General Surgeon, Dr E

A Private Hospital

A Report by the

Health and Disability Commissioner

(Case 07HDC11318)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Overview

This report examines the information and care provided to Mr A by general surgeon Dr E and staff at a private hospital.

Mr A was admitted to the private hospital for gastric bypass surgery. However, abnormal liver function blood tests (increasing the risks of surgery) were not noticed until immediately prior to surgery, by which time Mr A had been anaesthetised. Dr E decided to operate without advising Mr A of the increased risks, which Dr E subsequently estimated increased the risk of death fivefold.

Mr A was discharged from the private hospital six days after surgery, during which time his liver function tests deteriorated. However, this deterioration was not noticed by the clinical team, and no plans were made for investigating the cause of the abnormal results.

Mr A was readmitted a week later to a public hospital for an emergency operation for a perforated bowel. Unfortunately, Mr A developed complications following the operation, including liver failure, and he died a few days later in hospital.

In this report, I consider Dr E's and the private hospital's responsibilities to Mr A, particularly in relation to the requirement for fully informed consent prior to surgery. The standard of documentation and the general standard of care have also been considered.

Parties involved

Mr A (dec)	Consumer
Ms C	Complainant/consumer's sister
Ms B	Complainant/consumer's sister
Ms D	Consumer's partner
Dr E	Provider/general surgeon
Dr F	Anaesthetist, the private hospital
Dr G	Pathologist
Dr H	Consumer's general practitioner
Dr I	General surgeon, public hospital
Ms J	Registered nurse
Dr K	Dr E's registrar
Ms L	Dr E's registered nurse
The private hospital	Provider
The public hospital	A public hospital

Complaint and investigation

On 27 June 2007, the Health and Disability Commissioner (HDC) received a complaint from Ms C and Ms B about the services provided to their brother, Mr A, by surgeon Dr E. The following issues were identified for investigation:[1]

The appropriateness of care provided to Mr A by Dr E from 1 August 2005 to 16 February 2006.

The appropriateness of care provided to Mr A by the private hospital from 1 to 8 February 2006.

An investigation was commenced on 4 September 2007.

Information was obtained from Ms C, Ms B, Ms D, Dr H, Dr E, Dr I, Dr F, Dr G, and the private hospital.

Independent expert advice was obtained from general surgeon Professor André van Rij.

Information gathered during investigation

Background

8 August 2005
Mr A, then aged 50, consulted Dr E on 8 August 2005 at his regular clinic (as a private patient) to discuss the possibility of an operation to manage obesity. At the time, Mr A weighed in excess of 150kg.[2]

Mr A had had long-standing problems with his weight, and had been unable to lose weight "in a sustained fashion". Dr E recalls that Mr A described a history of high blood pressure, and had been investigated in the past for liver problems. Dr E stated:

> "I do recall his mentioning that he had previously been noted to have abnormal liver function tests and that some investigation had been undertaken at [a public] Hospital by a gastroenterologist a number of years previously without any significant conclusion being drawn. [Mr A] was unaware of having had a liver biopsy although it transpires (following information provided by his sisters) that a liver biopsy had been performed at [a public] Hospital in July of 1995."

[1] The investigation was extended on 2 April 2008 to include the care provided by the private hospital.

[2] At the time of his subsequent admission to the private hospital on 1 February 2006, Mr A weighed 158.5kg.

Dr E was not "particularly perturbed" by Mr A's mention of abnormal liver function tests, "given that no important disease had been revealed".

At the end of the consultation, Dr E requested a number of blood tests, which he thought included liver function tests (LFTs).[3] In fact, LFTs were not requested. Dr E advised:

> "[T]he oversight clearly occurred by either the LFTs not being requested (by my failing to tick the LFT box on the form), or not being performed by the laboratory, as sometimes happens."[4]

There is no record in the clinical notes of a discussion of Mr A's medical history relating to his liver. Subsequent to the consultation, Dr E wrote to Mr A's GP, Dr H:

> "[Mr A] is almost certain that he wishes to proceed with gastric bypass but not quite ready to commit."

22 August 2005
Mr A consulted Dr E for a second time on 22 August. Although Dr E reviewed the results of the tests, he did not notice that the LFTs had not been performed. He subsequently stated:

> "I also failed to note or reflect on [Mr A's] abnormal prothrombin ratio of 1.4 which is a little prolonged,[5] and had I been thinking about severe liver disease it might have alerted me to significant hepatic abnormality."

Dr E did notice that the blood tests indicated "the presence of significant insulin resistance", but he discounted this result as having no clinical significance. He stated:

> "Although [Mr A] was not diabetic, my experience through my clinical studies and research meant that I would have expected [non-alcoholic steatohepatitis][6] in the presence of such significant insulin resistance, however this is not usually of any clinical significance and indeed has not been so in over 1,000 other patients operated on by me for gastric bypass."

[3] See **Appendix 1** for blood test results.

[4] Dr E has amended his system to include a standard computer-generated form to prevent a similar case recurring.

[5] Normal prothrombin ratio is 1.

[6] National Digestive Diseases Information Clearing House definition: "Non-alcoholic steatohepatitis or NASH is a common, often 'silent' liver disease. It resembles alcoholic liver disease, but occurs in people who drink little or no alcohol. The major feature in NASH is fat in the liver, along with inflammation and damage. Most people with NASH feel well and are not aware that they have a liver problem. Nevertheless, NASH can be severe and can lead to cirrhosis, in which the liver is permanently damaged and scarred and no longer able to work properly."
http://digestive.niddk.nih.gov/ddiseases/pubs/nash/

Dr E described the intended operation (gastric bypass) to Mr A and discussed the risks of surgery, which Dr E rated as a 1% risk of death and a 5–10% chance of major complications. At Mr A's request, arrangements were made for him to talk to a patient who had undergone the same operation.

Dr E wrote to Mr A's GP on 24 August 2005:

> "[Mr A's] various blood tests are reasonably satisfactory with the exception of a very high fasting insulin of 379, which is indicative of severe insulin resistance."

Mr A signed a consent form on 5 November 2005, consenting to general anaesthesia, and on 6 November 2005 he signed a consent form to agree to the gastric bypass operation, with a possible cholecystectomy and liver biopsy.[7] The consent form included the statement:

> "I agree that I have received a satisfactory explanation of the intent, risks and likely outcomes of the above Operation/Procedure and of any related treatment that becomes necessary.
>
> …
>
> I am aware that I may ask for more information and can share in making decisions about treatment."

Subsequent to this appointment, Mr A completed a form ("Health Questionnaire/Nursing Assessment Form"), which set out his personal details, including medical history. Mr A ticked the form to indicate that he had previously had surgery, or been admitted to hospital. On 7 November 2005, Mr A signed an agreement stating that he would pay $21,000 for the operation and postoperative care.

1 February 2006

Mr A was admitted to the private hospital on the afternoon of 1 February 2006 for the planned operation of gastric bypass surgery.

