Nelson Marlborough District Health Board

General Surgeon, Dr C

Anaesthetist, Dr D

A Report by the

Health and Disability Commissioner

(Case 11HDC00531)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

Background

1. Ms A was seen by a surgeon, Dr G, at a surgical outpatients clinic at a public hospital (Hospital 1). Dr G confirmed a diagnosis of symptomatic gallstones. Ms A was placed on the waiting list for an elective laparoscopic cholecystectomy.[1]

2. A month later, Ms A attended a nurse-led pre-admission clinic. Records indicate that at this time, Ms A confirmed that she did not consent to the use of blood and blood products.

3. Ms A was admitted for surgery in 2011. Surgeon Dr C and anaesthetist Dr D met with Ms A to discuss the operation and to complete the process of obtaining her informed consent. When surgery commenced a short time later, Dr C was unaware of Ms A's views in relation to blood and blood products. The matter was not raised during the surgical "Time Out", when any issues of concern are brought to the attention of the theatre team.

4. Surgery commenced at 9am. There were difficulties with access and visibility and, at 9.50am, it was decided to convert to open surgery. Ms A's gallbladder was removed and the operation ended at 11.15am. There had been some bleeding during the surgery, but not enough to cause concern. Ms A was transferred to the Recovery Unit at 11.25am.

5. There were concerns about Ms A's condition from about midday. Initial measures taken to address these were unsuccessful, and it was thought that Ms A was probably bleeding internally. Dr C instructed that Ms A was to be given blood, at which point he was advised of her treatment refusal.

6. Dr C determined that further surgery was needed to identify and address the cause of the bleeding. Ms A, still partially sedated, confirmed that she would not accept blood. Permission was sought from Ms A's mother to override Ms A's directive. Mrs B advised that she could not do this.

7. Ms A was returned to theatre and surgery commenced at 2.55pm. No obvious bleeding point was identified. Dr C determined that the best course of action was to pack the liver bed and close the abdomen, so that Ms A could be transferred to a facility better equipped and staffed to manage the situation. Arrangements were made to transfer Ms A by helicopter to Hospital 2. By the time the helicopter crew arrived at Hospital 1, it was decided that transfer was inappropriate. Ms A's death was confirmed at 6.59pm.

Decision summary

8. The primary learning from this case is that material information must be communicated to senior members of the operating team before surgery. The unusual features of this event did not relate to the procedure — common and relatively low

[1] Surgical removal of the gallbladder through several small incisions in the abdomen.

risk — but to the patient. In this case, the only senior player in the room who did not know that the patient had declined blood products was the surgeon. Notwithstanding the surgeon's individual responsibility, common sense, let alone good practice, demands that this information is known to all senior members of the operating team. In this case it was not. Teams and systems should do better than this.

9. Ms A's refusal of blood and blood products was information that the anaesthetist and surgeon needed to know prior to surgery and in time for other plans and preparations to be made, should these have been necessary, following an appropriate discussion with Ms A. The arrangements and systems in place at Hospital 1 did not support the timely communication of this information. In addition, Ms A's refusal of blood and blood products should have been raised during the surgical "Time Out". Accordingly, NMDHB breached Rights 4(1)[2] and 4(5)[3] of the Code of Health and Disability Services Consumers' Rights (the Code).

10. Dr C did not know about Ms A's refusal of blood and blood products until her condition began to deteriorate following the first operation. Notwithstanding the organisational deficiencies, Ms A's refusal of blood and blood products was documented in her clinical records, including in documents recently prepared for this surgery. Dr C did not read Ms A's notes sufficiently to obtain this information before commencing her surgery. This was a failure to provide services with reasonable care and skill and, accordingly, a breach of Right 4(1).

11. Dr D determined that, given the surgery Ms A was to undergo and her particular risk profile, her refusal of blood and blood products was not sufficiently significant for him to need to communicate that issue to other members of the team. Accordingly, he did not discuss her treatment refusal with the operating surgeon preoperatively, and he did not raise the issue of her treatment refusal when Dr C converted to an open procedure. It is also more likely than not that Dr D did not raise the issue during the surgical "Time Out". In these circumstances, Dr D failed to take reasonable steps to co-operate with his colleagues to ensure quality and continuity of services. This was a breach of Right 4(5) of the Code.

Complaint and investigation

12. The Commissioner received a complaint from Mr and Mrs B, via the Coroner, about the care provided to their daughter, Ms A, by Dr C and Nelson Marlborough District Health Board (NMDHB). The following issues were identified for investigation:

[2] Right 4(1) of the Code states: "Every consumer has the right to have services provided with reasonable care and skill."
[3] Right 4(5) of the Code states: "Every consumer has the right to co-operation among providers to ensure quality and continuity of services."

- *Whether surgeon Dr C provided Ms A with adequate information and obtained her informed consent for her surgery.*
- *Whether surgeon Dr C provided Ms A with an appropriate standard of care.*
- *Whether Nelson Marlborough District Health Board provided Ms A with an appropriate standard of care.*

13. The scope of the investigation was extended to include the following issue:

- *Whether anaesthetist Dr D provided Ms A with an appropriate standard of care.*

14. The parties directly involved in the investigation were:

Ms A	Consumer
Mrs B	Consumer's mother/complainant
Mr B	Consumer's father/complainant
Hospital 1/NMDHB	Provider
Dr C	General surgeon
Dr D	Anaesthetist

15. Also mentioned in this report:

Dr E	Medical practitioner
Mr F	Ms A's brother
Dr G	General surgeon
RN H	Registered nurse
RN I	Registered nurse
RN K	Charge nurse manager
RN J	Anaesthetic nurse
RN L	Scrub nurse
RN M	Scrub nurse
RN N	Circulating nurse
Dr O	Anaesthetist
Dr P	Consultant, Hospital 2
Dr Q	Surgeon, Hospital 2
Dr R	Registrar, Hospital 2
Dr S	Surgeon
Dr T	Anaesthetist
Hospital 2/DHB2	Public hospital in main centre

16. Information was reviewed from: Ms A's family, Nelson Marlborough District Health Board and its staff, District Health Board 2, the Coroner, Dr E, and ACC.

17. Independent expert advice was obtained from a general surgeon, Dr Michael Rodgers **(Appendix 1)**. To assist with the assessment of this complaint, preliminary advice was also obtained from an anaesthetist, Dr Nigel Robertson **(Appendix 2)**.

Information gathered during investigation

GP referral, 2010

18. In 2010, Dr E referred Ms A (aged 31 years) to the surgical service at Hospital 1.[4] Dr E noted that Ms A was experiencing daily right-sided abdominal pain, and that an ultrasound showed a single 14mm gallstone.

Personal wishes

19. Ms A's parents, Mrs B and Mr B, provided HDC with a copy of a statement their daughter had written and signed, entitled "MY PERSONAL WISHES". The statement, dated the day of Ms A's appointment with Dr E, set out Ms A's "treatment instructions in the event of [her] incapacity":

> "I direct that NO **TRANSFUSIONS OF WHOLE BLOOD, RED CELLS, WHITE CELLS, PLATELETS OR PLASMA** be given to me under any circumstances, even if health-care providers believe that such are necessary to preserve my life. I refuse to predonate and store my blood for later transfusion.
>
> …
>
> Regarding **MEDICAL PROCEDURES INVOLVING THE USE OF MY OWN BLOOD**, except diagnostic procedures such as blood samples for testing i [sic] refuse all.
>
> …
>
> **I give no one any authority to disregard or override my instructions set forth herin** [sic]."
>
> This legal directive is an exercise of my right to accept or to refuse medical treatment in accord with my deeply held values and convictions …"

20. A full copy of Ms A's statement, which she had her father laminate, is attached as **Appendix 3**. Mrs B stated that their daughter carried the document with her, and that it was in her wallet when her personal belongings were later returned to the family by the hospital.

21. The wording of this statement is similar to that used in a "Health Care Directive", completed and signed by Ms A prior to a diagnostic laparoscopy at Hospital 1 in February 2006. This 2006 statement, a copy of which was held with Ms A's records at Hospital 1, stated that Ms A was a Jehovah's Witness (see **Appendix 4**).[5]

22. The 2010 statement contains no reference to Ms A being a Jehovah's Witness. Ms A's family advised HDC that Ms A had ceased to be a practising Jehovah's Witness

[4] Dr E is a general registrant practising in general practice.
[5] Ms A's hospital records also include directives or statements refusing blood and blood products completed in 1997 and 1999.

earlier in 2010, but that her views in relation to accepting blood and blood products were unchanged (ie, she would not accept these). Ms A's brother, Mr F, stated that his sister had researched the use of blood transfusions and made an informed decision not to accept these.

23. Dr E advised HDC that, to the best of her knowledge, Ms A did not discuss her directive or views in relation to blood and blood products during their appointment in 2010, or at any other time during their consultations.

Outpatient appointment

24. Ms A met with general surgeon Dr G. Dr G confirmed symptomatic gallstone disease and diagnosed mild cholecystitis.[6] It was agreed that Ms A would have a laparoscopic cholecystectomy in the near future. Dr G prescribed a five-day course of antibiotics in the interim.

25. Dr G advised HDC that he recommended Ms A have a laparoscopic cholecystectomy "as the only proven and gold standard treatment of symptomatic gallstone disease". He stated that other possible treatment options were not discussed as no other treatment is recommended in fit patients with symptomatic gallstones.

26. The clinical record for this consultation includes a hand drawn diagram of a gallbladder, which Dr G referred to during his consultation with Ms A. Next to the diagram Dr G wrote "95%" and "1%". Dr G told HDC that he discussed with Ms A the "common, serious, potential complications of a Laparoscopic Cholecystectomy, a 1% risk of bile duct injury and a 5% conversion rate to an open procedure". Records also show that at this appointment, Ms A was given a brochure with further information about laparoscopic gallbladder surgery, including details of the procedure, its risks, alternatives, and the recovery process.

27. Dr G told HDC that during this consultation, Ms A did not mention her views in relation to blood and blood products or show him her 2010 statement. He did not see the 2006 directive on her file. Dr G stated that, had they known that Ms A would not accept blood or blood products, they would have approached the case differently, as there is a risk of bleeding with any operation. He said that they would have gone into more detail about the risks of bleeding and the alternatives to blood transfusions. Dr G stated that he did not specifically discuss bleeding with Ms A "because it's very unusual and it's not usually a problem".

28. Mrs B told HDC that following this appointment, Ms A told her that she had shown staff her papers and that it would be a small operation.

Pre-admission Clinic

29. In 2011, Ms A attended a Pre-admission Clinic appointment with registered nurse (RN) H. RN H advised HDC that she remembered Ms A from her 2006 admission. RN H stated that Ms A was somewhat overweight, but that otherwise she was a fit, healthy young woman with no co-morbidities of concern.

[6] Inflammation of the gallbladder.

30. At this appointment, RN H had a copy of an electronically generated "Patient Admission Information" form, setting out basic patient information (name, address, date of birth, etc), Ms A's scheduled admission date, the procedure, GP details, and contact details for Ms A's nearest relatives. The form showed Ms A's religion as Jehovah's Witness. It also indicated that Ms A was under the care of general surgeon Dr C.

31. During the appointment, RN H completed a "DAY STAY 24 HOUR STAY ASSESSMENT AND CARE PLAN". Under "Health Questionnaire Review", RN H noted "JW" and "see [perioperative] sheet". On the next page, in response to the question, "Do you have any religious/spiritual needs to be considered when planning your care?", RN H wrote: "Jehovah's Whitness [sic] (No blood products)." RN H and Ms A signed the form. RN H also completed the nursing history section of a "[HOSPITAL 1] ANAESTHESIA AND PERIOPERATIVE RECORD" form, on which she wrote: "J/Whitness" (sic).

32. RN H told HDC that she recorded Ms A as a Jehovah's Witness on the basis of information from three sources: the "Patient Admission Information" form, previous clinical records, and Ms A's verbal response to the question about religious/spiritual needs. RN H cannot recall whether Ms A said anything further about this, but believes Ms A verbally confirmed that she was a Jehovah's Witness. RN H does not recall seeing a copy of the statement Ms A completed in 2010. RN H stated that had she been shown this, she would have taken a copy for the clinical notes.

33. Ms A's diagnostic tests that day were unremarkable. Her haemoglobin was 144g/L[7] and platelets were 272 x 10^9/L.[8] RN H stated that on the basis of information from Ms A that she bruised easily, a coagulation screen was ordered, the results of which were also normal. RN H noted that Ms A had no co-morbidities aside from a high body mass index, and there was nothing in her assessment of Ms A that day warranting discussion with an anaesthetist.[9]

34. RN H stated that it is usual practice in circumstances such as these to order a "group and hold". This involves identifying the blood type by the ABO group system and having that available for use and to be further typed if it is later needed. "Group and hold" is used when the need to transfuse is possible but not expected. For patients having major surgery or any procedure where blood loss is more likely, blood will be "cross-matched", or fully typed, so that it is available for immediate use if needed. RN H advised HDC that because of Ms A's directive to decline blood products, a "group and hold" was not ordered. However, in response to the provisional opinion, RN H stated that a "group and hold" was not ordered because of a combination of factors: at the time, Ms A did not meet the pre-admission criteria, as a "group and hold" was indicated only for major surgery where the risk of bleeding was high, and RN H was

[7] The normal range for women is 115–155g/L.
[8] The normal range for women is 150–400 x 10^9/L.
[9] Ms A had a body mass index (BMI) of 34.1. The BMI system has known limitations but is used to indicate whether a person is underweight, overweight, or an ideal weight for his or her height. A person with a BMI above 25 is considered overweight, and a person with a BMI above 30 is considered obese.

also cognisant of Ms A's wishes. NMDHB advised that ordering a "group and hold" would have been usual protocol for a patient undergoing this procedure.

35. RN H provided HDC with a protocol listing the tasks to be completed during the pre-admission process. The protocol includes:

> "Spiritual needs discussed and considered and suitable planning implemented"

and:

> "Any issues of concern relayed to the appropriate member of the Multi-discipline team. (Surgeon, secretary, [Day Stay Unit/Inpatient staff, Charge Nurse Manager or High Dependency Unit])."

36. RN H stated that she did not think the fact that Ms A was a Jehovah's Witness was an issue that needed to be flagged to the anaesthetist prior to surgery. She said that she knows that there is a section of the consent form signed by either the anaesthetist or the surgeon regarding blood and blood products.

Hospital admission

37. A few days later, Ms A presented at Hospital 1. Records show that her scheduled admission time was 7.30am. RN I was the day stay nurse responsible for preparing Ms A for theatre that morning. RN I explained that this involved a range of tasks, such as ensuring all of the necessary documentation had been completed, taking observations, making sure Ms A had a gown and stockings, and explaining to Ms A what would happen following surgery.

38. RN I told HDC that she would have checked the paperwork completed by the pre-admission nurse, and explained the "Informed Consent to Treatment" form to Ms A. RN I said that she would have explained to Ms A that the surgeon might ask her to sign the section of the consent form relating to blood products, and that as there is a risk with all surgery, the anaesthetist might talk to her about bleeding and that part of the consent form. RN I completed a "PREOPERATIVE ASSESSMENT PATIENT QUESTIONNAIRE", which includes a "Theatre Pre-Op Checklist". She recorded on the checklist that consent had not yet been obtained, that no "group and hold" had been ordered, and that Ms A had requested the return of any body parts removed.

39. Charge nurse manager (Theatre Day Stay Pre-admission) RN K advised HDC that if there is anything in particular the team needs to be aware of, the day stay nurses usually put a "Post-it" note on the front of the file as a "quick visual reminder". RN K stated that the fact that a patient is a Jehovah's Witness is the type of issue that she would expect to see flagged in this way.

40. RN I stated that she may have put a "Post-it" note on the front of Ms A's file saying "no group and save as JW", but cannot recall whether she did so. RN I cannot recall whether she discussed Ms A's refusal of blood and blood products with any other staff that morning.

41. Ms A was taken to the theatre suite and, at 8.10am, was given pre-anaesthetic medications.[10]

NMDHB's consent form and Informed Consent policy

42. At the time of these events, NMDHB used a two-page "Informed Consent to Treatment" form, comprising four sections: "Procedure", "Anaesthetic", "Blood/Blood Products", and "Request for Body parts". The section for consent to the procedure was on page one, and the other three sections on page two.

43. The section pertaining to the use of blood and blood products is as follows:

> *"Blood/Blood Products*
>
> *I have read or had explained, and understand the risks and benefits of the use of blood and blood products and have had the opportunity to discuss the use of each.*
>
> *I agree/do not agree (cross out that which does not apply) to the use of these products if required. If agreeing, I am aware that I can withdraw consent at any time.*
>
> *I have discussed this with _____ , _____ , whose signature appears below..."*
>
> *Health Professional Designation*

44. NMDHB's Informed Consent policy at that time stated: "The responsibility for obtaining consent lies with the health professional who is to perform the procedure."

45. In relation to the use of blood and blood products, the Informed Consent policy stated:

> "Consent: Written consent for the use of blood and blood products must be obtained from the patient or a person legally entitled to consent on their behalf.
>
> Additionally, when consent is being obtained for an anaesthetic, consent should also be obtained for the use of blood products if there is a significant risk (i.e. 1% or more) of these products being required in the particular circumstances."

46. NMDHB confirmed to HDC that it expected the health professional who obtained consent for anaesthesia also to obtain consent for the use of blood and blood products, if this consent was required.

47. NMDHB advised that the health professional responsible for completing the section of the form pertaining to the return of body parts would be "the person responsible for removing them, typically the surgeon".

Surgeon Dr C

48. Ms A was taken to the theatre holding cubicles, where she met Dr C for the first time. Dr C believes that this would have been at 8.15am or thereabouts.

[10] Paracetamol, domperidone, and ibuprofen.

49. Dr C advised HDC:

> "[It] is not uncommon for the surgeon who undertakes the surgery to have not seen the patient or done the work up for the surgery in the outpatient clinic. This is often undertaken by a colleague, who may then be away, or on leave or who has a much longer waiting list …"

50. Dr C told HDC that he introduced himself to Ms A as the operating surgeon, and confirmed the planned operation. He stated that he then went through Ms A's outpatient notes and the referral for surgery, the surgical notes to confirm her history, and the relevant blood tests and ultrasound report.

