daughter/wife rather than celebrate a birth. The staff will also have been traumatised and will have spent a lot of time wondering 'what if?' and wishing they could have done something else or something more to save [Mrs B].

This case has been comprehensively reviewed and examined already by obstetric, anaesthetic, and transfusion specialists. Their reports are remarkably consistent and extremely thorough, and the smallest details have been analysed. Lessons from the case have been taken to heart and small changes made.

At the core of the case is the feeling that: if someone dies — something must have gone wrong or been done wrong. I don't think that is true in this case. Even with the benefit of hindsight I can't see any errors or omissions that — were they avoided — could have led to another outcome. This was a case managed by experienced staff, in an excellent obstetric unit who are used to difficult cases, with lots of help rapidly available. The staff quickly identified a problem and worked rapidly and appropriately to fix it. They could not save [Mrs B] — but it was not through error or lack of effort. Obstetric haemorrhage is still a major cause of death despite advances in medical care (UK figures suggest a rate of just under 1 per 100,000 pregnancies — so in New Zealand we would expect approximately 1 death every 2 years).

There is quite a lot of discussion in the various reports about potassium and its role in events and it may not be obvious why to a non-medical person. The reason is that [Mrs B] suffered a cardiac arrest after a comparatively small loss of blood. On the face of it this sounds like a nonsense statement as the cause of her death was haemorrhage — however she suffered her first arrest at an estimated blood loss of 2–3000ml. Whilst this is a lot her expected blood volume — given her size and the fact that blood volume expands in pregnancy — would be around 8000ml. Given volume replacement (which she was receiving) this doesn't quite make sense — it's not 'enough' to cause a [person of this age] to arrest. The haemoglobin measured during resuscitation of 63 is low but normally values down to 50 can be survived and much lower values are often recorded in acute haemorrhage.

Hence the search for 'something else' that may have caused the arrests. I don't know why they happened either — although I note the signs of an old infarct in [Mrs B's] heart at post mortem so I wonder if she may have been less likely to tolerate physiological disturbance. But there was nothing in her prior medical history to indicate this — and I am not sure anything could have been changed anyway.

Expert Advice:

1. Comment on the adequacy of pre-operative planning between the anaesthetic and obstetric team.

As far as I can tell this was of a good standard — this case was flagged as high risk and an anaesthetist tried to see [Mrs B] but she had gone home — other than that everything seems excellent. This was an arranged case performed during daylight hours when the maximum support was available. The case was given extra time, a suitable obstetric anaesthetist was assigned and informed several days before, another experienced obstetric anaesthetist was immediately available as back-up, the patient had blood cross matched, an ultrasound was done to identify the position of the placenta, a cell-saver was used, and most importantly at the morning briefing the teams talked. This briefing seems to have involved anaesthetic, obstetric, and nursing staff and the risks of bleeding and plans to mitigate this were explicitly discussed.

2. The overall standard of the resuscitation

a. Did the anaesthetic team respond appropriately to [Mrs B's] deterioration?

From the information provided they seem to have responded appropriately. As mentioned (above) preparation seems to have been excellent with 4 units cross matched, 2 large intravenous lines being placed, a cell saver being set up, and a second anaesthetist organised to be immediately available. When bleeding started volume replacement, blood pressure support, and request for help were done simultaneously. A rapid infuser was set up (lets large volumes of warm fluids be given rapidly), blood was requested and administered, a massive transfusion protocol was activated, uterotonics were administered and lots of helpers arrived. [Mrs B] was resuscitated 4 times from cardiac arrest and large volumes of blood, blood products, fluids and cardiac support drugs were administered.

b. The standard of communication and coordination between the anaesthetic and obstetrics team.

This is very difficult to comment on without actually being present but … we know there was a briefing and everyone agrees it was thorough, we know that the anaesthetic team gave a lot of uterotonics which they would have discussed with the obstetricians, and we know the obstetricians used a variety of surgical techniques to try and stop the bleeding which they would have discussed with the anaesthetists. Also no one mentions communication issues in any of the reports. I suspect there was appropriate and timely communication.

c. Should the resuscitation fluid have contained potassium?

This is well covered in the anaesthetic review, but the simple answer is 'yes'. The amount of potassium in the fluid makes little or no difference to serum potassium and has significant advantages. The use of this fluid in this situation would be regarded as correct by all anaesthetists.

d. Was the monitoring of haemoglobin and electrolytes in this case at an appropriate standard.

Hindsight bias tends to make decisions seem easy when the outcome is known. In this case the only way you could have improved the monitoring of electrolytes and haemoglobin was by placing an arterial or central line at the beginning of the case. Once the haemorrhage starts the priority is replacing volume, giving uterotonics, getting extra staff and sending for blood. An arterial line was eventually placed but as is often the case in an emergency this was challenging to site.

So, should this case have started with an arterial or central line? Well — this wasn't a particularly high-risk case. The pregnancy had been relatively uncomplicated, [Mrs B] had an elevated BMI — but particularly in this obstetric unit — it was not exceptionally high. [Mrs B] had a placenta previa but it did not have high risk features and was not a placental accreta or percreta. In my opinion this case did not warrant an arterial or central line to begin with. Once bleeding commenced the priority is to first resuscitate the patient — then if possible, to send samples to the lab — this was attempted and the confused results, while seeming less than ideal, are typical of those obtained in an emergency. Samples are often difficult to obtain and labs may think they are haemolysed (these are automated analysers) when they are not and the transfer of information is never as rapid or closed loop as ideal. Whether abnormal results are phoned through or posted on-line is contentious as although phoning makes sure the result is delivered it is: labour intensive, time consuming, and the result may be given to someone else who then has to relay it to the anaesthetist. Electronic results are instantaneous but have to be looked at and refreshed.