The admitting nurse, registered nurse (RN) Ms J, noted in the documentation that Mr A had had arthroscopies of his right shoulder in 1997 and 1998, and a liver biopsy in 1995. Ms J stated that although she cannot clearly recall Mr A's admission, she would have recorded this having been informed of the biopsy by him. As the biopsy had been performed 10 years earlier and there was no other medical history regarding liver disease, and given that there was no blood test result available yet, she "would not have found it important at that point to advise [Dr E]" of the biopsy. RN Ms J added that she expected that this history would have been known to Dr E prior to admission, as a result of the preadmission assessments performed.

[7] The consent form for surgery was signed by Dr E on 28 October 2005, and for anaesthesia by anaesthetist Dr F on 1 February 2006.

An Integrated Progress Plan (IPP) was partially completed. This is a private hospital document designed specifically for patients who are going to have gastric bypass surgery. The IPP sits at the end of the patient's bed and is used by nursing staff as a generic guide to the care required on a particular day. It is in effect a clinical pathway document and complements the patient clinical records (the "Integrated Progress Notes") which is where nursing staff and doctors write notes. There is a separate page in the IPP for the day prior to surgery and each subsequent day following surgery.

RN Ms J wrote the following on the front sheet of Mr A's IPP:

> "[History of] hypertension, sleep apnoea, gout, insulin resistance, reflux.
> Safe procedure with quick post op recovery."

Blood tests were performed, including LFTs, as well as other routine preoperative procedures (ECG, chest X-ray). The LFT blood sample was received by the laboratory at 4.30pm.

The LFT blood test of 1 February comprised 11 separate tests. The blood result has a single asterisk after two of the tests (indicating an abnormality), and three asterisks (showing significant abnormality) after four of the tests. There is no evidence that the result was brought to the attention of medical staff.

The LFT results were sent by facsimile at 5.17pm to Dr E's office at the gastroenterology clinic. The clinic is in the same building at the private hospital as the ward to which Mr A had been admitted. However, the LFT results did not reach the ward until 10.27pm (apparently by separate facsimile from the laboratory). This accords with Ms J's recollection that the blood test results had not arrived by the time she wrote the nursing notes at the end of her evening shift at 10pm.

Anaesthetist Dr F assessed Mr A in the evening. Dr F cannot recall when the LFT results became available, but believes that it was probably not until the morning of the operation, on 2 February. He completed a form that described his assessment of Mr A. This includes the statement: "'Fatty liver' for years" and, immediately below that comment, written in Dr F's writing and in brackets, the LFT results. There is no notation to state that the blood results were subsequently added. Dr F stated:

> "My understanding was that the surgeon and the team were aware of the results and ready to proceed with the surgery because a fatty liver (which was the working diagnosis[8] at the time) improves with reduction in body mass."

Dr F prescribed a sedative to be administered at 9pm, and noted that no premedication was required the following morning prior to surgery.

[8] There is no reference in the clinical notes to any liver abnormality prior to Dr F's assessment on the evening of 1 February.

Dr E visited Mr A on the ward at some time between 7pm and 8pm. Dr E stated that his usual practice is to review blood test results the evening prior to an operation. He said that the results were not available when he visited Mr A, whom he found "comfortable and … confident that he had made the right decision". Dr E did not discuss Mr A's LFT results as he was "unaware of them and had no particular reason to be specifically alerted to them".

Dr E added:

> "Where I am suspicious that the results will be of importance to me I would ordinarily ask the nursing staff to call me once they are available, or I would ask them to make a call to the laboratory to see if the results were available. In the case of [Mr A] there was no reason for me to be particularly suspicious … For that reason I was content that it was not critical that the results be viewed by me that evening."

2 February 2006
Mr A was the first patient on the theatre list for 2 February. When he was transferred to theatre, the preoperative check list (completed by the nurse who had been on duty on the ward overnight) confirmed that the blood results were present in the clinical records, countersigned by the theatre nurse.

The private hospital advised:

> "It is not a nurse's responsibility to interpret blood results; however, it is a nurse's responsibility to advise the consultant if the results are abnormal. The [laboratory] indicates any abnormality on the reports by placing an asterisk after the abnormal result."

Dr F stated that Mr A's anaesthesia commenced at 8.20am, and added:

> "[W]ith [Mr A] already under anaesthesia, after a discussion with nurses, I became aware that there was a possibility that the surgeon was not aware of the LFT results. I asked them to contact [the surgeon] to clarify the situation. The surgeon arrived, and we discussed the case directly."

Dr E, who was at a routine, fortnightly clinical pathology meeting from 7.30am until 9am, was contacted on his mobile phone to advise that Mr A's LFTs were abnormal, but that he had already been anaesthetised. Dr E proceeded to the private hospital from his pathology meeting to commence his operating list.

Dr E stated:

> "I realised that [Mr A] must have underlying cirrhosis and I was certainly perturbed that this meant that if we proceeded with surgery we would do so at a significantly greater than normal risk of death because of the potential for liver decompensation in this circumstance. Given the knowledge that he had previously

> not had a major problem found in his liver after investigations by a gastroenterologist … and armed with the knowledge that he had very severe insulin resistance I believed that almost certainly his cirrhosis was on the basis of NASH[9] and insulin resistance and as such would be expected to improve or possibly even resolve following gastric bypass … For this reason I made the decision to proceed with surgery with the full knowledge that the risks were increased but that the course of action that we were about to embark on would almost certainly be the only means of improving his liver function."

Dr E subsequently advised that, based on the LFT results, the "risk of dying would be several times greater" than previously advised to Mr A, "perhaps of the order of 5%".

The operation[10] commenced at 9.40am and concluded at 11.44am.

Once Mr A had woken from anaesthesia, Dr E discussed with him the abnormal LFT results[11] and "[the] failure to have recognised this prior to surgery".[12] Dr E also discussed his decision to proceed to surgery without waking Mr A from anaesthesia. Dr E stated:

> "[Mr A] understood all that I was saying, and while being a little perturbed by it agreed that it was right that I had elected to proceed with surgery."

As noted above, there is no contemporaneous record of this discussion.

In contrast, Ms D stated:

> "I do believe that if [Mr A] had been informed of the significance of his blood tests he would have wanted them further investigated before going ahead with the surgery. He was an extremely intelligent man."

Postoperative care
Mr A recovered seemingly uneventfully from surgery. Of note, the nurse recorded on 5 February:

[9] See page 3, footnote 7, for definition of nonalcoholic steatohepatitis (NASH).

[10] Laparotomy and transected silastic ring gastric bypass.

[11] In his subsequent letter of 13 February 2007 to Mr A's sisters, Dr E described the LFTs taken before surgery as "grossly abnormal", and indicative of "quite serious cirrhosis of the liver".