51. Dr C stated that he then went through the informed consent process, whereby he "discussed the general risks of surgery (bleeding and infection) and then went on to discuss the more unusual risks of bile duct injury including the possible need to transfer and the possible need to convert to 'Open'". Dr C further stated:

> "Through this process, I found no information that the patient was a Jehovah's Witness or was refusing blood. At no time during the consent process, did she volunteer to me that she would refuse all transfusion of blood or blood products, even during my discussion on the risk of bleeding during surgery."

52. In response to the provisional opinion, Dr C submitted that he indicated to Ms A that conversion to an open operation would be necessary if the safety of the laparoscopic surgery was impeded by excessive bleeding, infection or uncertain anatomy. Dr C acknowledged that he made no written note on the consent form of that conversation.

53. Dr C was satisfied that surgery should proceed. He and Ms A signed the "Procedure" section of the consent form. The form states that Ms A consented to a laparoscopic cholecystectomy. The risks documented by Dr C were bleeding, infection, and common bile duct injury (see **Appendix 5**).

54. Dr C stated that for laparoscopic cholecystectomies, he always discusses three big issues: risk of bleeding, risk of infection, and risk of damage to the common bile duct, and in that overall context the risk of having to convert from laparoscopic to open surgery. Dr C stated: "I always indicate that the laparoscopic surgery bleeding is usually not an issue, a couple of [teaspoons] of blood is sometimes quite a lot. We very seldom have major issues with bleeding." Dr C noted that he does not routinely discuss the use of blood transfusions with patients undergoing a laparoscopic cholecystectomy unless he considers that it should be raised because of any matter particular to the patient. He stated: "Had I known [Ms A] was declining blood products on the day of surgery, I most certainly would have advised her that, although rare, there is always the chance that there may be a complication that will require transfusion", and that he would have discussed her options with her.

55. Dr C stated that talking to a patient about his or her surgery and completing the consent process would usually take about ten minutes. He does not recall that his

discussion with Ms A was unusual in any way, or that she had any specific questions. Dr C recalled:

> "[Ms A] seemed a normal young lady. She was for me a little bit short and rotund because that make[s] surgical challenges so sort of alarm bells were ringing a little bit but didn't detract from her need to have surgery and that doesn't stop us operating, it just makes, sometimes makes it more challenging."

56. Dr C noted that the best time for a patient to tell a surgeon that he or she does not accept blood products is in the outpatient setting, when there is time to go into all the intricacies. Dr C stated:

> "If you don't want to have blood then the important thing is to be fully informed about the consequences, what the options are should we get into trouble with bleeding and in lap choles, in the unlikely event that we get into bleeding, what the options are. There are a number of things that Jehovah's Witnesses apparently will accept. They will accept cell savers, they will accept various agents to try and stop clotting, and as I said in the submissions, we had a cell-saver here but it's not sitting in theatre primed and ready to go, it needs setting up, it needs a tech to set it, to prime it, that can take an hour or more, and it's stored in the back room somewhere and some people have never even seen it.[11] It's not something that's commonly used in surgery, it's used in other fields of surgery. Orthopaedics use it far more than we do. So there's that option, there's the option of the Recombinant factor VII[12] which is very expensive, we don't routinely keep it at [Hospital 1], it's kept at [a] Hospital which is 120 kilometres away, so that if she had indicated acceptance of surgery with those sort of things being available then the only option at that time would be to cancel the surgery such that we could have got the Recombinant factor in, organised to have the cell saver available, organised to have somebody prime it and be happy with its function. Getting that information in the theatre setting is just not appropriate."

57. In response to the provisional opinion, anaesthetist Dr D submitted that Hospital 1 and the other NMDHB hospital have never had a cell saver system for general surgery. NMDHB confirmed that neither hospital had (or have) a cell saver system for use in theatres.

Anaesthetist Dr D

58. Dr C left and Ms A was then seen by Dr D, who had also provided anaesthetic services to Ms A in 2006.

59. Dr D stated that obtaining consent for anaesthesia was a collective process that began in the pre-admission clinic, where Ms A was given written and verbal information. Dr

[11] A cell saver is a machine that recovers blood lost from a patient during surgery and re-infuses it into the patient.
[12] Recombinant Factor VIIa is an artificial form of a protein in the blood that works with other clotting factors to help the blood to clot and therefore stop bleeding.

D noted that as Ms A was "a reasonably fit young lady (ASA 2) … no further requirements were flagged to warrant anaesthetists' involvement at that stage".[13]

60. Dr D stated that in these circumstances, he would have seen the surgical list the night before, showing only Ms A's name and the scheduled procedure. Dr D noted that the other patient on Dr C's list that morning was a "difficult" case, which Dr C had discussed with him several days previously. However, Ms A was "relatively simple from all our perspectives at that stage. It was a booked routine laparoscopic cholecystectomy".

Consent for anaesthesia

61. Dr D stated that he first reviewed Ms A's notes on the morning of surgery, and it was then that he saw the 2006 directive at the front of her previous notes and became aware of Ms A's refusal of blood and blood products. Dr D said that his discussion with Ms A about anaesthesia covered the specific factors outlined on the anaesthesia and perioperative record, ie, general anaesthetic, local anaesthetic, intravenous infusion and analgesia. He noted that all risks greater than 1% were discussed, "which did not specifically include bleeding in what was perceived to be a routine laparoscopic cholecystectomy in a young reasonably fit woman". Dr D stated that he specifically said to Ms A, "I respect your beliefs", as he routinely does with all Jehovah's Witness patients.

62. Dr D recalled that Ms A's discussion with him that morning was mostly about the fact that she was so glad to be having the operation, because of the problems she had been having with infection, stones, and pain. Ms A's family also noted that she was "sick of the pain".

63. Dr D and Ms A signed the anaesthetic section of the consent form.

Blood and blood products

64. The section of the consent form relating to blood and blood products was not completed (see **Appendix 5**).

65. Dr D stated that he saw no reason to complete the blood/blood products section of the consent form, "because the incidence of bleeding in this procedure is extremely low … it's there but it is extremely low and it fits in with the DHB policy of less than 1%". Dr D stated that he has never discussed bleeding in these circumstances, "unless [the patient has] had some sort of issue of clotting disorders or anything like that that may actually affect it". Dr D stated further that he had never in his career had to transfuse a patient having either a laparoscopic or an open cholecystectomy.

66. NMDHB advised HDC that it considers that the section of the consent form relating to the use of blood products should have been completed in this particular case, because Ms A had an advance directive on file indicating that she was a Jehovah's Witness and that in the event of her incapacity she refused the transfusion of blood

[13] The ASA physical status classification system is a system for assessing the fitness of patients before surgery. There are six categories of patient; ASA 2 refers to a patient with mild systemic disease.

products. NMDHB stated that even though the risk of bleeding was not significant as set out in its policy (ie, it was less than 1%), "the use or otherwise of blood products was of particular significance to her as a Jehovah's Witness and indeed the health professionals involved in her care in the unlikely event that she did experience severe blood loss".

67. Dr C noted that as he obtained Ms A's consent first, he would not have seen the section of the consent form relating to blood and blood products even if this had been completed by Dr D.

Risk of bleeding

68. Reports in the literature regarding the risk of bleeding in patients undergoing a laparoscopic cholecystectomy vary.

69. According to the Uptodate literature review site:[14]

> "BLEEDING COMPLICATIONS — The incidence of uncontrollable bleeding from laparoscopic cholecystectomy is 0.1 to 1.9 percent and can occur from three distinct sites — the liver, arterial sources, or port insertion sites."

70. Research by Robin Kaushik states:[15]

> "Bleeding has been reported to occur with an incidence of up to nearly 10% in various series, and may occur at any time during [laparoscopic cholecystectomy] … or in the postoperative period. It can range from minor haematomas to life-threatening injuries to major intra-abdominal vessels."

71. And further:

> "The reported incidence of uncontrollable bleeding in [laparoscopic cholecystectomy] can be up to 2% (reported range, 0.03% to 10%), but the exact figure may actually be much higher. Various factors may be responsible for this under-reporting, such as (i) lack of an exact definition of bleeding complications; (ii) many series have reported vascular injuries only but have not considered bleeding from other sites or postoperative bleeding; (iii) a publication bias; (iv) fear of litigation; and (v) absence of proper documentation at various centres. When bleeding occurs, the [laparoscopic cholecystectomy]-related mortality reportedly goes up to nearly 15%, especially when the bleeding remains unrecognized."

72. In relation to the risk of bleeding requiring transfusion in patients undergoing cholecystectomy, my surgical expert, Dr Michael Rodgers, refers to a study in Glasgow which reported that 1.1% of patients required transfusion.[16]

[14] www.uptodate.com
[15] Kaushik, R, "Bleeding complications in laparoscopic cholecystectomy: Incidence, mechanisms prevention and management", *J Minim Access Surg*, 6(3): 59–65 (July–Sep 2010).

Transfer to theatre

73. Dr C stated that it is his usual practice, once he and the anaesthetist have both seen a patient, to discuss with the anaesthetist "any issues which might have a significant impact on the operation (cardiac risks, duration of surgery, epidurals etc) whilst the patient is being transferred by the theatre staff into the operating room". Dr C noted that in Ms A's case, the anaesthetist "did not indicate to me any concerns that he had about the patient. Bleeding is not a common issue with [laparoscopic cholecystectomy] surgery and the need for transfusion even more unusual."

74. During an interview with HDC staff, Dr D confirmed that he did not discuss Ms A's refusal of blood and blood products with Dr C at any point prior to surgery. Dr D stated: "The only time I mentioned [it] to him is when … we obviously had the disclosed bleeding problem in recovery …" (see below).

75. Ms A proceeded to theatre.

Surgical Safety Checklist

76. NMDHB uses a "Surgical Safety Checklist", which was adapted from a World Health Organization (WHO) checklist. This is an initiative aimed at reducing unnecessary surgical deaths and complications, by identifying a set of safety checks that can be performed in any operating room, in order to "reinforce accepted safety practices and foster better communication and teamwork between clinical disciplines".[17]

77. Like the WHO checklist, the NMDHB "Surgical Safety Checklist" (the Checklist) has three sections: "SIGN IN", for issues to be checked before the induction of anaesthesia; "TIME OUT", for issues to be checked before skin incision; and "SIGN OUT", for issues to be checked before the patient leaves the operating room. The Checklist is attached as **Appendix 6**.

78. Within the "Time Out" section of the Checklist, there is a section entitled "ANTICIPATED CRITICAL EVENTS", which includes:

> "**SURGEON REVIEWS:** WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS?
>
> **ANAESTHESIA TEAM REVIEW**S: ARE THERE ANY PATIENT SPECIFIC CONCERNS?"

79. NMDHB has a set of guidelines to provide direction for the completion of the Checklist. The guidelines provide no further detail as to what constitutes a patient specific concern.

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[16] Quinn, M, Suttie, S, Li, A, Ravindran, R, "Are blood group and save samples needed for cholecystectomy?", *Surg Endosc*, 25(8): 2505–8 (Aug 2011).
[17] World Alliance for Patient Safety, *Implementation Manual Surgical Safety Checklist (First Edition)* (Geneva: World Health Organization, 2008).

80. NMDHB advised HDC that Hospital 1 started using a "Time Out" system in 2006, and that prior to roll-out of the WHO system it had adopted the system used in [another DHB]. The DHB stated that all staff attended in-service training, and meetings were held with Senior Medical Officers to introduce the system.

81. Although NMDHB's checklist is very similar to the WHO checklist, the latter includes an additional step in the "Sign Out" section, which requires the surgeon, anaesthesia professional and nurse to review key concerns for recovery and management of the patient. NMDHB advised that this step was removed after a DHB-wide review of the form, as users felt it was covered in other ways.

Use of the Checklist for Ms A

82. Records show that the Checklist was completed for Ms A, and that blood loss of greater than 500mls was not anticipated.

83. A number of staff present in the operating theatre were asked what they recalled about the use of the Checklist that morning.

84. Dr C stated that he has no specific recollection of any surgical "Time Out", but presumes it took place as is the norm before every operation.

85. Dr D initially stated that he did not think the "Time Out" process was in use at Hospital 1 at the time of these events. When Dr D was advised that the DHB had confirmed that the process was in use at that time, he stated: "Clearly, I cannot say with any confidence about what was said around this process." Dr D subsequently explained that he did recall a checklist process in place at the time of Ms A's operation, but was not certain when the WHO guidelines were adopted.

86. Dr D also stated that as the proposed procedure carried an extremely low risk of requiring blood and blood products, Ms A's refusal of these "was not considered to be an issue for the 'Time Out' process". However, he stated further that as other members of the team recall being aware from the "Time Out" that Ms A was a Jehovah's Witness (see below), he or somebody else must have mentioned it.

87. RN J was the anaesthetic nurse that morning. She stated that, given the time that had elapsed since these events and the fact that she had looked after a lot of patients in the meantime, she cannot recall what concerns she raised during the "Time Out" process. She stated further:

> "I can't say with absolute certainty that I voiced that she was a Jehovah's Witness … but based on my usual standard of nursing care and the routine I had acquired doing the 'time out' since it was established, I am pretty certain that I would have if the anaesthetist didn't raise this concern."

88. RN J also advised HDC:

> "It is not practice to write down on the surgical safety checklist what kind of concerns the surgeon, anaesthetist, or nursing staff raise. It is just a tick box for

> prompting, hence there is no written evidence of this particular matter. The anaesthetist as well as the surgeon are encouraged to participate in the 'time out' when asked if there are any concerns."

89. RN L recalled that she was supervising another nurse that morning, RN N, who was in the role of scrub nurse for the first time.[18] RN L is "reasonably confident" that she was aware at the start of the surgery that Ms A's religious belief did not permit the use of blood and blood products.

90. RN N stated: "At the start of theatre at the 'time out' session, I can only be about 95% sure that it was identified that [Ms A] was a Jehovah's Witness."

91. RN M was the circulating nurse.[19] She does not recall being informed that Ms A refused blood and blood products, either in association with the Checklist or through it being mentioned by another team member.

92. Dr D was asked whether, at the commencement of surgery, he had any reason to believe Dr C did or did not know about Ms A's refusal of blood and blood products. He stated:

> "I don't think — at the time, I mean, realistically, I mean I thought about this at great lengths and I felt that does it really matter to him because we're doing the transfusions and things, yes it would matter if it was going to be a case that had a potentially high bleeding problem, but for something which was really a routine and was put on before a very difficult case which we would never ever, and even [Dr C] said in all his surgical experience he has never known anybody require transfusion for a gall bladder operation, and the incidence is rare, and so does he need to know because it's a Jehovah's Witness at that stage. I never really gave it a thought. I knew and I never gave it a thought, I just presumably assumed that in fact he knew."

Surgery

93. Records show that Ms A's vital signs were being monitored from 8.45am and surgery commenced at 9am. In a report later completed by Dr C for a sentinel event investigation, he wrote that on commencing the surgery, "the immediate finding was of a large amount of fat covering the [gastrointestinal tract] and upper abdomen". Dr C noted a "stiff, fatty liver … which could not be folded easily, making visibility more difficult". An additional (fifth) port was placed. Dr C stated that when he began dissecting the gallbladder from the liver, difficulty was encountered with the gallbladder being firmly embedded in the liver. Dr C stated:

> "Exposure then became a problem as the liver could not be satisfactorily folded out of the way (stiff with fat = Steatosis) and owing to the proximity of critical

[18] Scrub nurses work directly with the surgeon(s) within the sterile field.
[19] Circulating nurses co-ordinate, plan, and implement the nurse-related activities during an operation, but do not scrub in with the surgical team.

> structures (Hepatic vessels and Common Bile Duct), it was decided to abandon the Laparoscopic approach with inadequate visibility and to convert to 'Open'."

94. This occurred at 9.50am. Dr C stated that with this approach, the operative team was able to dissect the gallbladder away from the liver with a much clearer view of the anatomy. He stated that they did not encounter any abnormal structures or ducts, and the gallbladder was successfully removed.

95. Dr C stated further: "Some bleeding had occurred during the open operation, but not enough to cause concern and the operative area was dry at the end." Dr D documented blood loss of about 500mls.

96. Records show that the operation ended at 11.15am.

Postoperative deterioration

97. At 11.25am, Ms A was transferred to the Post Anaesthesia Care Unit (PACU or Recovery Unit), in a stable, unconscious condition. Dr D and RN J handed over Ms A's care to the recovery nurse.

98. Dr C and Dr D returned to theatre to commence their second surgery for the day.[20]

99. Records show that from about midday, Ms A's pulse began trending upwards and her blood pressure downwards. An entry on the "POST ANAESTHESIA NURSING RECORD" states: "[Patient] low [blood pressure]. Fluid rate increased. Head of bed lowered. Catheter inserted (for) hourly measure. Arranged to go to [High Dependency Unit]." It was also noted that the anaesthetist had been informed. It is unclear whether all of this information was documented at the same time; no times are noted.

100. A further entry states: "13.30hrs Hb — 61. — Anaesthetist notified."

101. Dr C recalled that he had probably been operating on the second patient for 1½–2 hours when it became evident that he would need to take Ms A back to theatre in an attempt to stop the bleeding. He said that he was advised that Ms A's blood pressure was dropping. Dr C told HDC:

> "The most likely reason is fluids. The concern is always blood because when I converted to the open operation there had been some bleeding from under the surface of the liver which we diathermied[21] and I put a drain down there just in case because that's a routine procedure for me, and she certainly wasn't bleeding a lot into the drain but certainly her clinical picture indicated she was bleeding. So my instruction was 'Cross match and give her some blood'."

102. Dr C stated that it was at this point that he learned that Ms A was a Jehovah's Witness and that she refused blood. Dr C could not recall whether it was a nurse or the

[20] Records show that this surgery commenced at 12.05pm.
[21] Diathermy is a technique for stopping bleeding involving the use of an electrical current to cauterise small blood vessels.

anaesthetist who told him this. Dr D recalled that it was he who informed Dr C that Ms A could not be given blood.

103. Dr D recalled that it was when nursing staff came into theatre to report concerns about Ms A for a second time that "lights were starting to flash". Dr D said that he made sure the patient they were then operating on was stable, and went to see Ms A. Dr D said that Ms A was pale, and a Haemacue indicated bleeding.[22]

104. Dr D stated that he went back into theatre where Dr C was still operating on his second patient, and said: "[Dr C], we have a problem, she's bleeding. We need to bring her back to theatre." Dr D stated that when he initially told Dr C that Ms A was bleeding, Dr C said, "Well give her blood," at which point Dr D told Dr C that they could not do so because she was a Jehovah's Witness.