The relevance of the high potassium is unclear as it is such a complex situation with haemorrhage, a massive transfusion, surgery, CPR and multiple drugs being administered all at once. Also it should be noted that ALL the recommended treatments for elevated potassium were administered with no change in the clinical situation.

e. Was the use of the cell-saver appropriate and was it used appropriately?

The use of a cell-saver would be regarded as best practice. However once major bleeding starts, they are often abandoned as they cannot suck blood rapidly enough to maintain a clear surgical field. The paperwork was apparently not fully completed but, in the circumstances, this is not unexpected and is not relevant.

3. Is the Massive transfusion protocol adequate and was it adhered to?

I believe the protocol was adhered to — as evidenced by the large volumes of blood administered (12+ units) and the appropriate mix of other products administered (plasma, platelets, and cryoprecipitate).

Massive transfusion protocols (MTP) are an attempt to save time and avoid error in a crisis. Triggering an MTP alerts blood bank and support staff that a major haemorrhage has occurred and the rapid provision of a series of boxes containing blood and blood products occurs rapidly and, in a stepwise fashion. Triggering an MTP lets blood bank know that this IS their priority until the MTP is cancelled. MTPs are used world-wide and by every major Australasian hospital. There is some variation amongst them, but they are all broadly similar and have proven lifesaving in major haemorrhage. I am not qualified to judge whether this MTP is of high standard but I believe it to be so — and the staff that designed it ARE well qualified and will have researched and studied the topic — as is detailed in the documents provided.

4. Did the age of the blood products have an influence on [Mrs B's] potassium levels?

As blood is stored potassium levels rise and can raise the potassium in the recipient. However, there is no evidence that this causes harm as the vast majority of potassium in the body is intracellular and extracellular potassium is rapidly taken up by the cells. The volumes of blood administered in this case are large (12+ units) but transfusions of 20, 40, or more units can occur in acute haemorrhage and do not usually result in such high potassium values or cardiac arrest — even if the potassium was elevated the treatment for raised potassium — calcium, insulin/dextrose, and salbutamol was administered with no benefit. This implies other processes had caused/were causing the cardiac arrest(s).

5. Any other system issues that may have contributed to [Mrs B's] death?

It is unfortunate that the blood fridge near the obstetric unit was not working at the time of [Mrs B's] death, but most obstetric units or theatres don't have one and blood arrived rapidly when it was sent for.

It is also unfortunate that the consultant obstetrician was off sick — but a senior obstetric registrar assisted by another obstetric registrar is an excellent team — and an obstetric consultant seems to have attended promptly when called for.

6. Any other matters you wish to comment on:

When I am assessing or reading about a case like this I always ask 3 questions. Firstly: could the adverse outcome realistically have been predicted and prevented? Secondly: once things started to go wrong could something else reasonably have been done to improve the outcome?

Thirdly: What lessons can I (we) learn from the case?

My conclusions are:

Haemorrhage was discussed as a possibility but the severity and the associated early cardiac arrest could not have been predicted or prevented despite everyone's best efforts.

Once things started to go wrong there seems to have been a team based approach to do everything possible to save [Mrs B] and I can't think of anything else they could have done.

I don't learn anything from this case other than sadness for the outcome and its effect on so many people and the re-enforcement of the deadly nature of obstetric haemorrhage."

Appendix C: Adverse Event Review

CMDHB completed an Adverse Event Review (AER) into Mrs B's death. Its findings included:

- The emergency response in theatre was timely and appropriate, and the decision to perform the hysterectomy was made early and appropriately.
- The unavailability of a blood fridge in the theatre delayed the administration of the first four units of red blood cells by about 10 minutes.
- Point-of-care blood gas testing within the theatre complex would improve the timely communication of issues such as inadequate sample size, haemolysed (broken down) samples and abnormal results.
- There was no accurate measuring of blood loss in theatre (swabs were counted but not weighed).
- There was no specific guideline for the management of women with placenta praevia.
- There was no specific Senior Medical Officer (SMO) back-up for the Fellow rostered on the elective CS theatre list.
- Blood tests were not taken at the frequency specified in the MTP.
- The volume of cell saver blood given back to Mrs B was not recorded.
- Although a multidisciplinary debriefing process took place after Mrs B's death, there was no coordinated process for managing debriefings following a death in theatre.

The AER made the following recommendations:

- Ensure there is a process in place to minimise the impact if the theatre blood fridge is unavailable in the future.
- Ensure point-of-care blood testing is available in theatre.
- Introduce routine weighing of blood swabs in addition to counting.
- Develop a guideline for the management of women with placenta praevia.
- Ensure that there is a specific SMO back-up for a Fellow rostered on the elective CS theatre list.
- Review the MTP.
- Review the controlled documents relating to the cell saver.
- Develop an organisational procedure that ensures there is a coordinated process for managing the debriefing of staff following a death in theatre or any other critical event.

Appendix D: Relevant policies

CMDHB's Massive Transfusion Protocol (MTP) (dated 12 December 2016) states that blood tests including coagulation profile (a screening test for abnormal blood clotting), platelets, full blood count, arterial blood gases, and calcium are to be undertaken every 30 minutes after the third box of blood products is delivered to the patient.