[12] Ms D, Mr A's partner, recalls that a doctor advised Mr A of his abnormal blood results either prior to his leaving the ward for theatre, or the evening before. Ms D cannot recall who the doctor was, although she stated that it may have been the anaesthetist, Dr F. The other possibility was that the doctor was Dr E's registrar, Dr K. Dr K has since left New Zealand and now works as a surgeon overseas. He was contacted during the course of the investigation and stated that he had no discussions with Mr A about his liver function tests, before or after the operation. There is no record of any preoperative discussion as described by Ms D.

> "Passed urine — very dark/bilirubin[13] stained? Or concentrated?
>
> …
>
> Whites of eyes do look yellow tinged."

A diuretic (20mg of frusemide) was administered on 5 and 6 February. The reason for its administration is not recorded in the clinical notes. Dr E subsequently advised:

> "It is common for patients undergoing gastric bypass surgery, and indeed many other forms of major surgery, to develop significant fluid retention following surgery, which leads to oedema[14] of the lower limbs and/or more generalised oedema. This is always a little worse in the more insulin resistant individuals and is potentially worse again in those with a degree of liver dysfunction. It would not be unusual for us to give patients Frusemide on 1, 2, 3 or 4 days following gastric bypass to deal with fluid retention. While I don't see a specific mention in the notes as to his postoperative weight or level of oedema it will have been for this reason that we chose to give Frusemide."

On 6 February, the nursing staff recorded: "urine remains dark in colour".

Documentation

There is no record of the 1 February evening visit, nor of any other subsequent visit by Dr E to review Mr A from 1 to 8 February. Dr E has subsequently given an account of the discussions he said he had with Mr A, and these are set out in this report, but there is no contemporaneous record of these assessments and discussions, and no reference by a third party in the clinical notes to a visit by Dr E to review Mr A.

There is no record in the IPP (which has a section for the nurse to complete stating whether the patient has been seen by the surgeon or the anaesthetist) or the progress notes on 2, 4, or 6 February that Mr A was reviewed by a surgeon or an anaesthetist. On 5 February, it is noted (unsigned) on the form that Mr A was seen by the "RMO", and that he was to have 60ml of fluid, orally, per hour.

Discharge

Mr A was discharged home on 8 February. Prior to discharge, Mr A was reviewed by RN Ms L, a nurse employed by Dr E to assist him in the care of his patients. In relation to post-discharge advice concerning Mr A's liver function, RN Ms L wrote:

> "It has also been advised that [Mr A] stop drinking alcohol because of his LFT and state of his liver — [Dr E] has also talked with [Mr A] about these facts."

[13] The orange-yellow pigment of bile.

[14] The accumulation of fluid in interstitial spaces of tissues.

The Integrated Progress Plan for the day of discharge was not completed, although there is a section related to advice given on discharge. The discharge summary was completed by RN Ms L. The summary states:

> "**This is an important document**. If you require medical assistance within the next 7 days please take this to your family doctor."

The summary contains no reference to Mr A's liver function or any intended investigations. Ms D stated:

> "I do not recall having any issues with the care that [Mr A] received during his stay at the private hospital, but I know that [Mr A] certainly wasn't that well when we returned [home]. We were not told about his blood tests having deteriorated, or the need to have them repeated anytime soon, and think we only had a copy of the letter that also went to his GP."

Medical review in the private hospital
As noted above, there is no record of a medical assessment in the period following Mr A's operation, apart from a note on 3 February by Dr E's registrar, Dr K:

> "Doing well. No soreness or fever. Talked about his liver problem and discussed about future. Mobilising well and doing fine."

Dr E described the medical reviews of Mr A during his admission:

> "I or my medical staff would have visited [Mr A] on every day of his hospital admission and almost certainly on two occasions each day. We ordinarily have between 2 and 10 patients in the ward, and the ward round is accomplished usually in the space of half an hour. Discussions are a mix of assessing the patients' progress and commenting on this to them, reassuring them where required and/or simply having some social interaction with them when all is well. In [Mr A's] case there is no doubt that his postoperative course was uneventful with the exception of slight deterioration in his liver function tests, as evidenced by his bilirubin rising to a little over 200. This was not accompanied by any significant signs of liver decompensation and so all in all his postoperative course was an uneventful one — much to our relief."

Dr E subsequently advised that "there was no sign of postoperative deterioration in liver function".

Liver biopsy
As part of a research project, a liver biopsy was taken by Dr E during the operation on 2 February. Mr A had formally consented to the biopsy prior to surgery. Pathologist Dr G stated that, some time between 6 and 8 February, he contacted the private hospital to discuss the biopsy and spoke with a member of the clinical team. Dr G stated that he would usually speak to Dr E, but occasionally to other members of the clinical team. Dr G was told that Mr A had had a liver biopsy in the past. Dr E states

that Dr G did not hear of the previous liver biopsy from him, and that "the most likely explanation … is that Dr G called the hospital and someone looked at the hospital form … and read it off to him".

The summary of the biopsy report states:

> "Predominantly macronodular cirrhosis with features consistent with alpha-1 antitrypsin deficiency[15] … I understand there has been a previous liver biopsy. It would be of interest to review that biopsy."

The report was sent to Dr E, and a copy was also sent for discussion at the regular clinico-pathology meeting. Dr K stated:

> "At our usual meeting with the pathologist, where the whole team of doctors from [the gastroenterology clinic] attends, we were made aware of the underlying liver cirrhosis. At this time I do not recollect the exact biochemical diagnosis with certainty, but probably it was alpha-1 antitrypsin deficiency."

Events after discharge

A letter was written to Mr A's GP, Dr H, on 9 February to advise him of the surgery performed on 2 February. No mention is made in the letter of any abnormal LFTs, and the only follow-up mentioned is for six weeks' time in Dr E's outpatient clinic. Although the letter is above the name of Dr E, he advised that it was sent by his registrar. Dr E accepts that the letter "does not give an adequate picture".

Dr K confirmed that, although he cannot recall whether he wrote this letter specifically, "[i]t was routine practice at [the private hospital] for the registrar to do a discharge letter". Dr K added that the letters "would be usually checked by [Dr E] in my initial tenure of appointment".

On 15 February, as part of the routine postoperative follow-up procedure, Mr A was telephoned by Ms L. Mr A reported that he had been suffering from diarrhoea, and also "black stools". He was told to take a sample to his GP when he next passed similar stools.

Ms D stated:

> "[Mr A] became less well and then appeared to develop a [urinary tract infection] … He was reluctant to drink and then developed some abdominal discomfort, and subsequently black stools. I was naturally very concerned, and we had been in contact with [Ms L] as stated. I believe that if [Dr H] had been aware of [Mr A's] perilous health he may have requested repeat bloods etc — but his discharge letter did not give him any cause for concern."

[15] Alpha-1 antitrypsin deficiency is an inherited disorder that can cause lung disease in adults, and liver disease in adults and children.