105. Dr G was contacted at home. He came in to take over the operation Dr C was then performing, so that Dr C could attend to Ms A.[23] Another surgeon had already agreed to take on the third patient on Dr C's list that day. Arrangements were also made to free up one of the three theatres, all of which were scheduled for use that afternoon.

Assessment by Dr C

106. Dr C stated that once he had unscrubbed, he attended Ms A in the Recovery Unit, where she was conscious, but still drowsy from the anaesthetic. Dr C stated: "Having confirmed her clinical condition, I asked her again for her consent to transfuse, and this was verbally refused."

107. During an interview with HDC staff, Dr C stated: "She was sedated, you know, she was certainly not a legally competent person at that time …"

108. Dr C stated further:

> "Realising the urgent need for blood to provide further clotting support to control the bleeding, I decided to phone her parents in an effort to get their support for transfusion, but they also adamantly declined. They did consent to Tranexamic Acid and recombinant Factor VIIa, the latter of which was urgently ordered from [another hospital] as it is not routinely stored at [Hospital 1]."

109. At 2.30pm, Dr C documented Ms A's condition. His notes included:

> "Clinically bleeding.
> HB 61 BP ↓ Pale Abdomen distended
> ? Liver bed Drain only 150mls
> Needs to be reopened
>
> [Patient] categorically refuses blood or blood products (Jev Witness)
> Mother concurs

[22] A Haemacue is a device for measuring haemoglobin levels at the bedside. Haemacue testing is more immediate but less specific than laboratory testing.
[23] Records show that Dr G took over from Dr C at 2.20pm.

Apparently will accept recom VIIa
— on the way from [another centre]

Urgent reopen in theatre to pack/control bleeding."

110. In his statement for the Coroner, Dr C wrote: "Whilst waiting for a free theatre, Tranexamic Acid was given, together with clear fluids and arrangements were made to bring recombinant Factor VIIa from [another centre] — all products acceptable to their faith." Records show that Ms A was given Transexamic Acid (1g) at 2.05pm.

Mrs B

111. Mrs B recalled that she had been told to call the hospital after midday, which she did. She stated that she eventually got through to the Day Stay Unit, and was told that her daughter was still in the Recovery Unit. Mrs B stated that she was on her way to the hospital when Dr C telephoned her. She thinks that this would have been at about 2.30pm. Mrs B stated that this was when she was first told that there was something wrong. She said that Dr C told her they needed to take Ms A back to theatre, when there was a theatre available.

112. Mrs B said that it was during this conversation that Dr C first asked for her permission to override her daughter's directive to refuse blood. Mrs B said that she told Dr C she could not go against her daughter's wishes. Mrs B said that when she asked Dr C how she could do as he was asking, he said, "Because you're her mother." Mrs B stated that following this call, she returned home to try to contact her family.

113. Mrs B advised HDC that she has found it very hard to get over Dr C's request that she override her daughter's treatment refusal. In response to the provisional opinion, Dr C apologised for the distress caused to Mrs B. He stated: "[A]t that time, on the information available to him and in an emergency situation [he] hoped that [Ms A's] parents might consent, hence his call to [Mrs B]."

Second operation

114. In an untimed entry in the clinical records, anaesthetist Dr O wrote:

"Return to [operating theatre]
— concealed bleeding post lap → open chole
— [Discussed with] patient (sedated)* re blood products → in no circumstances.
— Hartmanns 3000, Pentastarch 500
*? [decreasing loss of consciousness] on transfer to [operating theatre]
(pupils [approximately] 5mm)"

115. At 2.29pm, Ms A's haemoglobin was 45g/L.

116. Records show that induction of anaesthesia commenced at 2.45pm, and surgery commenced at 2.55pm.

117. In his statement for the Coroner, Dr C wrote:

> "On re-opening the abdomen, about 2500mls of blood and clot was retrieved and blood was seen to be welling up from the depths of the liver area.[24] In view of the critical levels of haemoglobin and potential difficult dissection, I decided not to expose her to further potential blood loss, but rather to pack off the area and transfer her to a better equipped facility for angiography and possible embolisation. The abdomen was dry on closing, indicating adequate control."

118. At 3.26pm, Ms A's haemoglobin was 11g/L.

119. The operation concluded at 3.50pm. Ms A remained in the operating theatre.

Hospital 2

120. Contact was made with Hospital 2. It is unclear from the clinical records exactly who was contacted by whom, and when.

121. Dr P was the consultant on duty at Hospital 2's Intensive Care Unit. Dr P advised HDC that he recalled having two or three conversations with the surgeon at Hospital 1, but that he could not remember the exact timing and content of these calls.

122. Dr P believes that he was contacted before Ms A's second operation. He stated:

> "Pre-operatively her haemoglobin level was 45, which in a Jehovah's Witness who refused blood product transfusion I felt was life threatening. Post-operatively her haemoglobin was 11 which is almost incompatible with survival. At some stage I suggested using concentrated factor VII, which if used early enough before severe dilutional anaemia has occurred might control the bleeding.
>
> I thought [Ms A] was almost certainly going to die and accepted the transfer mainly to help manage this difficult and distressing situation."

123. Dr O noted in an untimed entry on the "OPERATIVE RECORD": "[Discussed with] Hospital 2 [Intensive Care Unit] — willing to transfer — suggest fVIIa to cover transport."

124. Dr C recalled speaking to the Hospital 2 on-call surgeon, and to an intensivist. Dr C could not recall, and did not document, the names of the doctors with whom he spoke or the times of these calls, although he stated that he spoke to the surgeon on call after he had unscrubbed following Ms A's second surgery (ie, after 3.50pm).

125. Colorectal and general surgeon Dr Q recalled that while he was operating at Hospital 2, he received a call from a surgeon about a young Jehovah's Witness patient. Dr Q recalled:

> "[The] patient became profoundly shocked in the post anaesthetic care unit and was taken back to the operating theatre where [the surgeon] encountered significant bleeding the source of which he was unable to identify and was unable

[24] Dr O noted blood loss of about 3000ml in the abdomen.

to fully control. I understand he 'packed the patient' and called me in [Hospital 2] to accept the patient.

(I have previously treated a patient with a similar problem successfully with a 'cell saver' auto transfusion device.)"

126. Dr C wrote a clinical note in anticipation of Ms A's transfer to Hospital 2. In relation to the second surgery, he noted:

"— Difficult surgery
— Myself and house officer
— No specific liver equipment

∴ [Hospital 1] is not a good place to try to fiddle to get vascular control with the blood situation so precarious

Thank you for agreeing to help with her management.
Your ICU and our anaesthetist are liaising over haemostatic control (recom VIIa etc)."

127. At 5pm, Novoseven was issued by the Blood Bank.[25] Administration commenced at 5.10pm.

Further contact with Mrs B and family

128. In the meantime, Mrs B had left home and started driving to the hospital for a second time. She recalled that she was on the way when she received a telephone call from a nurse.[26] Mrs B said that the nurse also asked if they could give Ms A blood, saying, "[Y]ou don't know how sick your daughter is." Mrs B said again that she could not override her daughter's wishes.

129. Mrs B stated that she was almost at the hospital when she received another telephone call from a nurse, telling her that she needed to get to the hospital as soon as possible. Mrs B cannot recall the name of the nurse to whom she spoke, or whether it was the same nurse who had called her previously.

130. RN K stated that she telephoned Mrs B, who was by then very near the hospital. There are some discrepancies between the accounts provided by Mrs B and RN K, including the likely timing of the call(s), but RN K confirmed that she asked Mrs B whether they could give Ms A blood. RN K stated:

"I can't really remember word for word, but I explained that [Ms A] had deteriorated that she was bleeding and would they consent to us giving blood. And [Mrs B] said no."

131. Mrs B stated that while she was on her way to the hospital, she made a further call to her son, Mr F. Mrs B left a voicemail message at 3.27pm, during which she reported having been told that Ms A was going to die.

[25] Novoseven is a trade name for Recombinant Factor VIIa.
[26] She was approximately 9km from the hospital.

132. Mrs B stated that she arrived at the hospital just after 3.30pm, where she met her daughter-in-law and a family friend in the hospital carpark. They stated that they were met by a nurse, who told them they would not be able to see Ms A for about 45 minutes.

133. RN K stated that it was she who met Mrs B on her arrival at the hospital, and that she thought that this was shortly after Ms A had returned to theatre.

134. RN K said that she then spent most of her time with Ms A's family. She talked to them further about the possible consequences, and said that Dr O came out of theatre "well into the second operation", and also spoke to the family. RN K said that the family were told that it was not looking good for Ms A, "and I remember saying to them you know that I respected their beliefs but I had to ask the question. I couldn't not ask the question."

135. Within the next hour or so, Ms A's father and brother also arrived at the hospital. Mrs B and family recalled that "the nurse" asked a number of times if they could give Ms A blood, and that the anaesthetist also came and asked the same question.

136. Ms A's family stated that when they saw Ms A following her surgery that afternoon, she was cold and not moving at all.

Helicopter

137. Records show that at 4.30pm, a referral was made by Hospital 2 to their retrieval and transfer service.

138. A helicopter left Hospital 2 at 5pm and arrived at Hospital 1 at 5.30pm.

139. At 5.40pm, Ms A was assessed by Hospital 2's Intensive Care registrar Dr R. Dr R's notes include: "Pale. … Warm central, cool peripheries. Pupils fixed and dilated. [Heart rate] 129 / [blood pressure] 71/49 … [bilateral air entry]."

140. Dr R noted that after a telephone discussion with Dr P, they confirmed that they would take Ms A to Hospital 2 if Ms A's family and the medical staff at Hospital 1 wished this. Dr R noted further: "[Discussed with family] → futility explained in view of likely hypoxic brain injury. Decision made to stay in [Hospital 1]."

141. At 6.30pm, Dr C documented:

> "Bleeding controlled by laparotomy and packing.
> But Hb <2g/b — hardly compatible with life
> Not allowed to transfuse
> Pupils fixed @ 7mm
> Patient to stay in [Hospital 1] as successful outcome unlikely."

142. Ms A's death was confirmed at 6.59pm.

Post mortem

143. Ms A's death was reported to the Coroner.

144. The post mortem report states: "No precise bleeding site was identified." The pathologist stated:

> "It is noted that the laparoscopic procedure was converted to an open procedure due to mobilisation and visualisation of the fatty liver which is confirmed microscopically. No direct failure of haemostasis[27] is noted at the operative site.
>
> No other pre-existing natural disease is noted.
>
> Cause of death appears to be due to significant blood loss from the operative site, resulting in hypovolaemic shock. In this setting the low circulating blood volume results in reduced oxygenation to systemic tissues leading to multi organ dysfunction and ultimately cardio-respiratory arrest, which has been the likely mechanism of death."

Sentinel event investigation

145. NMDHB investigated Ms A's death as a sentinel event.[28] As part of this investigation, a surgeon from NMDHB, Dr S, reviewed the medical records. A copy of Dr S's report is attached as **Appendix 7**.

146. The sentinel event investigation report concluded:

> "In summary [Ms A] died as a consequence of post-operative bleeding following cholecystectomy. Her outcome is likely to have been different had she not refused blood products to treat this complication when it developed on religious grounds. That being said [Ms A] had the right to make informed choices regarding her medical treatment and it was appropriate that the staff involved in her care respected her decision in this regard.
>
> Finally, although one might question whether major surgery should be undertaken in [Jehovah's] Witnesses, we are advised that most surgeons wouldn't disqualify such individuals from surgery provided that they are fully informed about the risk of bleeding and likelihood of death if this occurs."

147. There were no recommendations arising from the sentinel event investigation.

Proposed policy change

148. NMDHB advised HDC that its Informed Consent policy and the consent form were to be revised, making it clear that the surgeon or health professional completing the

[27] A surgical procedure to stop the flow of blood.

[28] NMDHB advised HDC that the event was reported as a sentinel event to the Health Quality and Safety Commission, but that the Commission did not consider it satisfied the criteria for that classification and it was not included in the DHB's 2010/2011 serious and sentinel event report.

consent to treatment is also responsible for completing the consent for blood/blood products.

Additional information from Dr C

149. In light of Dr C's request to Mrs B for permission to override Ms A's directive and give her blood, HDC asked Dr C what he would have done had Ms A's parents agreed. Dr C stated:

> "[My] whole focus is on patient well-being, and if her parents had said 'Go ahead and give her blood', I would like to have sought some other opinion if possible, like certainly a phone call to our Chief Medical Officer would have been appropriate, and ideally a legal mind somewhere to say where do I stand because it's my impression that if you give somebody a blood transfusion and they've specifically said 'No I don't want it' then I could be accused of assault, but at the end of the day I'd much rather have a live patient to deal with those sort of problems than have to deal with [this] situation."

Medical Council of New Zealand

150. Dr C no longer has a practising certificate from the Medical Council of New Zealand (MCNZ). In March 2012, MCNZ resolved that Dr C should undergo a performance assessment. In May 2012, Dr C agreed not to undertake any further clinical work until MCNZ agreed that he could do so. Dr C resigned from Nelson Marlborough District Health Board.

Responses to provisional opinion

151. Relevant information from the responses to the provisional opinion has been incorporated above. The following submissions are also noted.

Mr and Mrs B

152. Mr and Mrs B were given the opportunity to comment on the "Information gathered" section of the provisional opinion. They noted that while Dr D sighted the 2006 directive at the front of their daughter's notes on the morning of her surgery, Dr C apparently did not. Mr and Mrs B ask why Dr C did not see that no consent form for blood and blood products had been completed, and whether it would not be normal to sight these forms when going through the consent process with a patient.

153. Mr and Mrs B also note Dr C's statement that "alarm bells were ringing a little bit" in light of the surgical challenges Ms A presented in relation to her weight. Mr and Mrs B query whether this would not have prompted Dr C to "thoroughly research her notes looking for anything he would find a challenge".

154. Mr and Mrs B are concerned about the length of time that elapsed between their daughter's condition starting to deteriorate postoperatively (at approximately midday) and her being returned to theatre for further surgery (2.55pm). They consider that this delay denied their daughter "a fighting chance to survive".

155. Mr and Mrs B consider that Dr C's statement that "[Hospital 1] is not the place to fiddle with vascular bleeding" implies that he was "an amateur" who felt unsure of

what he was doing and was not taking their daughter's complications seriously. They consider that Dr C should have immediately arranged for her transfer rather than re-operating.

156. Mr and Mrs B also question whether Dr D could have recommended to Dr C that he arrange for Ms A's immediate transfer, or decided to arrange this himself.

157. Mr and Mrs B consider that NMDHB should have ensured that Hospital 1, as the only hospital within a radius of 140km or more, was equipped at all times to handle vascular bleeding.

NMDHB

158. NMDHB had no further comment in response to the provisional report.

Dr D

159. Dr D submitted as follows:

- Communication of the risk of bleeding should have been initiated by the surgeons early in the decision to operate.
- There is no evidence that either Dr G or Dr C had considered or knew of Ms A's refusal of blood products.
- Disclosure of information at the checklist (Time Out) stage is too late in the process to be effective — discussions about bleeding and blood products need to take place during the initial outpatients clinic, "as it is too late in the theatre setting".
- There should be a process to ensure that the surgical team is aware that the patient is refusing blood products, and that is best done at the surgical outpatients clinic.
- DHB policy did not require him to tell Dr C that Ms A had refused blood products, and he was entitled to assume that Dr C knew that already.
- But for Dr C's failure to obtain the relevant information from the file, Dr D would not be the subject of this investigation.
- "My surgical colleagues let me down by not properly acquainting themselves with the file before taking on the operation and then relaying these key facts to me as a requested service speciality sub-contracted to perform the tasks of anaesthesia."
- Ms A's Jehovah's Witness status was obvious from the file.
- The finding with regard to him goes against current practice and teaching.

160. Dr D obtained an opinion from anaesthetist Dr T, who stated that he considers Ms A's refusal of blood was an important "other" matter to be discussed at "Time Out". Dr T stated: "[T]here is no single person with the responsibility to mention her belief, but the anaesthetist and surgeon would usually mention it." He stated that, overall, he agreed with the advice given by HDC's expert advisor, Dr Nigel Robertson.

161. Dr T considered that it would have been good practice for Dr D to have confirmed with Ms A in a private environment that her directive was still valid, that she understood the consequences of it, and that the particular restrictions were still current.

162. Dr T considered that it was unacceptable that Dr C did not know of Ms A's refusal of blood products from the preoperative period. Dr T stated that information is usually known through direct discussion with the patient, and/or reading the notes. He considered it was no less acceptable that Dr C still did not know of the refusal when he converted to an open cholecystectomy. Dr T stated:

> "That [Dr D] did not mention this is unfortunate, and it is one of many periods during the process that the discussion should have occurred. I do not consider it to be [Dr D's] responsibility to provide [Dr C] with that information, but it would have been productive for him to ensure he was aware when the risks of bleeding increased. I consider, the surgeon should however have known independently, and the discussion to be a system safety check to reduce negative outcomes."

163. Dr T stated that Dr D should have communicated Ms A's refusal during the surgical checklist, and both Dr C and Dr D should have communicated with each other on the day about the refusal and, perhaps more significantly, Dr C should have independently discussed the issue with Ms A preoperatively.

Dr C

164. Dr C submitted as follows:

- There were no appropriate systems or alerts in place at NMDHB to ensure that Ms A's records were appropriately noted to identify her refusal to accept blood. There was also no system to ensure that information known to some members of the surgical team was shared with all members.
- Had alerts been in place, Dr G would have been aware of Ms A's status and relayed that information to Dr C in the surgical documentation.
- Normally significant issues identified in the pre-admission documents would be flagged for the attention of the relevant clinicians, and he found no indication of any such notices. He stated that "[t]he fact that the patient was present in the Operating Holding Area indicated to [him], as per usual [Hospital 1] practice at the time, that all these checks had been satisfactorily completed and no potential problems identified".
- On the day of surgery he "embarked on a search through [Ms A's] file seeking relevant surgical information".
- Ms A did not inform Dr G or her general practitioner of her refusal of blood products, saying that "it is fundamental that a patient who refuses a blood transfusion, for any reason whatsoever, should advise their medical practitioner of this crucial piece of information". However, he noted that Ms A had informed a number of health practitioners of the information.

- The file should have confirmed Ms A's status from her 2006 admission in a manner that could not be missed.
- "The only circumstances when body parts would be returned to a patient are the products of significant limb amputations when these might need special care according to some religious beliefs."
- The absence of a "group and hold" for this procedure did not alarm him and would not have indicated to him any religious significance or refusal of blood products.

Opinion: Introduction

165. Ms A was admitted to Hospital 1 for what was expected to be a routine laparoscopic cholecystectomy. Her death later that day was completely unexpected.

166. It is not my role to determine the cause of Ms A's death, and I do not intend to speculate on the circumstances in which Ms A's death might have been avoided. However, in my view, there were deficiencies in aspects of the care provided to Ms A. Before I consider those deficiencies, it is necessary first to set out the law regarding the right to refuse treatment, and the status of Ms A's treatment refusal as it applied in this case.

Right to refuse treatment

167. Right 7(7) of the Code states: "Every consumer has the right to refuse services and to withdraw consent to services." This is consistent with the New Zealand Bill of Rights Act 1990, which states: "Everyone has the right to refuse to undergo any medical treatment."[29] A consumer may record his or her decision to refuse services in an advance directive, which is a document that records a consumer's consent to, or refusal of consent to, services in the event the consumer becomes incapacitated and unable to consent. Right 7(5) of the Code gives consumers the right to use an advance directive in accordance with the common law.

168. Ms A's 2006 and 2010 statements were advance directives refusing the administration of blood and blood products, and indicate a consistent position with regard to her refusal of blood products. It is clear from these documents that she had thought about the specific treatments she would and would not accept, and that she understood that her refusal of treatment might result in her death.

169. Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent. This applies to making a choice to give consent to, or a choice to refuse consent to, services.[30]

[29] Section 11 of the Bill of Rights Act 1990.
[30] Rights 6 and 7 of the Code.

170. It is acknowledged that advance refusals of life-saving treatment raise very difficult issues. Such decisions bring into conflict the fundamental right of consumers to refuse treatment under the New Zealand Bill of Rights Act and the Code, and the statutory and ethical obligations on doctors to provide the necessities of life.

Ms A's advance directive and refusal of treatment

171. In Ms A's case, the initial basis for not administering blood or blood products was Ms A's treatment refusal, as communicated to RN H during the pre-admission clinic, and in accordance with Right 7(7) of the Code. Dr C stated that prior to taking Ms A back to theatre, he asked her if they could give her blood and she refused. Dr C said that at that time, Ms A was still under sedation and "certainly not a legally competent person". The situation was then urgent, and waiting for Ms A to regain full consciousness was not an option. By this time, therefore, Ms A's advance directive was applicable.[31]

Reason for Ms A's refusal of treatment

172. I agree with Ms A's family that the reason for Ms A's refusal of blood and blood products is not relevant in relation to her treatment at Hospital 1.[32] The key information — the information that those involved in her treatment needed to know — was that Ms A had made a valid decision not to accept certain treatments, including the use of blood and blood products.

173. There is no evidence that any of the staff at Hospital 1 who had contact with Ms A prior to her surgery saw Ms A's 2010 directive. However, hospital staff knew about Ms A's decision to refuse blood and blood products, Ms A was aware that staff knew this, and it was documented.

Opinion: NMDHB

174. I have some concerns about the care provided to Ms A by individual clinicians, and I will comment on these below. However, in my view, Ms A was also let down by the systems and arrangements in place at Hospital 1, and inadequate communication among the staff involved in her care. Responsibility for these failings lies with NMDHB.

[31] For further information on competence and anaesthesia, see the findings of the Health Practitioners Disciplinary Tribunal in 271/Med09/113D (21 December 2009).

[32] According to the clinical records and staff at Hospital 1, Ms A refused blood and blood products because she was a Jehovah's Witness. According to Ms A's family, Ms A was no longer a practising Jehovah's Witness, and she declined blood and blood products for other reasons (see paragraph 22). The statement that Ms A signed in 2010 supports the family's view; it specifies treatments she would and would not accept but does not explain the basis for her views. This is in contrast with the statements Ms A had signed in 1997, 1999, and 2006, which stated explicitly that she was a Jehovah's Witness. However, RN H states that at the pre-admission clinic, Ms A verbally confirmed that she was a Jehovah's Witness. In addition, one of the forms that Ms A signed that day recorded that she was a Jehovah's Witness.

Preoperative care: relevant information not communicated — Breach

175. Ms A was seen by surgeon Dr G at an outpatient clinic approximately one month prior to surgery. Dr G recommended a laparoscopic cholecystectomy, and Ms A was placed on the list for surgery. She attended a pre-admission clinic appointment with RN H a few days prior to her surgery, during which it was noted that Ms A was refusing blood and blood products.

176. My surgical expert advisor, Dr Michael Rodgers, states that it is common practice in New Zealand for patients to be assessed preoperatively by one surgeon and operated on by a different surgeon. Dr Rodgers noted also that this is not ideal, and issues can be missed. However, in this case, it was not the fact that Ms A was seen preoperatively by Dr G and then operated on by Dr C that led to Dr C not knowing about Ms A's refusal of blood and blood products when surgery commenced, as Dr G did not know about it either.

177. Nevertheless, most of the staff involved in her surgery did know that Ms A was refusing blood and blood products. Notwithstanding the fact that in Ms A's case the procedure carried a low risk of bleeding, it is unacceptable that when surgery commenced, the surgeon was unaware that Ms A did not accept blood and blood products.

178. The unusual factor in this case was not the nature of the procedure, but rather the nature of the patient.

179. NMDHB needed a system in place that enabled its staff to obtain relevant information in a timely fashion, so that:

a) Ms A could be provided with appropriate information, including information about the risks associated with her treatment refusal, and any options to mitigate these risks; and
b) if, after an appropriate discussion with Ms A, other plans and preparations were necessary, there was sufficient time to make these.

180. According to Ms A's general practitioner and Dr G, Ms A did not discuss her treatment refusal with them. It was during the pre-admission clinic appointment that Ms A was asked whether she had any religious or cultural beliefs to be considered when planning her care, at which point she confirmed that she would not accept blood and blood products. The pre-admission nurse, RN H, documented this.

181. In my view, it is at this point that NMDHB's process failed. Given that there was nothing documented to indicate that consideration had been given to Ms A's treatment refusal and its implications, the issue needed to be drawn to the attention of the anaesthetist and the surgeon.

182. RN H did not order a "group and hold" owing to a combination of factors, including Ms A's wishes regarding blood products. The protocol detailing the tasks to be completed during the pre-admission process required the pre-admission nurse to relay any issues of concern to the appropriate member of the multidisciplinary team, but the

protocol did not identify what matters were issues of concern and/or whether the refusal of blood and blood products was one such issue. Accordingly, Ms A's refusal of blood and blood products was documented in the clinical notes, but not communicated to the anaesthetist and surgeon.

183. The arrangements in place at Hospital 1 at that time were such that neither the anaesthetist nor the surgeon reviewed Ms A's notes until the morning of her surgery.

184. While there would have been nothing to prevent Dr D or Dr C from reviewing Ms A's notes earlier, I am concerned that there was no system in place at Hospital 1 to bring Ms A's refusal of blood and blood products to their attention before her admission. In my view, Ms A's refusal of blood and blood products was an issue of concern that should have been communicated to the anaesthetist and surgeon after it was identified at the pre-admission clinic appointment. Furthermore, I note that RN I, the day-stay nurse responsible for preparing Ms A for theatre reviewed the pre-admission documentation prepared by RN H, and noted that no "group and hold" had been ordered. However, there is no evidence that she flagged that to the surgical team or any other staff. This was a further missed opportunity to ensure that Ms A's refusal of blood and blood products was communicated to the anaesthetist and surgeon prior to surgery.

185. Without such communication, what should have occurred did not. In particular, the operating surgeon had no knowledge of Ms A's treatment refusal, and consequently there was no discussion with Ms A about the implications of her treatment refusal, or consideration given to the need for any additional preparations or an alternative plan. Reference has been made to ordering Factor VII in advance or arranging for Ms A to have the surgery at a larger hospital.

186. As I have stated previously: "Communication of information to the right person at the right time is critical to safe care."[33] DHBs must have clear, robust processes that support the timely communication of relevant information. NMDHB did not have a system in place to ensure that senior members of the clinical team were alerted to significant information regarding Ms A. Accordingly, NMDHB breached Right 4(1) of the Code.

187. I note that the Royal College of Surgeons of England *Code of Practice for The Surgical Management of Jehovah's Witnesses* (2002) provides:

> "Any surgery on Jehovah's Witnesses must be preceded by a full and frank discussion between the surgeon, the anaesthetist, and the patient, or the patient's parent or guardian."[34]

188. In my view, it would be appropriate for NMDHB to review policy and practice at other DHBs in relation to this matter. I note, for example, [another] DHB's Haematology Department Protocols and Guidelines. In the section on treating adults

[33] Opinion 09HDC01505, page 23.
[34] Paragraph 19.

who decline blood products, the first point under "General Principles of Treatment" states:

> "It is crucial that the patient's wishes are known, acknowledged and communicated to senior members of the relevant clinical team as early as possible to allow appropriate planning and subsequent action to take place."[35]

Consent form — Adverse comment

189. Dr D did not document Ms A's refusal of blood and blood products on the consent form, on the basis that the risk of her needing transfusion was less than 1%. Dr D notes that he had never previously had to transfuse a patient having either a laparoscopic or an open cholecystectomy. The literature on this is far less definitive (see paragraphs 68–72), but I accept that in Ms A's case it was reasonable to assess the risk as less than 1%.[36]

190. I will comment later on Dr D's responsibilities in this regard. However, NMDHB's policy was that "when consent is being obtained for an anaesthetic, consent should also be obtained for the use of blood products if there is a significant risk (i.e. 1% or more) of these products being required in the particular circumstances". Dr D's decision not to document Ms A's refusal of blood and blood products was, therefore, in accordance with the policy.

191. Despite this, NMDHB advised HDC that it considers that the blood and blood products section of the consent form should have been completed in Ms A's case, because she had an advance directive on file indicating that she was a Jehovah's Witness and that in the event of her incapacity she refused the transfusion of blood products. NMDHB stated that even though the risk of bleeding was not significant as set out in its policy (ie, it was less than 1%), "the use or otherwise of blood products was of particular significance to her as a Jehovah's Witness and indeed the health professionals involved in her care in the unlikely event that she did experience severe blood loss".

192. In my view, NMDHB's policy should have reflected its expectation that even if the risk of a patient needing blood or blood products is below 1% (or any specified threshold), the blood/blood products section of the consent form should be completed for all patients who refuse these.

193. Although there does not appear to have been any confusion in this case as to whose responsibility it was to complete the blood/blood products section of the consent form, I note NMDHB's intention to amend its policy to provide greater clarity regarding who is responsible for completing the different sections of the consent form.

[35] http://redbook.streamliners.co.nz/index.htm?toc.htm?47837.htm
[36] ie, Ms A was young, reasonably fit, and had only one identified risk factor (her weight). Her ASA score was 2.

Inadequate communication in theatre — Breach

194. In my view, Ms A's refusal of blood and blood products was also a matter that needed to be raised during the theatre "Time Out", as part of the Surgical Safety Checklist process. The Checklist requires members of the surgical team to identify "any patient specific concerns" prior to skin incision. While I accept that the risk of bleeding was low, I consider that Ms A's refusal of blood and blood products was a "patient-specific concern" that should have been identified at that stage.

195. There was nothing documented on the Checklist to indicate that the issue was raised, and the recollections of the staff present in theatre vary.

196. Dr D stated initially that he did not think the "Time Out" process was in use at Hospital 1 at this time and, on being advised that it was, said that he could not say with any confidence what was said during this process. He also stated that given the extremely low risk of Ms A requiring blood or blood products, it "was not considered to be an issue for the 'Time Out' process".

197. The anaesthetic nurse stated that she cannot recall what concerns she raised, but on the basis of her usual standard of nursing care and "Time Out" routine, she is "pretty certain" that she would have voiced that Ms A was a Jehovah's Witness, if the anaesthetist had not.

198. Of the three other nurses who were asked about this, one is "reasonably confident" she was aware of Ms A's beliefs at the start of surgery but did not comment on how she was informed of this, one is "95% sure" Ms A was identified as a Jehovah's Witness during the "Time Out" process but did not say by whom, and one does not recall being informed that Ms A refused blood and blood products, either during completion of the Checklist or by it being raised by another staff member.

199. On the basis of Dr D's recollection, his views on the significance of Ms A's refusal of blood and blood products, and in the context of his other actions and inactions, about which I will say more later, I consider it more likely than not that he did not raise the issue.

200. The fact that Dr C was not aware of Ms A's refusal of blood and blood products until her condition began to deteriorate postoperatively is, in my view, a strong indication that either the matter was not raised during the "Time Out", or that Dr C was not involved in the process. If Dr C was not involved in the "Time Out", it should not have proceeded. At least two other people present do not recall Ms A's refusal of blood and blood products being raised during the "Time Out".

201. I find it more likely than not that Ms A's refusal of blood and blood products was not raised at that time.

202. When asked whether Ms A's refusal of blood and blood products should have been raised during the "Time Out", my anaesthetic expert, Dr Nigel Robertson, states "[u]nequivocally". He states further that "[a]ny concerns specific to the case can be raised by any member of the theatre team at Time-out".

203. I would go further than this: concerns specific to the case and patient *must* be raised by any member of the theatre team who is aware of them. All team members have a responsibility to raise issues and ask questions, and DHBs must promote an organisational culture that encourages this.

204. Surgical checklists are about preventing deaths by "reinforcing accepted safety practices and fostering better communication and teamwork between clinical disciplines".[37] It is not possible to know whether, had Ms A's refusal of blood and blood products been communicated effectively during the "Time Out", the course of events subsequently would have been different. However, Dr C acknowledges that had he known on the day of surgery that Ms A was declining blood and blood products, he "most certainly" would have advised her that, although rare, there is always the chance of a complication requiring transfusion, and that he would have discussed her options with her. In these circumstances, I consider that there was a failure in effective communication and co-operation by the surgical team that morning and, accordingly, a breach of Right 4(5) of the Code.

Postoperative care — No breach

205. Ms A was transferred to the Recovery Unit at 11.25am. Records indicate that her condition started to deteriorate at about midday. I accept Dr Rodgers' advice that the care provided to Ms A in the Recovery Unit prior to her return to theatre was adequate, and that the time between recognising her deterioration and returning to theatre was within normal bounds.

Request to override treatment refusal — Other comment

206. Mrs B recalled that following the deterioration in her daughter's condition in the afternoon, at least three members of staff — Dr C, a nurse, and an anaesthetist — asked for permission to override Ms A's treatment refusal and give her blood. Dr C and charge nurse manager RN K acknowledged that they asked Mrs B for permission to give Ms A blood.

207. As Mrs B herself told staff, she did not have the authority to override her daughter's instruction. Ms A had made it clear that she did not accept blood and blood products; staff had no reason to question the validity of Ms A's refusal; nor does it appear that they did so.

208. While I appreciate that it is extraordinarily difficult for staff to be unable to provide treatment that they believe could be life-saving, to ask Mrs B for permission to give her daughter blood was to ask her to make a decision she was not entitled to make.

209. NMDHB should ensure that its staff are fully cognisant of a patient's right to refuse treatment, and the circumstances in which a person is legally entitled to consent on another person's behalf.

[37] See footnote 17.

Conclusion

210. The primary learning from this case is that material information must be communicated to senior members of the operating team before surgery. The unusual features of this event did not relate to the procedure — common and relatively low risk — but to the patient. In this case, the only senior player in the room who did not know that the patient had declined blood products was the surgeon. Notwithstanding the surgeon's individual responsibility, common sense, let alone good practice, demands that this information is known to all senior members of the operating team. In this case it was not. Teams and systems should do better than this.

211. Ms A's refusal of blood and blood products was information that the anaesthetist and surgeon needed to know prior to her surgery and in time for other plans and preparations to be made, should these have been necessary following an appropriate discussion with Ms A. The arrangements and systems in place at Hospital 1 did not support the timely communication of this information. In addition, Ms A's refusal of blood and blood products should have been raised during the surgical "Time Out". In these circumstances, I find that NMDHB breached Rights 4(1) and 4(5) of the Code.

Opinion: Dr C

Adequacy of preoperative care — Breach

212. Dr C reviewed Ms A's clinical records for the first time on the morning of her surgery. In response to my provisional opinion, he said that he "embarked on a search through Ms A's file seeking relevant surgical information".

213. Dr C went through Ms A's outpatient notes and the referral for surgery, the surgical notes to confirm her history, and the relevant blood tests and ultrasound report. He then met with Ms A at approximately 8.15am — less than an hour before surgery commenced. Dr C stated that in the course of reviewing Ms A's notes and speaking with her, he found no information that she was a Jehovah's Witness or that she refused blood.

214. When surgery commenced, Dr C was not aware that Ms A did not accept blood and blood products. In response to my provisional opinion, Dr C submitted that "it is fundamental that a patient who refuses a blood transfusion, for any reason whatsoever, should advise their medical practitioner of this crucial piece of information". However, he noted that Ms A had informed a number of health practitioners of the information.

215. Dr C did not know what alternatives, if any, were acceptable to Ms A. While I accept that the risk of bleeding in this case was low, Ms A's refusal of blood and blood products was indeed crucial information about his patient, and it is not acceptable that he was not aware of this. It would be reasonable for a patient to expect that the information provided would be passed to the relevant clinicians. In response to my

provisional opinion, Dr C agreed that it was reasonable for Ms A to expect that the information would be passed on.

216. The only time that Ms A was explicitly asked whether she had any religious or spiritual needs was during the pre-admission clinic appointment. At that time, she apparently confirmed that she was a Jehovah's Witness and did not accept blood and blood products. However, the fact that Ms A was a Jehovah's Witness and/or that she did not accept blood and blood products was recorded in at least four places in the records relating to her admission: on the "Patient Admission Information" form, on the "DAY STAY 24 HOUR STAY ASSESSMENT AND CARE PLAN" (twice), and on the "[HOSPITAL 1] ANAESTHESIA AND PERIOPERATIVE RECORD". The 2006 directive was also on file.