The following day, 16 February, Mr A was admitted to a public hospital with a one-week history of abdominal pain and malaena.[16] Dr E stated that, when he became aware that Mr A had been admitted to hospital, he telephoned Dr I, the surgeon caring for Mr A. Dr E stated:

> "I advised [Dr I] that [Mr A] had had an uneventful gastric bypass but that we had found gross cirrhosis of the liver at the time. The precise cause of this was not known to us, at that stage, but I imagined that it was on the basis of NASH."

Dr I's discussion with Dr E took place when Dr I was preparing for theatre. Dr I stated in his operation note:

> "[Mr A] had undergone gastric bypass surgery for morbid obesity at [the private hospital] recently. He [was] found at the time to have cirrhosis of the liver with varices probably on the basis of alpha-1 antitrypsin deficiency according to the biopsy taken at the time and related to me by [Dr E], the surgeon."

An operation was performed by Dr I and "an obvious perforation of the first part of the duodenum" was repaired. He also noted a nodular liver which was cirrhotic in appearance.

Deterioration and death

Following surgery at the public hospital, Mr A's condition deteriorated and he was transferred to intensive care. Mr A died of liver and renal failure a few days later. Dr E noted in the clinical record (dated and signed the same day) that he was called by the intensive care unit and told that Mr A had died.

Contact with GP

In a letter dated the following day (but sent three days later with a letter acknowledging Mr A's death), Dr E wrote to Mr A's GP, Dr H. In his letter, Dr E described the preoperative consultations with Mr A and set out further investigations to be performed. Dr E stated:

> "On reviewing our discharge information to you, I realise that there was one relatively important piece of information that we did not mention in that letter but which was alluded to in the findings of the operation note.
>
> [Mr A] clearly has had pre-existing liver disease, although the seriousness or nature of this has not been appreciated. On admission here he had a bilirubin of 100,[17] an albumin of 35 and an INR of 1.4. All of this alerted me to the presence of probably cirrhosis. Regrettably, for some reason his liver function tests had been omitted in the first battery of tests I had undertaken when I saw him in [the city],

[16] Malaena: blood visible in bowel motions, usually dark or black in colour.

[17] The result of the 1 February 2006 blood test was 103µmol/L.

and for that reason I was not alerted to it in advance. [Mr A] himself did not discuss with me any pre-existing liver problems or concerns.[18]

In the event, we did find an obviously cirrhotic liver and the biopsy of that is now back and suggests that this is almost certainly on the basis of an alpha-1 antitrypsin deficiency. Compounding features may well be insulin resistance and possibly alcohol. It will be important for him to have blood tests for the gene studies because this may be of relevance to family members and/or any offspring.[19] I have stressed the importance of abstaining totally from alcohol at the present time and would certainly be discussing this further and the biopsy findings when I review him in [the city]. I am happy to initiate those gene studies, although am equally happy that you do so.

The pre-existing presence of cirrhosis and portal hypertension certainly, unfortunately, put [Mr A] at a greater risk of peptic ulceration following surgery, and clearly this is what transpired. Whether this could have been prevented by our sending him out on Losec[20] is, of course, uncertain."

In his letter of 23 February to Dr H, Dr E stated:

"I was very sorry to learn that the decompensation following his further surgery [at the public hospital] was such that he died in liver failure.

… We are, of course, all very sorry and sad that this occurred. It is possibly regrettable that we did not appreciate more thoroughly the extent of his liver disease prior to surgery. However, on reflection this might have made very little difference. He had good reason to pursue the surgery and even if I had known he had been cirrhotic I probably would have pressed ahead with this and clearly at that stage the diagnosis of Alpha 1 Antitrypsin deficiency cirrhosis was unknown. In the event, this diagnosis probably means that within a relatively short space of time (one to two years) [Mr A] would have been in significant trouble with deteriorating liver function. He might have been a candidate for a transplant although his weight would certainly have not made him a good candidate. Regrettably we could not expect major weight loss to have any significant impact on his liver disease, given that this was not related primarily to steatohepatitis but to Alpha 1 Antitrypsin deficiency. Under these circumstances it seems that

[18] Dr E advised HDC that the reason why he told the GP that Mr A had not discussed any "pre-existing liver problems or concerns" was because Dr E believed that the abnormal LFTs were due to "a degree of fatty liver, and under most circumstances this will be of no consequence". Therefore, Dr E believed that there was "no reason to believe there was a significant or serious underlying liver problem".

[19] A diagnosis of alpha 1 antitrypsin deficiency was never confirmed. Mr A's son subsequently advised that he and his brother had been tested; one was found not to have the relevant gene, and one was found to be a carrier.

[20] Losec (omeprazole) is a drug prescribed to reduce the secretion of acid in the stomach.

> regardless of how we acted to proceed or not to proceed, his fate was relatively sealed. …"

Contact with family

A few days after Mr A died, Dr E called Ms D to explain what had occurred. Ms D does not recall many details of that conversation, but stated that at the time she did not have any concerns about the standard of care.

Mr A's sisters, Ms C and Ms B, wrote to Dr E on 20 January 2007:

> "We are seeking clarification about the procedures utilised by you for gathering prospective patients' health histories prior to gastric surgery. It appears, from what we have been told, that liver function tests were omitted from [Mr A's] 'work-up'. As part of this process, is a referral and health history obtained from patients' GPs or specialist? It was known that [Mr A] had haemochromatosis and had a liver biopsy under specialist care at [the public hospital].
>
> We are at a loss to understand how such important health information was omitted from [Mr A's] medical history. Had robust procedures been in place and a full medical history obtained, [Mr A] would have been better able to make an informed decision regarding the gastric surgery. In fact, he may have chosen not to proceed with the surgery."

In his letter dated 13 February 2007 to Mr A's sisters explaining his care, Dr E stated:

> "[Mr A's] underlying condition was cirrhosis of the liver caused by alpha-1 antitrypsin deficiency. This is a genetic disease about which he had no knowledge prior to coming to see me. Furthermore, his liver had deteriorated to such an extent that a diagnosis of alpha-1 antitrypsin deficiency meant that almost certainly he would have gone into liver failure and died in the next 12 months or so in any event.
>
> I was aware from [Mr A's] first consultation with me on 8 August 2005 that he had been thought to have some underlying liver problem and that this had been looked into but not taken further.
>
> …
>
> Fortunately he had an uneventful recovery from his gastric bypass surgery and we did not encounter deteriorating liver function (which so often occurs after major surgery in severely cirrhotic patients)."

In a further letter dated 23 May 2007 to Mr A's sisters, Dr E stated:

> "Please be assured that although I feel comfortable with the decision I took to proceed with surgery under the circumstances, I remain extremely embarrassed and uncomfortable by my failure to recognise the seriousness of the situation

ahead of surgery. Had we done so, we would have felt compelled to undertake a liver biopsy to determine the true nature of the underlying problem. The knowledge that his liver dysfunction was due to alpha-1 antitrypsin deficiency would have precluded my being willing to proceed with gastric bypass surgery."