217. In response to my provisional opinion, Dr C submitted that had any significant issues been identified in these documents, they would normally have been flagged for the attention of the relevant clinicians, and he found no indication of any such notices. He stated that "[t]he fact that the patient was present in the Operating Holding Area indicated to [him], as per usual [Hospital 1] practice at the time, that all these checks had been satisfactorily completed and no potential problems identified".

218. My surgical expert advisor, Dr Rodgers, comments that, prior to surgery generally in a situation such as this he would expect the surgeon to read through the clinic/referral letters and recent discharge summaries, and talk to the patient.

219. In my view, Dr C needed to read the notes to the extent necessary to satisfy himself that he had all of the information that he, as the operating surgeon, needed to know. I would expect that this would include recently prepared documents, completed for the purposes of the surgery. Dr C needed to know, before commencing surgery, that Ms A refused blood and blood products.

220. As stated in a previous opinion:

> "The onus is on the clinician to ask the relevant questions, examine the patient, and keep proper records. Only then is the clinician in a position to properly consider all the risks, review all available information, and then and only then, proceed to perform surgery."[38]

221. I note that Ms A had asked that body parts removed during the surgery be returned to her. This was recorded on the PREOPERATIVE ASSESSMENT PATIENT QUESTIONNAIRE. NMDHB advised that the health professional responsible for completing the section of the form pertaining to the return of body parts would be "the person responsible for removing them, typically the surgeon". The fact that Dr C did not complete the section of the consent form relating to body parts again suggests that he did not read notes containing information that was relevant to the services he was providing. In response to my provisional opinion, Dr C submitted: "The only circumstances when body parts would be returned to a patient are the products of

[38] Opinion 09HDC01505 (17 October 2011), p 22.

significant limb amputations when these might need special care according to some religious beliefs." I note that Right 7(9) of the Code gives every patient the right to make a decision about the return or disposal of any body part or bodily substance.

222. It was also recorded on the PREOPERATIVE ASSESSMENT PATIENT QUESTIONNAIRE that no "group and hold" had been ordered. This was another missed opportunity for Dr C to be alerted to information indicating that there had been a departure from standard practice in the preadmission process. NMDHB advised that it was usual practice at Hospital 1 to order "group and hold" for laparoscopic cholecystectomy patients. However, in response to my provisional opinion, Dr C submitted that the absence of a "group and hold" for a laparoscopic choleystectomy did not alarm him and would not have indicated to him any religious significance or refusal of blood products.

223. I remain of the view that Dr C did not read Ms A's notes sufficiently to obtain information he needed before commencing her surgery. This was a failure to provide services with reasonable care and skill and, accordingly, a breach of Right 4(1) of the Code.

Information and consent — Other comment

224. It is important to note that Dr C's failure to read Ms A's notes sufficiently to obtain the information he needed before commencing her surgery had significant implications with respect to providing her with relevant information and obtaining her informed consent.

225. Under Right 7 of the Code, consumers have the right to make an informed choice and give informed consent for medical treatment. Under Right 6(1) of the Code, consumers have the right to information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including an explanation of the options available, and an assessment of the expected risks, side effects, benefits, and costs of each option.

226. Dr C acknowledges that had he been aware of Ms A's views, his discussion with her prior to surgery would have been different. As he stated:

> "If you don't want to have blood then the important thing is to be fully informed about the consequences, what the options are should we get into trouble with bleeding and in lap choles, in the unlikely event that we get into bleeding, what the options are."

227. Dr C stated that the best time for a patient to tell a surgeon that he or she does not accept blood products is in the outpatient setting, when there is time to go into all the intricacies. Dr C also explained that at Hospital 1, alternatives are not necessarily on hand for immediate use; the cell-saving machine has to be brought to theatre, set up by a technician and primed, and Factor VII has to be brought from another hospital. However, as already mentioned, Dr C was mistaken in his belief that a cell-saving machine was available.

228. Ms A needed to know that although the risk of bleeding was low, if she bled to the extent that a blood transfusion was indicated, there were risks to her in refusing blood and blood products. She needed to know what those risks were, the alternatives open to her, and the limitations of those alternatives. I note in particular the comments of my anaesthetic expert, Dr Robertson, in this regard.[39] Ms A also needed to know whether these alternatives were available at Hospital 1 and, if not, her options for having the procedure at a larger hospital where they would be available.

229. Dr C stated that had he talked to Ms A about the risks and options associated with her refusal of blood products, and that had she wanted to proceed despite the fact that cell-saving equipment had not been organised and Factor VIIa had not been brought in, he would have been happy to go ahead. My surgical expert, Dr Michael Rodgers, advises that this would have been reasonable.

230. Dr C met Ms A for the first time less than an hour before surgery commenced. As I have stated previously, I do not consider it good practice to provide patients with information about surgical choices just prior to surgery, particularly in cases where the procedure is not urgent, as this does not allow adequate time for reflection.[40] Accordingly, I agree that it would have been less than ideal for Dr C to have discovered at this point that Ms A refused blood, as that would have required Ms A to make additional surgical choices. However, it would have been vastly preferable to finding out *after* the surgery, as occurred here. If Dr C had learnt of Ms A's refusal of blood and blood products when he spoke with her, and if she did in fact want arrangements made for alternatives to be available in the unlikely event of her bleeding, her surgery could easily have been deferred.

231. I accept that if Dr C had talked to Ms A about the risks and options relevant to her treatment refusal, she may indeed have decided to proceed, and it would not have been unreasonable to do so. Had that occurred, Ms A would have been making an informed choice; without this information she was denied that opportunity.

232. I note Dr C's comment that he seldom looks at the reverse of the consent form — the side documenting consent for anaesthesia, consent for blood/blood products, and request for body parts. I acknowledge his point that even if Dr D had completed the blood/blood products section of the form, this would have been after Dr C had documented Ms A's consent for surgery, so he would not have seen it.

233. I note also Dr C's comment that he sought consent from Ms A's parents for the administration of Tranexamic Acid and Recombinant Factor VIIa (see paragraph 108). The legal basis on which he sought their consent for this is unclear. As this was an emergency situation and Ms A had not previously refused these products, Dr C could administer them if clinically appropriate. Ms A's parents had no legal right to consent to, or refuse consent for, the administration of Tranexamic Acid or Recombinant Factor VIIa on Ms A's behalf.

[39] In particular, Dr Robertson considers that in this situation, cell-saving would have been of limited (if any) use, and Factor VIIa would have been ineffective.
[40] See, for example, Opinion 08HDC20258 (11 November 2009), page 15.

Laparoscopic and open procedures — Adverse comment

234. Ms A's family are concerned that Ms A consented to laparoscopic but not open surgery. It is correct that the consent form signed by Ms A confirms her consent to laparoscopic surgery. However, I accept that conversion to open surgery is, as Dr Rodgers states, "part and parcel of laparoscopic surgery". The critical factor here is whether the possibility of needing to convert to an open procedure was discussed with Ms A.

235. The notes taken by Dr G during his preoperative consultation indicate that he advised Ms A that in approximately 5% of cases, there is a need to convert to an open procedure. There is no evidence that Ms A raised any concerns about this. The written information provided to Ms A preoperatively states that a surgeon performing a laparoscopic cholecystectomy may find after starting the procedure that it is not safe to proceed laparoscopically and may decide to convert to open surgery.

236. Dr C states that in the case of Ms A, he discussed "the general risks of surgery (bleeding and infection) and then went on to discuss the more unusual risks of bile duct injury including the possible need to transfer and the possible need to convert to 'Open'".

237. In these circumstances, I find it more likely than not that Ms A was informed of a possible need to convert to open surgery. Dr Rodgers states that he would usually document the possibility of needing to convert to an open procedure on the consent form and in the clinic letter, but not all surgeons would necessarily document it. In my view, Dr C should have documented this on the consent form.

238. Dr Rodgers states that the fault in this operation would have been not to convert and it would not be appropriate to wake the patient to discuss. My anaesthetic expert, Dr Robertson, states that the surgeon "was already committed to an open procedure as a crucial part of the dissection had been completed by the time the decision to abandon the laparoscopic approach was taken".

Surgery — No breach

239. My surgical expert advisor states:

> "[Dr C's] surgery seems to have been done in a standard competent fashion. He converted to an open procedure appropriately and there was no bleeding at the end of the procedure.
>
> …
>
> Overall I would see [Dr C's] surgical approach as reasonable and competent."

240. As I have stated, it is not my role to determine the cause of Ms A's death. However, I do note that the pathologist identified no precise bleeding site, with no direct failure of haemostasis at the operative site. The pathologist confirmed that Ms A's liver was "fatty".

241. I note the comments of my anaesthetic expert advisor, Dr Robertson:

> "Information given from the post-mortem (report received) states that all vessels were adequately secured and that the bleeding was likely coming from the gall-bladder bed, either from continued ooze postoperatively or from a new bleeding point. The presence of a (apparently previously un-diagnosed) fatty liver, described as '… marked macro-vesicular steatosis' in the autopsy report was possibly significant in terms of liver morphology, thereby compounding the situation."

242. In these circumstances, I find no evidence that the surgical care provided by Dr C departed from accepted standards.

Response to deterioration — No breach

243. The precise sequence of events between midday, when it was recognised that Ms A's condition was deteriorating, and her return to theatre at 2.30pm is not clear.

244. Dr Rodgers states:

> "According to the recovery room chart [Ms A] started becoming noticeably tachycardic and hypotensive around 30 mins after her arrival and this persisted until her return to theatre. It appears she was given 2.5l of intravenous fluid without noticeable response before a decision was made to go back to theatre at 1430hr. So, in retrospect it seems clear she was actively bleeding for 2.5 hrs before going back to theatre.
>
> This amount of delay in recognising the problem and returning to theatre is probably within normal bounds. Even though in retrospect it seems obvious what the problem was, this is an unusual event after this sort of surgery and some degree of delay is to be expected. The explanation from [Dr D] that the initial problem was thought to be pain control is reasonable. I feel [Ms A's] care in recovery prior to the second operation was adequate.
>
> It is clear from the interviews that [Dr C] was doing all he reasonably could to free himself from the operation he was doing in order to attend to [Ms A]. His decision to proceed with a second operation to control ongoing bleeding is entirely reasonable and appropriate."

245. I accept Dr Rodgers' advice, and I find no evidence that Dr C's response to Ms A's deterioration departed from accepted standards.

Conclusion

246. Ms A's refusal of blood and blood products was information that Dr C, as the operating surgeon, needed to know before he commenced her surgery. The information was available in Ms A's clinical notes, including in documents recently prepared for this surgery. Dr C did not read Ms A's notes sufficiently to obtain this information. This was a failure to provide services with reasonable care and skill and, accordingly a breach of Right 4(1) of the Code.

Opinion: Dr D

247. Dr D provided anaesthetic services to Ms A during her first surgery. My anaesthetic expert advisor, Dr Nigel Robertson, concludes that "there were no significant departures from the standard of care of the anaesthesia provider, Dr D, that would have substantially altered the course of this case". However, Dr Robertson does identify several points at which Dr D's care was less than he would have provided in that situation.

248. I consider that there were several deficiencies in the care Dr D provided to Ms A (see below) and that these were largely attributable to the same erroneous belief, which was that, as Dr D considered that Ms A's risk of bleeding was low, her refusal of blood and blood products was not sufficiently significant for him to need to communicate that issue to other members of the team.

249. On this basis, Dr D:

- did not discuss Ms A's refusal of blood and blood products with the operating surgeon preoperatively;
- did not complete the section of the consent form relating to the use of blood/blood products; and
- did not raise Ms A's refusal of blood and blood products when Dr C decided to convert to an open procedure.

250. In response to my provisional opinion, Dr D submitted that his belief was not erroneous in relation to the risk of bleeding. I accept that, but I remain of the view that Ms A's refusal of blood products was a significant issue that he should have raised with the team, despite the low risk of bleeding. As stated above, the unusual features of this event did not relate to the procedure, or the risks related to the procedure, but to the patient.

Communication of Ms A's refusal of blood and blood products — Breach

Preoperative communication

251. The Medical Council of New Zealand states in its publication *Good Medical Practice: A Guide for Doctors (2011)* that in providing good clinical care, a doctor is expected to "keep colleagues well informed when sharing the care of patients", and that when working in a team, a doctor must "communicate effectively with colleagues both within and outside the team" and "share information necessary for the continuing care of the patient".

252. The Australian and New Zealand College of Anaesthetists (ANZCA) Code of Conduct[41] provides that communication with a wide range of people is a fundamental skill in anaesthesia. Section 5 of the Code of Conduct states:

> "The provision of safe, high quality medical care is increasingly dependent on complex and multilayered teams, centered on the patient. Anaesthetists should act

[41] http://www.anzca.edu.au/resources/professional-documents/documents/Code-of-Conduct.pdf.

collaboratively and cooperatively with integrity, honesty, respect, and without prejudice, in a spirit of co-operation with all those involved in the provision of optimal patient care (for example, colleagues, allied health professionals, administrators, support staff)."

253. I note that my expert advisor, Dr Robertson, considers that "communication and consent for surgery is a shared task involving all team members".

254. Dr D confirmed that he did not discuss Ms A's refusal of blood and blood products with Dr C at any point prior to the surgery. Dr D submitted in response to my provisional opinion that he was "entitled to assume that [Dr C was] armed with the same obvious information from the medical file that [he had] obtained". Relying on assumptions is unsafe and, in my view, good continuity of care is reliant on a high standard of communication, checking and testing of assumptions, and confirming mutual understanding. I consider that, notwithstanding the low risk of Ms A requiring a transfusion during surgery, Dr D had insufficient regard to the need to discuss Ms A's refusal of blood and blood products with the clinical team.

255. Dr D further submitted in response to my provisional opinion that discussions about bleeding and blood refusal need to take place during the initial outpatients clinic, "as it is too late in the theatre setting". In my view, Dr D should have been mindful that the refusal of blood and blood products was a matter that could have necessitated changes in the treatment plan and, accordingly, discussion with the operating surgeon was warranted.

"Time Out" and perioperative communication

256. I have considered Dr D's response to my provisional opinion that although he cannot recall whether he raised the issue during the "Time Out" process, he considers that the theatre nurses would have raised it. I note that Dr D initially told HDC that he did not think the "Time Out" process was in use at Hospital 1 at the time of these events. When Dr D was advised that the DHB had confirmed that the process was in use at that time, he stated: "Clearly, I cannot say with any confidence about what was said around this process." Dr D subsequently explained that he did recall a checklist process in place at the time of Ms A's operation, but was not certain when the WHO guidelines were adopted.

257. After considering Dr D's response, I remain of the view that it is more likely than not that Dr D did not raise the issue of Ms A's refusal of blood and blood products during the surgical "Time Out". As I have stated above, I also find it more likely than not that Ms A's refusal of blood and blood products was not raised during the surgical "Time Out". I have discussed my concerns about this, and commented on the fact that any member of the team could have done this, and somebody should have done so. In my view, Ms A's refusal of blood products was a "patient-specific concern" that should have been identified during the "Time Out" phase of the Checklist process.

258. When asked whether Ms A's refusal of blood and blood products should have been raised during the "Time Out", my expert, Dr Robertson, states "[u]nequivocally". He states further that "[a]ny concerns specific to the case can be raised by any member of

the theatre team at Time-out". Given the anaesthetist's role in the administration of blood and blood products, and of other products used when these are refused, I consider that Dr D should certainly have drawn Ms A's treatment refusal to the attention of the operating team. I do not accept Dr D's submission that Ms A's refusal of blood and blood products was not an issue for the "Time Out" process.

259. Dr D confirmed that the issue of Ms A's refusal of blood and blood products was not discussed when Dr C indicated that he was converting to an open procedure. When asked whether this issue should have been raised at this time, Dr Robertson said: "As part of an enhanced communication process, information sharing and risk identification, it should have been, in my view." Dr Robertson explained that "[i]dentifying the issue to the surgeon would have increased his vigilance and thoroughness in securing haemostasis" while acknowledging that, in this case, there was no evidence that this was substandard.

Conclusion

260. Dr D determined that, given the surgery Ms A was to undergo, and her particular risk profile, her refusal of blood and blood products was not sufficiently significant for him to need to communicate the issue to other members of the team. Accordingly, he did not discuss her treatment refusal with the operating surgeon preoperatively, and he did not raise the issue of her treatment refusal when Dr C converted to an open procedure. I also consider it more likely than not that Dr D did not raise the issue during the surgical "Time Out". In these circumstances, I consider that Dr D failed to co-operate with his colleagues to ensure quality and continuity of services. This was a breach of Right 4(5) of the Code.

Documentation — Adverse comment

261. Dr D did not document Ms A's refusal of blood and blood products, on the basis that the risk of her needing transfusion was less than 1%. Dr D notes that he had never previously had to transfuse a patient having either a laparoscopic or an open cholecystectomy. As stated, the literature on this is far less definitive (see paragraphs 66–70), but I accept that in Ms A's case it was reasonable to assess the risk as less than 1%.[42] In response to my provisional opinion, Dr D submitted that Ms A's refusal of blood products was already documented in the notes.

262. Dr Robertson comments that Dr D complied with the letter of the NMDHB protocol, in that the expected likelihood of transfusion was less than 1%. However, Dr Robertson states further that, in his view, the blood/blood products consent section should have been completed. Dr Robertson states: "[I]t is always better to document any discussion where an added or unusual risk (however rare) is identified." Dr Robertson does not consider this to be a major omission.

263. In response to my provisional opinion, Dr D submitted that his non-signing was consistent with the "DHB Informed Consent" policy and the advance directive on Ms A's file. NMDHB considers that this section of the consent form should have been

[42] ie, Ms A was young, reasonably fit, and had only one identified risk factor (her weight). Her ASA score was 2.

completed. I have previously outlined my concern that the DHB's expectations in relation to this matter were not reflected in its policy.

264. However, I note also ANZCA's "Guidelines of Consent for Anaesthesia or Sedation" (2005), which state:

> "The extent of documentation may be dictated by local legislation and practice but it is wise to record significant details of the consent as part of the patient notes, including reference to the discussion of relevant material risks and the agreement by the patient to undergo the treatment."