Response to HDC
In his response to this investigation, Dr E stated:

"In hindsight it seems particularly bad not to have noted the absence of liver function tests, given that [Mr A] had mentioned that his liver had been investigated on a previous occasion. However when, in the course of a consultation, one flicks through the results that have been obtained, one looks more for abnormalities than specifically to note what tests have or haven't been done. Particularly, when dealing with such a routine matter as gastric bypass patients (4–5 patients per week), all of whom have the same batch of tests requested. …

The next disappointing feature is that I was not aware of the abnormal liver function tests prior to induction of anaesthesia. This is because on this occasion the results were not available by the time I visited [Mr A] the evening before surgery. The results almost always are available and therefore it is particularly disappointing that in the one case where it might have made a difference the results were not available. I have performed over 1,000 gastric bypasses in patients since 1986, and several thousand other operations and can say that the specifics of this oversight have not occurred in any other case. We can simply do our best to inform ourselves of the relevant information prior to surgery, however in this specific population we rely heavily on the investigations that take place during the consultations in the out-patients and the blood tests done immediately before surgery are merely to give us the most up-to-date information. It would be extremely unusual for these to be the reason for a change of plan, as might have occurred in this case had we been aware of them."

Independent advice to Commissioner

The following expert advice was obtained from general surgeon Professor André van Rij:

"This report is based on the documentation provided to me on 25th October 2007, and which I have read in detail on two occasions and more specific reading as required.

I have no personal or professional conflict in this matter.

This is an account of a most unfortunate series of events leading to the death of [Mr A]. I have chosen not to recount the events as this has been well done in the documentation.

[Dr E] is a surgeon of considerable experience and good repute, especially in the surgical management of morbid obesity. […]

This is relevant to the events to emphasise the high quality surgical context in which [Mr A] was cared for and the familiarity of the staff and suitability of systems developed for bariatric surgical patients.

Even in such settings human oversights will occur and sadly some with serious outcomes. A very well oiled system as has been established at [the private hospital] for bariatric surgery is no exception. [Dr E], in his candid correspondence, confirms such an oversight occurred to him. I would suggest this oversight also was contributed to by his team.

It is also worthwhile to note the promptness and candidness with which [Dr E] addressed the issues, wrote letters and reports and his heartfelt apologies for and expressions of concern for this, his oversight. This was very commendable.

The main issues as I see them are:

a) Was the oversight of overlooking a single group of blood tests itself serious or was there more to it?

b) Was the decision to operate warranted?

c) Otherwise was adequate care given?

d) Was documentation adequate to reflect the care given?

There is little doubt that the condition which [Mr A] had — alpha-1 antitrypsin deficiency with hepatic insufficiency, was a relatively rare one and the coincidence with what transpired even more so.

There is also no doubt that the occurrence of perforated duodenal ulcer immediately after bariatric surgery is a rare event and even then can occur unheralded in the patient with no other associated risk factors.

a) The oversight of the LFT test on the night before surgery

In a busy work day and with efficient diligence on the [preoperative] round, missing an LFT for a bariatric case is not a significant event especially if these tests had been normal only a few months prior in a routine workup. In general the LFT has no immediate bearing on the surgical event in a well clinically stable bariatric patient.

If, however, the patient has had 'liver problems' then such an oversight should be far less likely. Even then in most of these patients it would not contribute to or influence the surgical outcome. In this group of patients liver dysfunction is well recognised and surgery is the cure.

In rare instances not having been alerted to an abnormal LFT could be of great consequence.

For such instances there should be safeguards in the work up to surgery including flags and cues. At [preoperative] assessment one would expect cues to be present. For example: a typed clinical summary to the GP, the admission booking letter for the hospital, clinic notes, prior blood tests which would signal 'the liver'. It is not clear whether [Dr E] used/uses these on his [preoperative] rounds.

Another safeguard is the participation of the surgical team registrars, nurses and anaesthetist and their expertise and ability also to respond to similar cues and to raise concerns. This responsiveness will vary with their respective experience with the bariatric patient. In this instance there was a team well equipped with 4–5 cases being seen per week.

Were these cues available? Yes they were.

i) The liver biopsy — at least raised the question though I agree with [Dr E] this of itself had not led to anything and therefore might be presumed to be inconsequential.

ii) [Mr A] signed a preadmission form on 09.11.05 which states he had a liver biopsy in 1995. This was countersigned by what appears to be a nurse on 01.02.06.

iii) The anaesthetist — at preadmission writes on 01.02.06 'Fatty liver for years'. He records the very abnormal LFT on the day before surgery but does not telephone [Dr E] until the next day once the patient is anaesthetised. This doctor's subsequent recollection does not match his own record. He did recognise there was something not quite right but assumed the surgeon already knew of it. Presumably he remained uneasy about this — it is unclear what actually prompted him to call — but only after the patient was asleep.

iv) Prior blood tests, at earlier visits, had provided cues that all was not necessarily that well.

a] INR of 1.4

b] Low platelet count — 86b/L (150–450) — this continued with asterisks on all full blood count reports before and after surgery. (I could find no acknowledgement of this abnormal test in the records provided.)

c] Ferritin 775 (20–500) and marginal change in Iron Binding capacity and saturation. Increased ferritin levels are associated with NASH.

d] Insulin resistance correlates with severity of liver damage. For [Mr A] this was quite high as remarked by [Dr E]: 'a very high fasting insulin of 379 which is indicative of severe insulin resistance'.

v) Clinical examination. Jaundice is said to become apparent when the bilirubin is over 50µmol/L — it is rather surprising that with a blood level twice this (103µmol /L) that close observation did not detect jaundice.

Then there are other cues that might have been present but were not:

- A GP referral letter — it is noted that for reasons of patient access [Dr E] accepts patient self referral. This seems to be the case here. It is standard practice for most specialists to expect access by GP referral, at least this is so in the public sector. This is for very good reason. The GP's advocacy and knowledge of prior illness (often forgotten by patients) are taken into account. I note no GP input regarding [Mr A] was sought — although relatively brief [preoperative] letters and [postoperative] information were promptly sent.

- Research files and protocols — it might be presumed that the clinical and biochemical status of the patient who had consented to participate in specific research would be known to some members of the team and have been recorded with more meticulous detail.

In my examination of the records provided — the very abnormal LFT tests were known to the surgical/anaesthetic team on the day before surgery.

Unfortunately these series of 'cues' from records and colleagues were not provided or available to [Dr E] in time and that is disappointing for such a well established team. There was in effect oversight after oversight. They should have done better.

[Dr E] certainly implied that had he had the results earlier he would not have done the operation.

What was the consequence of the oversights and the failure of the team to heed clues? It led to [Mr A] being anaesthetised and ready for surgery.

b) The decision to operate

Having the knowledge of these tests (and not hindsight after the eventual outcome) should [Dr E] have proceeded? To this there is no simple answer amongst his peers.

If the underlying cause was NASH — then surgery would be appropriate, although the risk would be greater.

If the cause might well not be NASH then surgery should be averted and fuller evaluation carried out.

Added to this is the question of consent. Would [Mr A] have still wanted the surgery with fuller consideration of the implications as told to him by [Dr E]. We cannot know. Bariatric patients are most often highly motivated and expectant to get on with their surgery. To back off now would be most disappointing and re evaluating the increased risk before proceeding would make no difference to their intent for surgery for the majority. It is noted that [Mr A], as noted in correspondence, needed some time to make up his mind and may not have fitted into that enthusiastic group.

The consent form included another procedure which might be done at the discretion of the surgeon (cholecystectomy for gallstones finding) but no consent for treating any other untoward findings for which it would be in the patient's interest for the surgeon to proceed with rather than waking the patient to seek specific consent and requiring another operation (such component is not uncommon in operative consent — but not unfortunately at [the private hospital]). The need for a decision in good faith for the patient's benefit is clearly expected of the surgeon and this form of consent would have at least given some affirmation of this. Even so [Dr E] had to make a decision.

[Dr E] having [Mr A] already prepared for surgery, weighed up the situation and made the decision to go ahead with the surgery in the belief the liver dysfunction was going to be NASH. His skill and expert understanding led him to make this call and I am sure acted for the best he knew.

Other equally capable surgeons would not be so sure (the bilirubin was high, not marginally elevated [and] the low platelet count unexplained) and perhaps driven more by the concern to first do no harm would have backed off and stopped the anaesthetic and re-evaluated the situation on another day. This could have led to a percutaneous liver biopsy, a diagnosis and avoidance of an unnecessary operation.

c) & d) Adequacy of care and documentation

These two issues are inextricably linked when assessing the documentation provided. The level of documentation was clearly inadequate particularly in the hospital record. This makes it almost impossible to say much about the care and express any great confidence in the adequacy of care and attention by the surgical team. It may have been and the patient did leave the hospital apparently in good time and anticipating a good recovery.

However some examples for concern are warranted:

- the actual weight[21] of the patient is never stated, nor BMI, nor height.
- there is a [preoperative] note to the private hospital but no reference to liver or abnormal bloods.
- the integrated record with patient's name and date attached is filed but there is no use made of these at all — empty pages. Such records can be very useful, this one includes whether the doctor has visited (always — blank). It is not clear what its purpose is in these notes.
- the Hospital discharge letter is completed by the nurse — no medical input is apparent.
- there is no record at all by medical members of the surgical team of visits nor of the concerns about liver function etc, except on one day (03.02.06 — 3 lines regarding talking on the first day [postoperatively] to the patient telling that there was a liver problem).
- the nurses notes were well done but they indicated need for medical input e.g. describing 'concentrated urine', 'small concentrated diuresis', without clarification in the notes that this might be due to a serum bilirubin of 208µmol/l in a patient [whose] 'whites of eyes do look yellow tinged'.
- the platelet count dropped to 62b/l — this was clinically worthy of noting in the daily plan.
- IV frusemide was prescribed when the nurses were describing concentrated urine without some rationale being recorded. It is said by [Dr E] this was for swollen legs in his later report for this enquiry.
- the written operative record by the surgical assistant describes a nodular cirrhotic shrunken liver, the operative typed report describes 'the liver slightly reduced and the site of obvious macronodular cirrhosis … and minor portal hypertension around the stomach'; and this is a report that starts with 'no obvious problems in the upper abdomen'.
- blood reports were signed off erratically — signed ?[initials].

This level of documentation is of an unacceptable standard — especially if it is to alert the nursing team and others of what is going on. How much did the surgical members of the team attend and know was going on? It also makes it difficult to recount what did go on when asked to do so as this enquiry has required. To this reviewer it seems to have led to an understatement of what was happening.

'[Mr A's] [postoperative] course was an uneventful one — much to our relief.'

It is difficult to accept that a bilirubin of 200micromol/L is not a significant event and that discharge of a patient with 'yellow tinged eyes' is a straightforward bariatric surgical discharge. The typed letter of discharge on 9 February about the liver dysfunction and biopsy does not fit this picture.

[21] Commissioner's note: The medication sheet records a weight of 160kg, written in RN Ms J's distinctive handwriting. However, height and BMI are not recorded in the clinical record.

The poor quality of the documentation by the surgical team hopefully was not mirrored in the quality of the clinical documentation required in their research which was going on along side.

In addition I respond to the specific questions asked by [the Commissioner] in seeking this report.

[For clarity, the questions asked of Professor van Rij have been inserted in his report.]

i) [Please comment generally on the care provided to [Mr A] by [Dr E].]

In the initial visits the assessment seemed appropriate with a suitable interval between visits to allow the patient to make a decision whether to proceed or not. The communications by [Dr E] especially post discharge were prompt and appropriate. It does appear to this reviewer that the situation as described by [Dr E] was rather understated. The matter of missed LFT test and other 'cues' has been commented on already. The in-hospital care was structured best exemplified by the records made by the physiotherapist.

ii) [Please comment generally on the adequacy of the consent process in this case.]

The Consent process has been alluded to above.

iii) [Mr A] advised [Dr E] at his first preoperative clinic visit that he had been investigated for liver problems in the past. Should this knowledge have prompted [Dr E] to investigate this past medical history in greater detail? If any, please state what further investigations would have been appropriate to perform prior to surgery.]

I believe it was the intent of [Dr E] to obtain LFTs he certainly did obtain other related tests including hepatic antigen serology. This would have alerted him and perhaps prompted obtaining further information from the patient's GP or Gastroenterologist. One does have to wonder about the interview with the patient as the anaesthetist was able to get a story of 'fatty liver for years'.

Attempt to get the liver report would have been prudent. In the light that no further action was taken it was on its own likely that this was non-contributory.

iv) [Should this knowledge of previous liver problems have prompted [Dr E] to take specific note of [Mr A's] LFTs in the preoperative stage?]

Previous liver problems should have been a cue to the team as discussed above. A bilirubin of 103µmol/L and abnormal enzymes and the other abnormalities should have tipped off anybody in the team.

v) [Please comment on the appropriateness of [Dr E's] actions in relation to the result of the blood test taken on 8 August 2005. In particular, please comment on [Dr E's] failure to note that the LFTs had not been performed, and that the INR was raised.]

This has been covered above. In August the oversight of missed LFT was modest as further opportunity to pick up on this were to come.

vi) [Please comment on the appropriateness of [Dr E's] advice to [Mr A's] GP (in a letter dated 24 August 2005) that the blood test results were 'reasonably satisfactory'.]