265. In response to my provisional opinion, Dr D submitted that local legislation and practice means that "[a]t NMDHB at the time, the 1% risk level meant that [his] actions were understandable". In my view, treatment with blood and blood products was clearly an issue of significance for Ms A. Even though the risk of her requiring a transfusion was low, I remain of the view that her treatment refusal should have been documented by Dr D on the consent form.

Recommendations

266. I recommend that NMDHB:

- Provide Ms A's family with a written apology for its breaches of the Code, to be sent to HDC within three weeks of the date of issue of this report, for forwarding.
- Provide HDC with a copy of its revised Informed Consent policy and consent form, within three months of the date of issue of this report.
- Review its pre-admission process to ensure that patients who refuse blood and blood products are brought to the attention of the surgeon and anaesthetist prior to the day of surgery, and report back to HDC within four months of the date of this report.
- Undertake an audit of the use of NMDHB's Surgical Safety Checklist at Hospital 1, and report back to HDC within four months of the date of this report.

267. I recommend that Dr C provide Ms A's family with a written apology for his breach of the Code, to be sent to HDC within three weeks of the date of this report, for forwarding.

268. I am aware that MCNZ processes are ongoing in relation to Dr C and I have asked MCNZ to keep me updated.

269. I recommend that Dr D:

- Provide Ms A's family with a written apology for his breach of the Code, to be sent to HDC within three weeks of the date of this report, for forwarding.

- Review his practice in relation to provision of anaesthetic services to patients who refuse blood and blood products, and, within three months of the date of this report, advise the Commissioner of the changes he has made, or intends to make.

Follow-up actions

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

- A copy of this report with details identifying the parties removed, except the experts who advised on this case and NMDHB, will be sent to the Medical Council of New Zealand, and it will be advised of the names of Dr C and Dr D.

- A copy of this report with details identifying the parties removed, except the experts who advised on this case and NMDHB, will be sent to the Royal Australasian College of Surgeons, and it will be advised of Dr C's name.

- A copy of this report with details identifying the parties removed, except the experts who advised on this case and NMDHB, will be sent to the Australian and NZ College of Anaesthetists, and it will be advised of Dr D's name.

- A copy of this report with details identifying the parties removed, except the experts who advised on this case and NMDHB, will be sent to DHBNZ (Shared Services) and the Health Quality and Safety Commission, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix 1 — Independent expert advice — Surgical

The following expert advice was obtained from surgeon Dr Michael Rodgers:

Preliminary advice

"**Summary of Events taken from the written record:**

Health Care Directive 2006
Witness document expressing [Ms A's] strong position on not wishing to have red cell, platelets or plasma. Also not wishing to predonate blood for later infusion.

Outpatients
Seen in outpatient clinic [2010] by [Dr G] (General Surgeon) with gallstones and laparoscopic cholecystectomy arranged. No discussion in letter of JW status or its implications for surgery. No mention in the referral letter (from [Dr E) of this issue. No mention in 2005 letter from [O&G specialist] about this issue despite [Ms A] undergoing a laparoscopy.

[Admission]
Religion listed as Jehovahs Witness. Preoperative Hb and Coagulation normal.

Consent form includes 'Bleeding' as a possible risk. Consent for blood products has not been signed (neither acceptance or refusal).

1125hr Arrived in recovery

1405hr Tranexamic Acid 1g given

1430hr Note from [Dr C]. 'Clinically bleeding. Hb 61 … Patient categorically refuses blood or blood products ... Urgent reopen in theatre …'

1450hr Note from Dr [O] 'Laparotomy for acute bleeding … 2 large abdominal packs … transfer to [Hospital 2] ICCU arranged … Family notified'

1655hr CXR shows RIJ line in brachiocephalic and ETT in R main bronchus. Report 'phoned to on call house surgeon'.

1830hr Note from [Dr C] 'Bleeding controlled by laparotomy and packing. But HB< 2g — hardly compatible with life. Not allowed to transfuse. Pupils fixed @7mm Patient to stay in [Hospital 1] as successful outcome unlikely.'

Untimed: Transfer note from [Dr C] 'cystic duct and artery confidently clipped but then further dissection unsafe ... convert to open ... fundus first dissection … dry operative area ... +/- 3hrs later in recovery — falling BP falling HB distended abdo. Reopened and bleeding seemed to be coming from areas of gallbladder bed. +/- 3 litres of blood/clots.'

Addenum [two days later]

'[Ms A] deceased at 1859 hours [date] … Family present in Theatre …'

Opinion:

The questions pertaining to this case are:

Was the Surgery done competently and was the bleeding recognized and acted on in a timely manner?

[Dr C's] surgery seems to have been done in a standard competent fashion. He converted to an open procedure appropriately and there was no bleeding at the end of the procedure.

At the second laparotomy it is not clear from his note how much active bleeding was occurring and whether or not it was venous or arterial — and it may well have been very difficult to see. He does not appear to have attempted a Pringle manoeveur (clamping of the portal inflow) which may have made visualization easier. Packing does seem a reasonable response to the situation, particularly if bleeding was venous.

Overall I would see [Dr C's] surgical approach as reasonable and competent.

According to the recovery room chart [Ms A] started becoming noticeably tachycardic and hypotensive around 30 mins after her arrival and this persisted until her return to theatre. It appears she was given 2.5l of intravenous fluid without noticeable response before a decision was made to go back to theatre at 1430hr. According to [Dr C's] note the Hb was 61 at this time, but according to the lab results it was 45 at 1429hr. In any case the exact number is immaterial to the management and outcome.

This amount of delay in recognizing the problem and dealing with it is probably within normal bounds. Even though in retrospect it seems obvious what the problem was, this is an unusual event after this sort of surgery and some degree of delay is to be expected.

Was [Ms A] consented adequately and was due thought given to the plan if there was bleeding?

While 'Bleeding' was listed as a possible complication on the consent form, the consent/refusal for blood products section was not signed. There is no documentation that cell saving was discussed at any time, a potentially lifesaving process that many Witness patients will accept.

Whether such detailed discussion is required for all Witness patients for all surgical procedures is less clear. There is evidence that transfusion rate after laparoscopic cholecystectomy is very low but not zero. Of 4,652 laparoscopic cholecystectomies done in Glasgow, '1.1% required transfusion (Quinn, Surgical Endoscopy 2011). The incidence of immediately life threatening bleeding would of course be much lower. During consent, [I] would expect surgeons and anaesthetists to refer to the possibility of life threatening bleeding, but describe it as a 'rare' complication.

I do note that [Ms A] underwent a laparoscopy in 2006 at the same hospital and any criticism applied to the current incident in terms of consent and planning might equally apply to that case.

Overall, based on the written information, I feel the surgeon and anaesthetist did not plan adequately for bleeding and did not fully explain all the options to [Ms A].

I also note that the surgeon seeing the patient in clinic was not the one performing the surgery. While this is common practice, it is not ideal and issues such as this can be missed.

Was the Surgery done in the 'correct' hospital with adequate facilities?
This is not a straightforward question to answer. In surgery we are always balancing risk and resources. While there [is] no doubt 'major' surgery on a Witness patient should be done in a facility with a cell saver and ready access to recombinant factor 7, it is not so clear what procedures are 'major'. Certainly a laparoscopy, as was done in 2006, seems reasonable but even that could have resulted in a similar scenario. Laparoscopic cholecystectomy would be considered an intermediate level surgery by most surgeons and performed as an overnight or day stay procedure in most hospitals. In a well consented patient I do not feel it is mandatory for this level of surgery to be done in a major hospital even in a Witness patient.

Would [Ms A] be alive if she had accepted a blood transfusion?
I think it likely that [Ms A] was not going to survive the initial bleed without a transfusion regardless of subsequent management. Usually when a patient is acutely bleeding the Hb takes a while to fall as the blood is diluted out by other fluid. The fact that her Hb was 45 before the second operation indicates to me that it would actually be lower with resuscitation fluid, and probably critically so. This proved to be the case.

Summary
In summary I feel the management was reasonable and did not indicate incompetence. However the documented consent process and planning was suboptimal in a patient who did not want a transfusion."

Supplementary preliminary advice

Dr Rodgers was subsequently asked for clarification as below:

1. What further planning you would expect a competent surgeon to do to prepare for performing a cholecystectomy on a patient refusing blood products?
2. Whether the "suboptimal" planning for this surgery would be viewed with mild, moderate, or severe disapproval by your peers?
3. Would [conversion to an open procedure] alter the risk factor for a patient refusing blood products to the point that the patient should have been woken to be informed of risks and for further consent to be obtained?
4. Would you consider an open cholecystectomy to be intermediate or major level surgery?

Dr Rodgers advised:

"The 'suboptimal' part is mainly to do with the lack of documentation. In 2006 at the time of her laparoscopy there was an extensive Jehovah's Witness document she signed and it was clearly stated on her consent form that she was a Jehovah's Witness. This does not appear to have been revisited for the cholecystectomy.

Perhaps the most obvious problem was that the consent section for blood products was not filled out. This would meet with 'moderate' disapproval in this context (operating on a Jehovah's Witness). The fact there was no documented plan for bleeding would not necessarily be regarded with disapproval if the blood transfusion consent had been adequately dealt with. The risk of bleeding was mentioned on the surgical consent and presumably was discussed. While in retrospect it is easy to see that more extensive discussion could have been done regarding Factor 7, cell saving or operating at a larger institution, I doubt the majority of General Surgeons would have done this in this context.

Conversion to open surgery is part and parcel of laparoscopic cholecystectomy, it would be unusual for the surgeon not to have mentioned this possibility. I personally always explain the chance of conversion and would usually document it on the consent form and in the clinic letter but not all surgeons would necessarily document it. However the fault in this operation would have been ***not*** to convert and it would not be appropriate to wake the patient to discuss. Open cholecystectomy is intermediate level surgery and entirely appropriate when there are anatomic or other difficulties during a laparoscopic approach."

Final advice

"My condolences again to [Ms A's] family. The history has now been well documented and I will not repeat it here.

The questions pertaining to this case and my opinion are:

Consent Process

While 'Bleeding' was listed as a possible complication on the consent form, the consent/refusal for blood products section was not signed. This seems at odds with the fact it was discussed by the anaesthetist with the patient. There is no documentation that cell saving, factor 7, blood banking or other options were discussed.

Whether such detailed discussion is required for all Witness patients for all surgical procedures is not clear to me but does seem prudent in hindsight.

I would expect the surgeon and anaesthetist to refer to severe potential complications — such as death, PE, severe bleeding — even if they do not reach an arbitrary 1% threshold.

[Ms A] was overweight and while that does increase the risk of most complications in a general sense, it would not have been a reason in itself to alter the consent information or proceed any differently.

I do note that [Ms A] underwent a laparoscopy in 2005 at the same hospital and in that case would have faced similar issues. At that time she completed an extensive Witness document detailing her desire not to have blood products. It would seem prudent to update such documentation before further surgery.

I also note that [Ms A] was seen by another surgeon in clinic and booked for surgery. This is common practice around the country. The issue of transfusion and her status as a Witness were not documented in the surgery clinic note and were in fact not discussed (according to the interview with [Dr G]). Nor did her GP have any information about this when the initial referral was made. Therefore it is not unreasonable that [Dr C] also did not know of this. Generally in this situation I would expect the surgeon to read through the clinic/referral letters, recent discharge summaries and talk to the patient. It seems that the information about [Ms A] not wanting blood products was not contained in any of these and not communicated to [Dr C] by those who did know until after the first surgery when he was told by the anaesthetist.

Risk Factors

There is evidence that the transfusion rate after laparoscopic cholecystectomy is very low. In a recent series of 4,652 laparoscopic cholecystectomies done in Glasgow, 1.1% required transfusion (Quinn, Surgical Endoscopy 2011). This is higher than in my own experience where I have never seen a patient transfused after a laparoscopic cholecystectomy. It is also an across the board figure and the rate of actually life-threatening bleeding would be lower. It might also be expected that an otherwise well patient of [Ms A's] age would have a much lower risk of transfusion.

Appropriateness of surgery being done at [Hospital 1]

In surgery we are always balancing risk and resources. Most would agree that 'major' surgery on a patient who will not have a blood transfusion should be done in a facility with a cell saver and ready access to recombinant factor 7 and appropriate surgical expertise if there is a problem. However it is not so clear what procedures are 'major'. Even an appendicectomy can result in major blood loss at times.

Laparoscopic cholecystectomy would be considered an intermediate level surgery by most surgeons, performed as an overnight or day stay procedure in most hospitals. I would imagine that Witness patients are undergoing this level of surgery at small hospitals in NZ now.

Even with the benefit of hindsight I would not criticize NMDHB or [Dr C] for doing this case at [Hospital 1]. However I do think moving forward, that some thought should be given to a national policy on this matter.

Initial Surgery

From what can be gleaned from the notes [Dr C] appropriately converted to an open procedure and there was no bleeding at the end of the procedure.

In one of the interviews it is noted that the Surgical Safety Checklist is used at [Hospital 1]. The fact that there was a lack of consent for blood products, and that the patient was a Jehovah Witness should have come at that point. The surgeon and anaesthetist do not mention this and it is not clear to me they were involved in the Checklist.

Time in Recovery

According to the recovery room chart [Ms A] started becoming noticeably tachycardic and hypotensive around 30 mins after her arrival and this persisted until her return to theatre. It appears she was given 2.5l of intravenous fluid without noticeable response before a decision was made to go back to theatre at 1430hr. So, in retrospect it seems clear she was actively bleeding for 2.5 hrs before going back to theatre.

This amount of delay in recognising the problem and returning to theatre is probably within normal bounds. Even though in retrospect it seems obvious what the problem was, this is an unusual event after this sort of surgery and some degree of delay is to be expected. The explanation from [Dr D] that the initial problem was thought to be pain control is reasonable. I feel [Ms A's] care in recovery prior to the second operation was adequate.

It is clear from the interviews that [Dr C] was doing all he reasonably could to free himself from the operation he was doing in order to attend to [Ms A]. His decision to proceed with a second operation to control ongoing bleeding is entirely reasonable and appropriate.

Second Operation

At the second laparotomy it is not clear from [Dr C's] note how much active bleeding was occurring and whether or not it was venous or arterial — and it may well have been very difficult to see. He does not appear to have attempted a Pringle manoeveur (clamping of the portal inflow) which may have made visualization easier. Packing does seem a reasonable response to the situation, particularly if bleeding was venous. He did an initial packing and then a more formal packing.

Overall I would see [Dr C's] surgical approach as reasonable and competent for a surgeon without hepatobiliary expertise. It is also clear that this re-operation needed to be done urgently and there was no option to transfer [Ms A] at that point.

Blood Transfusion and Survival

I do not believe [Ms A] would have survived without a transfusion at [Hospital 1]. It is possible she would have survived without a transfusion if the re-operation had been done within a shorter time frame and a hepatobiliary surgeon had been present — however this is speculative at best and the outcome might well have been the same regardless.

Recommendations

1. The usual standard as I understand it for discussing complications is not based solely on the frequency of a complication, but rather what a patient undergoing such a procedure would reasonably want to know. I suggest the NMDHB policy be changed to reflect this.
2. It is my view that the blood consent is filled in routinely for gallbladder surgery, and one would expect doubly so if it was known the patient was a Witness. I understand there will be expert anaesthetic opinion given and I will not comment further on this point.
3. It is likely that the proper use of the WHO check list (or a variant thereof) might [have] alerted the surgeon to the issue of lack of consent for blood products and the status of [Ms A] as a Witness. If not already done it would be worth reviewing this process at [Hospital 1] to make sure the surgeon is involved in the checklist. I do not however believe the surgeon would necessarily have done anything different if he had been aware.
4. If not already the case surgeons at [Hospital 1] might benefit from attendance at the DSTC trauma course where maneuvers to control liver bleeding, such as the Pringle maneuver and right hepatic pedicle ligation are covered to refresh their skills. However it is not clear that these techniques would have necessarily helped in this situation.
5. Whether patients who will not accept blood transfusion should undergo cholecystectomy at a small hospital such as [Hospital 1] needs to be considered for the future. If patients fully understand the small risks and wish to proceed regardless then that is not unreasonable. However I suggest that in the future the option of being referred to a major centre should be discussed. Of course, in this instance, the surgeons who might have had this discussion were not aware of the issue."

Appendix 2 — Preliminary independent expert advice — Anaesthesia

The following preliminary advice was obtained from anaesthetist Dr Nigel Robertson:

"Complaint Regarding:
[Ms A] (dec.)
[D.O.B.]
[NHI]
HDC Ref. 11/00531

Expert Advisor: Dr. Nigel N. Robertson, MB ChB (Edin.), FANZCA, Specialist Anaesthetist.

Thank you for your letter dated 18th October 2012 regarding the above-named deceased patient, [Ms A].

I have thoroughly reviewed the information supplied regarding this case and I am in a position to offer an opinion on the standard of anaesthesia services provided to her in relation to her surgery [in] 2011, as requested.

I can confirm that I have no known conflicts of interest with any aspect of this case.

In your correspondence, you listed a number of issues to be covered and I propose to respond to these as presented.

1. *The pre-admission process at [Hospital 1] with respect to anaesthesia*

It appears from both the documented information supplied and the commentary from nursing staff that the process of information gathering about [Ms A's] condition and co-morbidities was satisfactory. The patient questionnaire was completed with the help of a nurse at pre-admit and I note that the form has no place to document any religious or cultural beliefs related to perioperative care. [Ms A] did not volunteer any information about her requirements in relation to blood products on this form. It was clearly documented, however, on the Day Stay Care plan that she refused blood products and that the staff believed her to be a Jehovah's Witness. It is also clearly stated on the Anaesthesia Record that she was believed to be a Jehovah's witness. Her Healthcare Directive from 2006 was present in the notes but I note that the later document dated 10 September 2010 that she carried on her person endorsing the earlier directive appears not to have been sighted during this process.

Pre-operative blood tests were ordered by protocol and because of a history of bruising easily. All were essentially unremarkable from an anaesthesia risk-assessment perspective.

[Dr D], her attending anaesthetist, did not seem to have any visibility of her refusal of blood products prior to the day of surgery but given the nature and risk

profile of the case (laparoscopic cholecystectomy), this was not a significant factor in the outcome.

[Ms A's] directive was not documented in the FSA (first specialist assessment) letter written by [Dr G] and [Dr C] also had no knowledge of her refusal of blood products until well into the crisis. Whilst I do not believe that this contributed significantly to the outcome, given the low risk of the surgery, it could be viewed as a visible 'hole' in the Reason model of crisis development.