The report on the blood tests to the GP were abnormal and the description of 'reasonably satisfactory' understated this. However they were not to the point of necessitating not doing surgery, indeed some of these abnormalities may be an indication to do surgery — aspects of the metabolic syndrome.

vii) [Should the recognition of an abnormal fasting insulin of 379 have prompted [Dr E] to take specific note of the LFTs in the preoperative stage?]

The abnormal fasting insulin is a common feature and is reason for doing the procedure. On its own in this patient group if very high it could prompt the thought of a link to hepatic dysfunction.

viii) [On his admission to the private hospital on 1 February 2006, it was noted by the admitting nurse that [Mr A] had had a liver biopsy performed in 1995. Should this knowledge have prompted any further action?]

The nurse's knowledge of liver biopsy (or even the blood tests) — should it have prompted further action? This is discussed above but applied to all the members of the surgical team. This may have been a cue for the nurse if she was a regular team member knowledgeable in bariatric surgery — but not to the nurse for whom bariatric patient care is not a special part of regular practice. This also depends on expectation and designated role of this nurse.

ix) [Please comment on the adequacy of [Dr E's] preoperative assessment of [Mr A] on the evening of 1 February 2006.]

As described the context is of a busy capable practitioner's round who also has an expectation of others in the team to share information and be clinically alert. In private practice teams are smaller and therefore there are fewer opportunities to pick up important or relevant missing or overlooked data. [Dr E] writes of a skilled team working together.

An experienced surgeon is dependent on recognising the right 'clues'.

x) [In the context of his blood results, please comment on the appropriateness of [Mr A] being prescribed Clexane.]

Use of Clexane — is entirely appropriate. This was a high risk patient for DVT and this is the best documented approach. However in the light of the disturbed INR and thrombocytopenia caution should be shown. The initial dose was relatively lower. Mechanical pneumatic compression devices or stockings in these large patients are unreliable because of their leg size.

xi) [Should [Dr E] have made himself aware of [Mr A's] blood results prior to surgery?]

Clearly, yes, and [Dr E] also agrees this was an oversight. [Dr E] did check the results but did not pick up on the clue that the LFTs were not there.

xii) [Dr E] advised that, on the basis of the abnormal LFT result, there was a 'significantly greater than normal risk of death because of the potential for liver decompensation in this circumstance'. Please give your view on how much greater the risks were than those previously explained to [Mr A] by [Dr E]: 1% death, 5–10% major complications.]

Increased risk — both the liver abnormality and the specific event of duodenal perforation are rare in bariatric surgery and therefore estimating risk in manner intelligible and helpful to a patient is difficult.

The figure for overall complications as described by [Dr E] is 1% of death is reasonable estimate based on his own experience which is extensive and which he has documented. This includes all comers — i.e. events such as [Mr A] and includes patients with far greater known risk.

The increase due to abnormal liver function per se, being mindful of the common feature of hepatic steatosis due to obesity may be — mortality up to 5% — major complication 15%.

xiii) & xiv) [Please comment on the appropriateness of [Dr E's] decision to proceed with surgery without discussing the relevance of the blood results with [Mr A]. Was it appropriate for [Dr E] to perform the planned operation without further investigation?]

Proceeding to surgery is an important issue and has been discussed above.

xv) [Please comment on the adequacy of [Dr E's] documentation of his care.]

Documentation has been discussed.

xvi) [Please comment on the adequacy of the discharge letter (dated 9 February 2006) to [Mr A's GP.]

Discharge letter 9th February has been commented on. No reference to the state of the liver or of any concerns are expressed, [Dr E] fails to share any of the dilemma surrounding the operation or the cirrhosis — a matter which he had voiced to the patient, and for which he expressed relief in getting [Mr A] out of hospital so far so good. It left the GP with no cues for continuing care or for what was to come. This should have been done better.

xvii) [Dr E] stated (letter dated 21 September 2007) that 'there was no sign of post-operative deterioration in liver function' following surgery and prior to discharge. Please advise whether you concur with [Dr E]. In particular, please comment on whether the blood tests performed from 3 to 7 February 2006 indicate any deterioration in [Mr A's] liver function.]

It is hard to concur with the statement made. As commented above there was a significant understatement of what was happening in the recollections given by [Dr E]. (It is assumed these are based on the material provided for this assessment and that there is no other documentation.) This is an example: A change of bilirubin from 103 to 208µmol/L, yellow sclera and dark urine, and platelets having dropped to 62b/L, even though the raised enzymes remained just as raised, is hardly the picture of a straight forward bariatric procedure.

xviii) [Please comment on the appropriateness of [Dr E's] plans for investigating [Mr A's] abnormal LFTs following discharge.]

I could find none other than the intent for a 6 week review but what this would have entailed is not known.

xix) [Should [Dr E] have recommenced the prescription of Losec (or similar) to [Mr A] on discharge?]

Losec not recommenced. A number of patients receiving Gastric bypass are on Losec preoperatively to control symptoms of reflux. This was the case for [Mr A]. The operation in effect is a procedure that stops gastric reflux hence stopping Losec is a very sensible measure. The complication of [postoperative] perforated duodenal ulcer after bariatric surgery is a very uncommon one and may occur in patients with normal LFT after routine GBP as has been the experience of this reviewer. Whether reintroduction of Losec would have made a difference to the outcome in this patient because of the added risk with increased INR, low platelets, cirrhosis could be argued empirically but with little evidence from the bariatric experience.

xx) [Any other comment you wish to make.]

None

I trust this provides you with a fair and reasonable assessment to guide the decisions that need to be made."

Further advice
Professor van Rij was asked to provide further advice, in particular to give a view on the severity of any acts or omissions that he had considered in his earlier advice to be below an acceptable standard:

"1. [Commissioner's question:] Should the surgical team have noted the 'cues' to abnormal LFTs, and, if so, was the failure to note them a lapse in standards?
[Dr van Rij's answer:]
Yes and yes — severe

2. [Q:] In light of the LFT result, should the decision have been made to go ahead with the operation? If not, was this a lapse in standards?
[A:]
I have made it quite clear in my report — some reputable surgeons may have proceeded, others myself included would not. My impression from [Dr E's] report was that he would not have, had he known before the operation had started. In that case failure to recognise or to act on the knowledge of the LFT would have been a lapse as indicated in 1.

3. [Q:] You stated that the 'level of documentation is of an unacceptable standard'. Please comment on the severity of that departure from standard.
[A:]
The degree of this was severe — apart from two or three sentences there was no documentation by the medical team in the progress reports.

4. [Q:] You stated that a bilirubin of 103 and abnormal enzymes 'should have tipped off anybody in the team'. Please comment on the severity of the apparent failure to 'tip off' the team.
[A:]
This was severe and should not have got past any clinically aware member of the team in an elective case.