All other aspects of the pre-admit process were satisfactory.

2. *What, if any, additional information an anaesthetist should provide to patients such as [Ms A], who are undergoing this type of surgery and who do not consent to the use of blood/blood products?*

Communication and consent for surgery is a shared task involving all team members. The transcript from the discussion with [Dr D] describes his acceptance of her refusal of blood products. Given the low risk of significant haemorrhage for this type of surgery (much less than 1%, in my experience), it was not unreasonable to merely accede to her request, however counsel for perfection would suggest that he make absolutely sure that she understood all the consequences of her directive, including the (very low) risk of permanent disability or death. However this is not a major omission in context.

3. *Whether it is usual practice to perform a 'group and hold' for patients who are undergoing laparoscopic cholecystectomy?*

Not routinely for elective cases (such as [Ms A's]) and especially not for Jehovah's Witness patients (Christchurch Hospital Liaison committee for Jehovah's Witnesses protocol 2002) or other patients who specifically refuse blood and blood products for other reasons. If there is a specific indication (known bleeding tendency, acute and/or patient with sepsis, for example) then a group and hold would be performed.

4. *Whether, in your view, the section of the consent form pertaining to consent for blood/blood products should have been completed for [Ms A]?*

[Dr D] complied with the letter of the NMDHB protocol in that the expected likelihood of transfusion was less than 1%.

In my view, however, the Blood/blood products consent section should have been completed, to clearly document the discussion between [Ms A] and [Dr D]. Although [Ms A] had supplied a clear advanced directive, it is always better to document any discussion where an added or unusual risk (however rare) is identified. This omission was, however, not major (in context) and did not influence the outcome of the case, in my opinion.

5. ***NMDHB's policy in relation to consent for the use of blood/blood products.***

As presented, this is a sensible, well written document. The section on blood and blood products *implies but does not state* that the anaesthetist should obtain consent for the use of blood products for a risk of transfusion of greater than 1%. In this case, [Dr D] was not obligated to do so. I have no issue with the anaesthetist performing this task (and I frequently do in my own practice) but it appears that NMDHB is changing its policy on this and requiring the procedural health professional to obtain consent for blood/blood products. I have no other comment on this policy in relation to such consents.

6. ***Whether, in your view, [Ms A's] refusal of blood/blood products should have been raised during the time-out process and if so, by whom?***

Unequivocally yes, it should have been. The fact that the surgeon especially had apparently no knowledge of this ultimately vital issue prior to the situation becoming critical is unexplainable and regrettable. Whilst earlier knowledge of this (albeit low probability) contributing factor may not have prevented the eventual outcome, it may have led to a heightened awareness of the need for meticulous haemostasis during the open procedure and perhaps led to an expedited return to theatre when [Ms A's] condition deteriorated.

Any concerns specific to the case can be raised by any member of the theatre team at Time-out and the form from [Ms A's] laparoscopic cholecystectomy surgery appears to confirm that all members of the team were asked the question about specific concerns, as there are ticks beside each element of the team. The information on her refusal of blood/blood products was not volunteered, according to the transcripts from staff members. This is, again, an omission that might have influenced the course of events but **only if sufficient resource had been available to expedite [Ms A's] return to theatre (see below).** In practice, reading the transcripts of timing and available resources, it is unlikely to have altered the course of events.

7. ***Whether, in your view, the issue of [Ms A's] refusal of blood/blood products should have been raised when the decision was made to convert from laparoscopic surgery to open surgery?***

As part of an enhanced communication process, information sharing and risk identification, it should have been, in my view. However, the surgeon was already committed to an open procedure as a crucial part of the dissection had been completed by the time the decision to abandon the laparoscopic approach was taken. Raising the issue of a refusal of blood products, while desirable, would not have changed the requirement to complete the surgery by open incision ([Ms A] could not have been woken up and transferred to another hospital, for instance, and [Dr C] would be expected to be competent to complete the open procedure at [Hospital 1] without significant haemorrhage, as he did do). Clinically significant bleeding requiring blood transfusion is still rare for an open procedure, in my experience (I have not, from memory, transfused either a laparoscopic or open cholecystectomy in my career of 30 years as a physician) and therefore it was

reasonable to continue the surgery, in my view. Identifying the issue to the surgeon would have increased his vigilance and thoroughness in securing haemostasis but there is no evidence, in the information supplied, that this was sub-standard as the gall-bladder bed was reportedly dry at the conclusion of the open procedure. Information given from the post-mortem (report received) states that all vessels were adequately secured and that the bleeding was likely coming from the gall-bladder bed, either from continued ooze postoperatively or from a new bleeding point. The presence of a (apparently previously un-diagnosed) fatty liver, described as '… marked macro-vesicular steatosis" in the autopsy report was possibly significant in terms of liver morphology, thereby compounding the situation.

The failure to raise the issue at this time was an omission, the significance of which is uncertain as the team were already committed to the open procedure.

8. *The standard of care provided by [Dr D] during surgery and postoperatively.*

[Dr D] provided a good standard of care during the first case, for which he was the attending anaesthetist. His record was complete and there was nothing to indicate any failure of duty of care. He organised good pain relief commensurate with the conversion to open surgery by ordering a 'painbuster' infusion of local anaesthetic. The family submission questioned the contents of the 'painbuster' and the submitter may have mis-read 'Marcaine 0.25%' (a local anaesthetic agent) for 'Morphine' — it is definitely the former in the record.

[Dr D] was scheduled to continue the elective surgery list with [Dr C] and it was entirely reasonable for him to do so, given the low expected probability of post-operative complications from [Ms A's] surgery. I have no information regarding the staffing of the OR suite that day but I assume that all the anaesthesia staff were fully occupied managing their own patients in other OR's through the middle part of the day. [Dr D] handed over [Ms A's] care to the post-anaesthesia care unit (PACU) staff, as would be expected. [Ms A] was transferred to PACU at about 1125 hrs and [Dr D] presumably returned to the OR after handover to prepare for the next case. Looking at the PACU and fluid record, she was given 1000ml of crystalloid fluid at midday and her observations only began to become of concern from about 12.30 onwards, after [Dr D] had committed to the next case. He was then in the invidious situation of trying to manage two patients at once, as described in his transcript. On observing her directly (time not specified) he quickly established that she was likely to be bleeding and ordered further fluid boluses and some Tranexamic acid — both of which were correct options, although the latter was not administered until 1405 hours and probably would not have had any significant effect, given the almost certain dilutional coagulopathy by that time.

The crucial factors in this phase of the proceedings were the time at which [Dr D] recognised the problem (not stated) and notified [Dr C] but more importantly, when another operating room became available so that they could re-open [Ms A's] abdomen to try and remedy the situation. From the information supplied, it

would seem that all of the OR's were occupied until the on-call anaesthetist, [Dr. O], and his OR became available and she was returned to that OR at 1445hrs. This was the main rate-limiting step, as other resuscitative measures with blood and blood products that would have temporised the situation (and saved [Ms A's] life) were precluded by her beliefs and directives.

Her haemoglobin concentration was 61 g/l by haemocue at 1330 hrs and by the time she returned to the OR, it was 45 g/l or less — she was already *in extremis* ...

In summary [Dr D's] standard of care was appropriate and reasonable, given the extreme circumstances in which he found himself.

9. *Whether, in your view, there were any systematic or organisational issues that impacted adversely on the anaesthetic services provided to [Ms A]?*

I do not believe so. It was entirely reasonable for her to have her procedure at [Hospital 1], given the low risk profile of the procedure and even despite her directive and belief. The hospital was adequately equipped and staffed for routine anaesthesia and surgery. What might have influenced the outcome was earlier availability of an operating room and team to expedite her return for laparotomy once the problem had been diagnosed but this is not realistic in a small regional hospital, as this would require a team on stand-by. The surgical casemix is triaged on the basis of risk and the hospital is equipped and staffed to match. Transfer to [another hospital] as she deteriorated would have been unwise and extremely hazardous, given her instability and profound anaemia and it is far from certain that her outcome would have been any different; she died as a result of un-survivable anaemia, and this was a correctable and avoidable cause.

10. *Any aspects of the care provided to [Ms A] that you consider warrant additional comment?*

There are 2 further issues that I would like to comment on.

The first is the family submission that queries why a cell-saver was not available. In this case, a cell-saver would have been of very limited (if any) use for two reasons

- The abdomen was full of blood clot when re-opened which would have been unable to be processed by the cell-saver even if one was available
- Cell-savers do not preserve the clotting factors that were also desperately required by [Ms A] by the time of the second procedure.

It seems to be a common misconception that cell-saving is a complete substitute for blood or blood product administration amongst the Jehovah's Witness community. Cell-savers salvage red blood cells at the time of surgery and preserve red cell mass in mild to moderate bleeding by re-administration back to the patient, thereby mitigating the effects of anaemia. They do not preserve clotting factors. In [Ms A's] case, cell-saving would have been of little if any help (indeed article 4 of her 2006 directive would seem to preclude the use of cell-saving in any

case) as she was not bleeding significantly during the first case and had already clotted most of the haemorrhage into her peritoneal cavity by the time of the second case.

In another scenario (a hip joint replacement, for instance) cell-saving would be very useful in a Jehovah's witness patient and would be seriously considered, discussed and recommended to the patient as a tool to mitigate the consequences of post-operative anaemia (but not to preserve the effectiveness of the clotting mechanism).

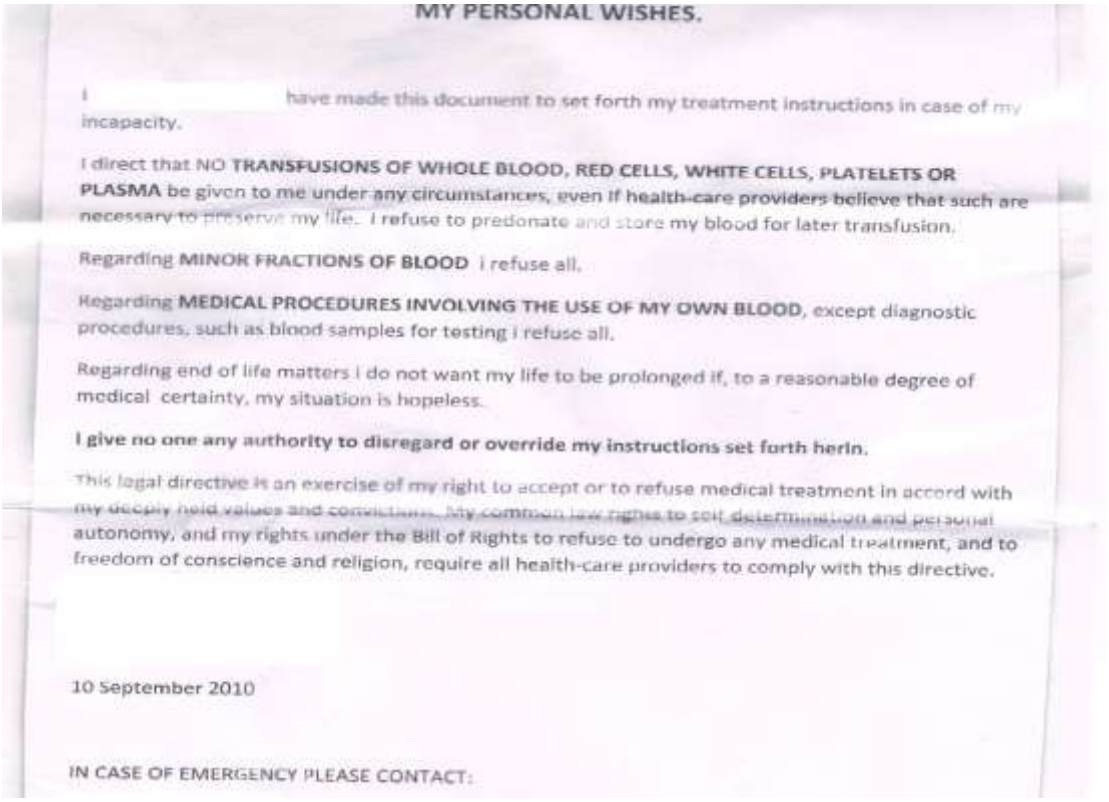
The second issue also results from the family submission. They queried the availability of Recombinant Factor VIIa (Novoseven). The mechanism of action of this compound relies on the substantially normal presence of other elements of the clotting cascade and these were clearly deficient by the time [Ms A] returned to the operating room. Therefore Factor VIIa would have been ineffective in this situation and this unfortunately is another misconception that we find in the Jehovah's Witness community; that Novoseven is an alternative to blood and blood products. It is manifestly not so. In fact its use in trauma and massive transfusion cases is now not recommended because of ineffectiveness and lack of cost-utility, except when all other deficiencies in the clotting cascade have been corrected and the patient is still bleeding.

In summary, this was a tragic outcome for an otherwise reasonably fit and well young woman. My thoughts are with her family, who have lost a beloved daughter, sister and sister-in-law and I hope that through this process, they obtain the facts to the best of our collective knowledge and achieve some closure and peace.

My thoughts are also with the team at [Hospital 1], who were placed in a terrible situation where they could have saved [Ms A's] life but were precluded from doing so by circumstances outside their control. As a fellow professional, I can empathise fully and hope that I never find myself in a similar situation.

Having thoroughly reviewed the information supplied, I conclude that [Ms A] died as a result of very profound anaemia that was preventable and that there were no significant departures from the standard of care of the anaesthesia provider, [Dr D], that would have substantially altered the course of this case."

Appendix 3 — Ms A's 2010 Advance Directive



MY PERSONAL WISHES.

I have made this document to set forth my treatment instructions in case of my incapacity.

I direct that NO **TRANSFUSIONS OF WHOLE BLOOD, RED CELLS, WHITE CELLS, PLATELETS OR PLASMA** be given to me under any circumstances, even if health-care providers believe that such are necessary to preserve my life. I refuse to predonate and store my blood for later transfusion.

Regarding **MINOR FRACTIONS OF BLOOD** I refuse all.

Regarding **MEDICAL PROCEDURES INVOLVING THE USE OF MY OWN BLOOD**, except diagnostic procedures, such as blood samples for testing I refuse all.

Regarding end of life matters I do not want my life to be prolonged if, to a reasonable degree of medical certainty, my situation is hopeless.

I give no one any authority to disregard or override my instructions set forth herin.

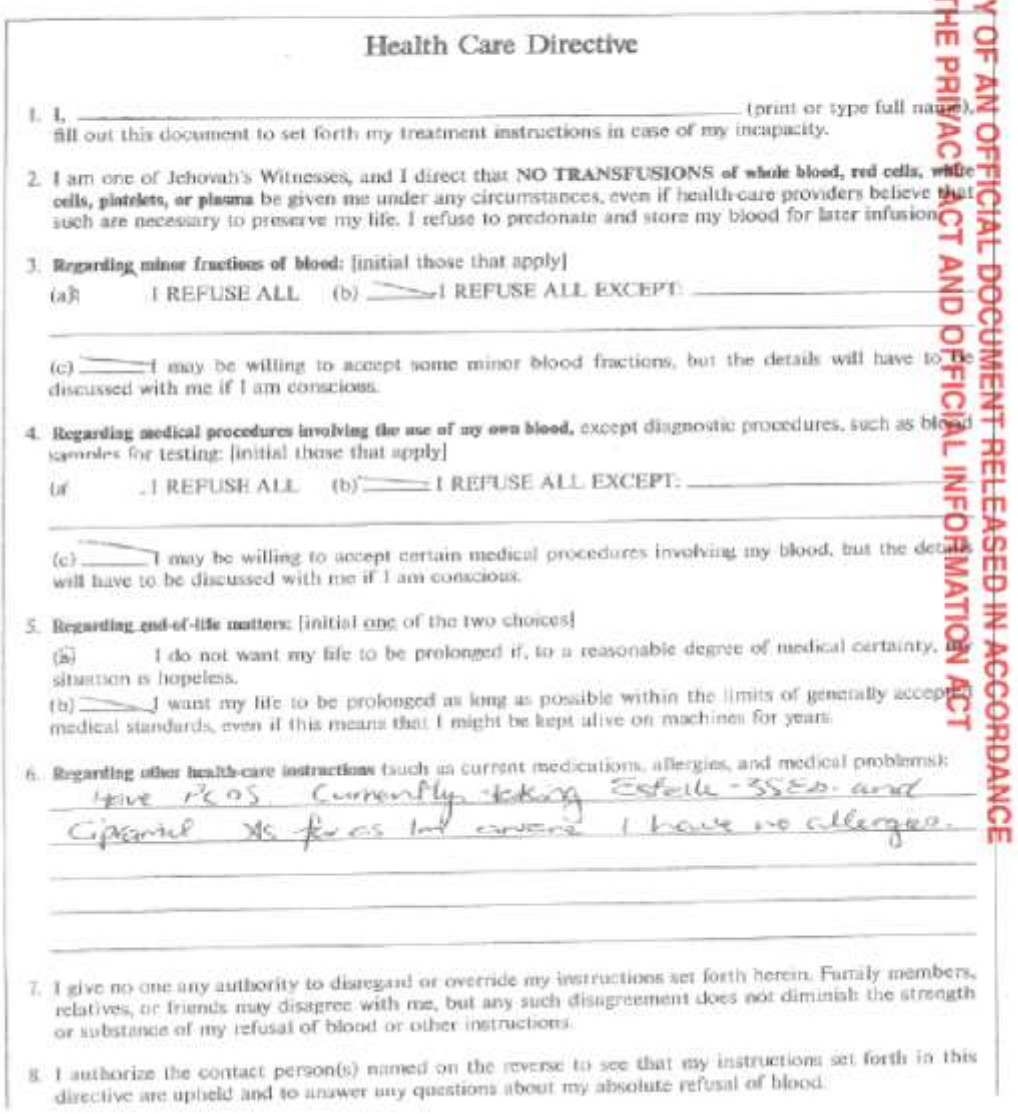
This legal directive is an exercise of my right to accept or to refuse medical treatment in accord with my deeply held values and convictions. My common law rights to self determination and personal autonomy, and my rights under the Bill of Rights to refuse to undergo any medical treatment, and to freedom of conscience and religion, require all health-care providers to comply with this directive.

10 September 2010

IN CASE OF EMERGENCY PLEASE CONTACT:

[Note: The legibility of the original document copied above is poor, as it had been laminated and folded.]

Appendix 4 — Ms A's 2006 Advance Directive



Health Care Directive

1. I, _____ (print or type full name), fill out this document to set forth my treatment instructions in case of my incapacity.

2. I am one of Jehovah's Witnesses, and I direct that **NO TRANSFUSIONS of whole blood, red cells, white cells, platelets, or plasma** be given me under any circumstances, even if health-care providers believe that such are necessary to preserve my life. I refuse to predonate and store my blood for later infusion.

3. **Regarding minor fractions of blood:** [initial those that apply]
(a) I REFUSE ALL (b) I REFUSE ALL EXCEPT: _____
(c) I may be willing to accept some minor blood fractions, but the details will have to be discussed with me if I am conscious.

4. **Regarding medical procedures involving the use of my own blood,** except diagnostic procedures, such as blood samples for testing: [initial those that apply]
(a) I REFUSE ALL (b) I REFUSE ALL EXCEPT: _____
(c) I may be willing to accept certain medical procedures involving my blood, but the details will have to be discussed with me if I am conscious.

5. **Regarding end-of-life matters:** [initial one of the two choices]
(a) I do not want my life to be prolonged if, to a reasonable degree of medical certainty, my situation is hopeless.
(b) I want my life to be prolonged as long as possible within the limits of generally accepted medical standards, even if this means that I might be kept alive on machines for years.

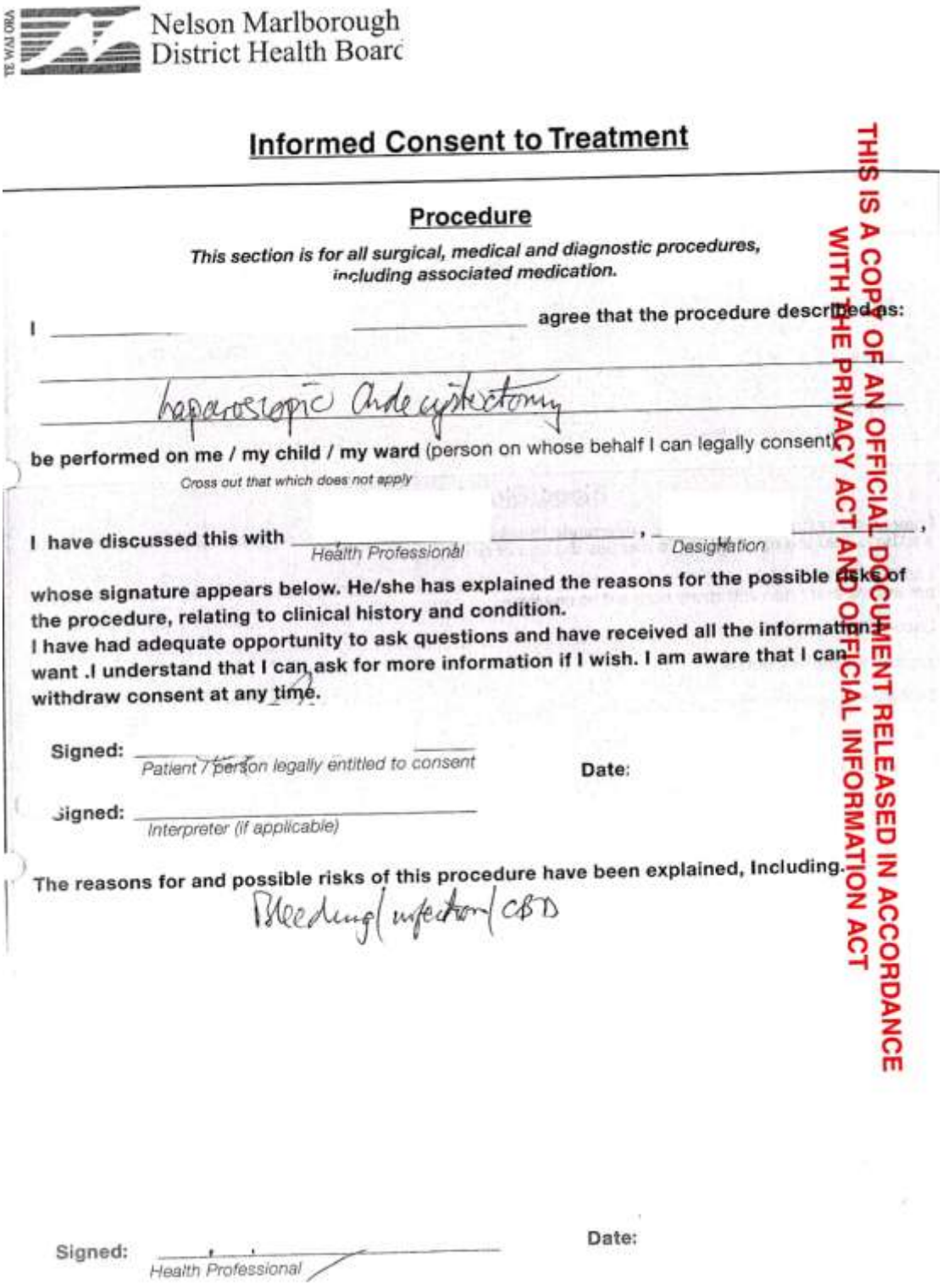
6. **Regarding other health-care instructions** (such as current medications, allergies, and medical problems):
Have PCOS Currently taking Estelle-35ED and Cipramil 20mg for GS but current I have no allergies.

7. I give no one any authority to disregard or override my instructions set forth herein. Family members, relatives, or friends may disagree with me, but any such disagreement does not diminish the strength or substance of my refusal of blood or other instructions.

8. I authorize the contact person(s) named on the reverse to see that my instructions set forth in this directive are upheld and to answer any questions about my absolute refusal of blood.

Names have been removed (except NMDHB and the experts who advised on this case) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

Appendix 5 — Consent form



Nelson Marlborough District Health Board

Informed Consent to Treatment

Procedure

This section is for all surgical, medical and diagnostic procedures, including associated medication.

I _____ _____ agree that the procedure described as:

laparoscopic cholecystectomy

be performed on me / my child / my ward (person on whose behalf I can legally consent).

Cross out that which does not apply

I have discussed this with _____ *Health Professional* _____, *Designation* _____,

whose signature appears below. He/she has explained the reasons for the possible risks of the procedure, relating to clinical history and condition.
I have had adequate opportunity to ask questions and have received all the information I want .I understand that I can ask for more information if I wish. I am aware that I can withdraw consent at any time.

Signed: _____ *Patient / person legally entitled to consent* Date:

Signed: _____ *Interpreter (if applicable)*

The reasons for and possible risks of this procedure have been explained, including.

Bleeding/infection/CBD

Signed: _____ *Health Professional* Date:

THIS IS A COPY OF AN OFFICIAL DOCUMENT RELEASED IN ACCORDANCE WITH THE PRIVACY ACT AND OFFICIAL INFORMATION ACT

Names have been removed (except NMDHB and the experts who advised on this case) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

Anaesthetic

I agree to a local / general *(cross out that which does not apply)* anaesthetic being given.

I have read or had explained and understand, the risks and benefits of the the proposed anaesthetic. I have had adequate opportunity to ask questions about the anaesthetic, alternative procedures and risks.

I acknowledge that I should not drive a motor veehicle, operate machinery or potentially dangerous appliances, drink alcoholic beverages or make important decisions for 24 hours after the procedure.

I have discussed this with _____ *Health Professional*, _____ *Designation*, whose signature appears below.

Discussion / comments: _____

Signed: _____ *Patient / person legally entitled to consent* Date: ___ / ___ / ___

Signer: _____ *Interpreter (if applicable)*

Signed: _____ *Health professional* Date: ___ / ___ / ___

Blood/Blood products

I have read or had explained, and understand the risks and benefits of the use of blood and blood products and have had the opportunity to discuss the use of each.

I agree / do not agree *(cross out that which does not apply)* to the use of these products if required. If agreeing, I am aware that I can withdraw consent at any time.

I have discussed this with _____ *Health Professional*, _____ *Designation*, whose signature appears below.

Discussion / comments: _____

Signed: _____ *Patient / person legally entitled to consent* Date: ___ / ___ / ___

Signer: _____ *Interpreter (if applicable)*

Signed: _____ *Health professional* Date: ___ / ___ / ___

Request for Body parts

I wish to have any body parts returned to me. I understand that in certain situations this may not be possible. This has been explained to me.

I have discussed this with _____ *Health Professional*, _____ *Designation*, whose signature appears below.

Discussion / comments: _____

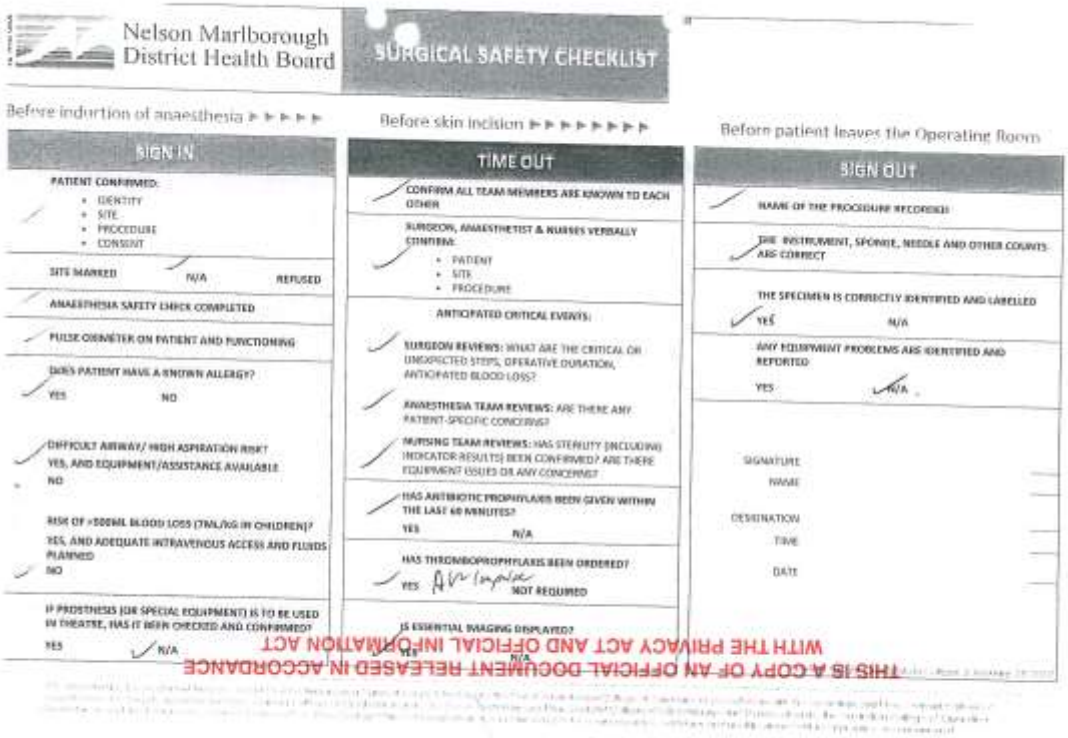
Signed: _____ *Patient / person legally entitled to consent* Date: ___ / ___ / ___

Signer: _____ *Interpreter (if applicable)*

Signed: _____ *Health professional* Date: ___ / ___ / ___

Names have been removed (except NMDHB and the experts who advised on this case) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

Appendix 6 — Surgical Safety Checklist



Nelson Marlborough District Health Board

SURGICAL SAFETY CHECKLIST

Before induction of anaesthesia ▶▶▶▶▶

SIGN IN

PATIENT CONFIRMED:
- IDENTITY
- SITE
- PROCEDURE
- CONSENT

SITE MARKED N/A REFUSED

ANAESTHESIA SAFETY CHECK COMPLETED

PULSE OXIMETER ON PATIENT AND FUNCTIONING

DOES PATIENT HAVE A KNOWN ALLERGY?
YES NO

DIFFICULT AIRWAY/ HIGH ASPIRATION RISK?
YES, AND EQUIPMENT/ASSISTANCE AVAILABLE
NO

RISK OF >500ML BLOOD LOSS (7ML/KG IN CHILDREN)?
YES, AND ADEQUATE INTRAVENOUS ACCESS AND FLUIDS PLANNED
NO

IF PROSTHESIS (OR SPECIAL EQUIPMENT) IS TO BE USED IN THEATRE, HAS IT BEEN CHECKED AND CONFIRMED?
YES N/A

Before skin incision ▶▶▶▶▶▶▶▶

TIME OUT

CONFIRM ALL TEAM MEMBERS ARE KNOWN TO EACH OTHER

SURGEON, ANAESTHETIST & NURSES VERBALLY CONFIRM:
- PATIENT
- SITE
- PROCEDURE

ANTICIPATED CRITICAL EVENTS:

SURGEON REVIEWS: WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS?

ANAESTHESIA TEAM REVIEWS: ARE THERE ANY PATIENT-SPECIFIC CONCERNS?

NURSING TEAM REVIEWS: HAS STERILITY (INCLUDING INDICATOR RESULTS) BEEN CONFIRMED? ARE THERE EQUIPMENT ISSUES OR ANY CONCERNS?

HAS ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES?
YES N/A

HAS THROMBOPROPHYLAXIS BEEN ORDERED?
YES NOT REQUIRED

IS ESSENTIAL IMAGING DISPLAYED?
YES N/A

Before patient leaves the Operating Room

SIGN OUT

NAME OF THE PROCEDURE RECORDED

THE INSTRUMENT, SPONGE, NEEDLE AND OTHER COUNTS ARE CORRECT

THE SPECIMEN IS CORRECTLY IDENTIFIED AND LABELLED
YES N/A

ANY EQUIPMENT PROBLEMS ARE IDENTIFIED AND REPORTED
YES N/A

SIGNATURE
NAME
DESIGNATION
TIME
DATE

Names have been removed (except NMDHB and the experts who advised on this case) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

Appendix 7 — Dr S's report for sentinel event investigation

"**[Ms A] (deceased) [DOB:]**

I have now reviewed [Ms A's] file regarding her laparoscopy cholecystectomy on [date]. [Ms A] was a 31-year-old woman who was seen in the Surgical Outpatient Clinic with biliary colic and she was placed on the wailing list for a laparoscopic cholecystectomy. She was consented for surgery by [Dr C] [on the day of surgery], and the consent form included the risks of bleeding, infection and common bile duct injury. [Dr C's] operation notes state that the operation was difficult due to inadequate exposure secondary to a large amount of intra-abdominal fat. She also has hepatic steatosis which impairs visualisation of the structures beneath the liver. The surgeon correctly placed an additional port for retraction, dissected the cystic duct and artery and these were ligated and divided. On dissecting the gallbladder from the liver bed he found entry into the liver with a ductal structure visible and elected to convert to open surgery. The cholecystectomy was completed using diathermy dissection and my impression from the operative note is that haemostasis was satisfactory at the time of closure of the abdomen. The anaesthetist's record shows a mean arterial pressure of greater than 80mmHg throughout her operation and a pulse rate of below 80 beats per minute. The time from commencement of laparoscopic surgery to conversion to open surgery was about 60 minutes. The anaesthetist documented blood loss of about 500ml.

In recovery there was a trend of increasing pulse and decreasing blood pressure from mid-day onwards. At 1.30pm her haemoglobin was documented as 61g per litre and tranexamic 1g was administered at 2pm. [Ms A] was noted to be pale, with a distended abdomen, and [Dr C] questioned bleeding from the liver bed and recognised the need for re-laparotomy. The time of skin incision was documented as 14:55. It seems as if blood products were discussed with her and a note was made that she did have sedation on board. She refused any blood products but her mother agreed to recombinant factor VIIa which was ordered from [another centre]. At the second laparotomy she was found to have 31 of blood and clots in the gallbladder fossa with no obvious bleeding point identified. Peritoneal lavage was performed and two packs were placed for haemostatic control. Transfer was arranged to [Hospital 2] ICU. At this stage [Ms A's] haemoglobin had dropped further to 25g per litre. She remained in theatre and was about to be transferred when she became bradycardic and haemoglobin was now 11g per litre. This is incompatible with life and no CPR was offered. [Ms A] passed away and was declared deceased at 7pm.

I have not seen the official post mortem report.

An abdominal complication such as bleeding occurs in less than 1% of patients following open cholecystectomy'.[1] [Ms A] did not have any history of coagulation deficiency and the only predictor of potentially difficult surgery was her body mass index. She had also signed an advanced directive to not receive any blood products in February 2006.

I consider [Dr C's] decision to convert to open surgery a wise decision. He also decided to re-explore her promptly once it was evident that she had internal bleeding. There are many potential sources of bleeding following any open cholecystectomy — the cystic artery, the right hepatic artery, the liver bed, omental fat and the abdominal wall. These have to be explored in a systematic fashion and any bleeding points dealt with as they are discovered. However, it is not unusual to not find a specific source of bleeding on relaparotomy after any major abdominal surgery. In that situation, packing the area of the most likely source is the appropriate thing to do and that is exactly what [Dr C] did.

The question of recombinant factor VIIa has also been raised. Most of the literature regarding the use of recombinant factor VIIa comes from the American Military and Trauma Surgery. It is used as an adjunct in the patient with massive haemorrhage who is undergoing damage control laparotomy. It is, therefore, almost always used in conjunction with a massive transfusion protocol and damage control laparotomy with the sole aim of controlling haemorrhage and limiting contamination. As a standalone treatment in a postoperative bleeding patient, I would consider it worthless. [Ms A] did demonstrate consumption coagulopathy as her final blood count revealed a platelet count of 50 and INR of 8.3. To correct such a deficiency would require plasma, platelets, cryoprecipitate and possibly factor VIIa. In my opinion, therefore, the presence or absence of this drug was irrelevant and administration did not make any difference to her outcome.

Finally, the risk of intra-abdominal bleeding is ever present in any major abdominal procedure and it is regrettable that this happened to [Ms A] who had an advance directive not to receive any blood products. Most surgeons will not disqualify a Jehovah's Witness from abdominal surgery provided that they are fully informed of the risks of bleeding and the likelihood of death should that happen.

Yours sincerely

[Dr S]
General Surgeon

1. Surgical Clinics of North America December 2008, volume 88, no, 6, page 1290."