5. [Q:] Should the knowledge by [Dr E] of a previous liver biopsy (as stated in [Mr A's] admission process to the nurse) have prompted any actions by [Dr E]?
[A:]
[Dr E's] initial reasoning and actions regarding this were reasonable at the initial assessment. Others of a more cautious nature may have tracked down the result. As it was that information was non-contributory.

6. [Q:] You state that [Dr E] should have made himself aware of the preoperative LFTs. Please comment on the severity of this lapse.
[A:]
This was for him personally mild when working in a team context. For his team it was a severe lapse — and perhaps vicariously as team leader [Dr E] has to accept some responsibility for this.

7. [Q:] Please comment on [Dr E's] failure to fully advise the GP in the letter of 9 February. If below the standard to be expected, please comment on the severity.
   [A:]
   The letter itself makes no reference to the problems surrounding preoperative liver function, the quandary of operating or not, the macronodular cirrhosis, the worsened post-op serum bilirubin, (>200!) jaundice and darkened urine (noted by the nurses), the alleged discussions with the patient regarding liver problems and required abstinence from alcohol. This was hardly a situation to be described in terms of 'The procedure itself went nicely and he made a straight forward recovery'. This was severely off the mark. There was attached with the letter an operative note (which is not clear — typed or handwritten) in which the macronodular changes and mild portal hypertension changes were reported. This does not however make up for failures in the letter.

8. [Q:] Please comment on the accuracy of [Dr E's] statement in his letter of 21 September 2007 that there were no signs of postoperative deterioration in liver function. If inaccurate, please state how inaccurate.
   [A:]
   From what one can gain from the limited information recorded by the medical team and the notes by nursing staff and blood reports then to say there was no deterioration is not correct. Indeed [Dr E] confirms in his own statement of 18 October 2007 … that there was a deterioration. A bilirubin which is already >100 doubling to over 200 cannot be interpreted in any other way than a deterioration. The statement is quite inaccurate — moderate severity.

9. [Q:] Please comment on the absence of plans for postoperative investigation of the abnormal LFTs. If below the standard expected, please comment on severity.
   [A:]
   As for the two preceding requests for comment, it is difficult to conceive that the communications by [Dr E] and the lack of arrangement of specific follow-up of liver function tests were about [Mr A]. Was it that there was confusion with another patient, or was it surgeon's optimism after having got through a difficult situation? This was a severe lapse."

Responses to provisional opinion

Ms D
[Mr A's] partner, Ms D, stated:

> "The summary of the clinical notes makes grim reading (from the perspective of a Charge Nurse Manager — even if my Specialty is Orthopaedic Outpatients). The comment '[Mr A's] [postoperative] course was an uneventful one — much to our relief' is a gross understatement — given the abnormal blood results, jaundiced appearance, and urine colour etc. I agree with the comments that the discharge letter does in no way reflect the true picture. With my medical background I have suffered great angst about what I could have done to prevent the outcome. If I had been aware of the significance of his post-op liver condition I would have been more pro-active in seeking medical assistance sooner — as I am sure would have his GP.
>
> I have had to relive this distressing event with this case, and am angry that [Mr A] and I had our time together cut short. I understand that his long-term outcome would have been poor, if his condition had been diagnosed and surgery not proceeded (unless he had a liver transplant — which would have been unlikely). However we (also his 2 sons, extended family and friends) would at least have had time to make the most of the time we had left together.
>
> In summary, … the clinical notes at [the private hospital] are woeful and [Mr A] was discharged with no true information about his apparent condition. I can live with the mistake of not noticing that there were no LFTs taken at initial consultation, but not that the surgery did go ahead without better informed consent about the significance of the ones that were done immediately pre-op.
>
> Although it has been a distressing time reliving all this period, I am grateful that his two sisters requested an investigation. …
>
> I hope that there are now better systems and documentation in place for all patients who are cared for by [Dr E's] team."

Ms C and Ms B
Mr A's sisters, Ms C and Ms B, stated:

> "We are relieved to note that the issues we raised regarding [Mr A's] care have been addressed, but in some respects remain unresolved for us. However, we are pleased to note that [Dr E] has implemented a more robust system to request blood tests."

Dr E
Dr E's legal counsel submitted in response to the provisional opinion:

> "The issue is simply stated; should [Dr E], on learning of the abnormal liver function test at a time when the patient had been anaesthetised and was ready for

surgery, have awoken him to advise him of the test result and of the greater risk of dying (5x) than had been advised when he signed the consent form.

The Commissioner had expert advice from Professor André van Rij who concluded correctly that [Dr E] had weighed up the situation and made the decision to go ahead with the surgery in the belief the liver dysfunction was going to be NASH. His skill and expert understanding led him to make this call and Professor van Rij is sure he acted for the best he knew. Professor van Rij notes that other equally capable surgeons would not be so sure for the reasons he gives; raising the possibility that the operation might have been unnecessary.

Professor van Rij poses the rhetoric question as to whether the patient would still have wanted the surgery with fuller consideration of the implications as told to him by [Dr E] and says 'we cannot know'.

[Professor van Rij's] report and the Commissioner's opinion do not take into account what happened post operatively. [Dr E] is clear that he discussed the situation fully with the patient. The registrar's note of 3 February reports that the patient 'talked about his liver problem and discussed about future'. The best guide to the patient's view is that there is no evidence of any complaint by the patient on this account."

Informed consent

Dr E's legal counsel provided a report from Associate Professor John Dixon of Melbourne University (see **Appendix 2**). Dr Dixon advised that "there is usually no unanimous opinion but that those [surgeons] who proceed with the surgery have accepted knowledge of a risk that the patient is unaware of". Accordingly, [Dr E] submitted that "a finding of breaches of Rights 6 and/or 7[22] would not be supportable".

Preoperative assessment

The legal counsel submitted that the "cues" that pointed towards abnormal LFTs were not remarkable in the context of Dr E's practice. It was also disputed that as leader of the team Dr E must accept overall responsibility for the failure to note the LFTs.

Postoperative care

The legal counsel provided a report from Associate Professor Ed Gane of Auckland Hospital (see **Appendix 3**). Dr Gane advised that, in his opinion, Mr A's liver function "did not deteriorate markedly in the early postoperative period". Dr Gane also quoted two prognostic models to conclude that (using a model published in 1999) Mr A's predictive postoperative mortality was 30% or, using a later model from 2007, 20%.

Documentation

[22] Code of Health and Disability Services Consumers' Rights

The legal counsel submitted:

> "[I]t is clear that the documentation taken as a whole was not structured as is usual in public hospitals and familiar to Professor van Rij and the Commissioner. When the true purpose of the integrated progress plan is understood, together with the purpose of the notes which constitute the nursing records plus records of deviations from the plan or deterioration in the patient, the picture is very different. It is not accepted that the documentation was 'woeful' or anything like it."

Summary
In summary, the legal counsel submitted on behalf of Dr E:

> "It is not contended that everything was done perfectly; there are very few processes not capable of improvement and quite clearly [Dr E] (and [the private hospital]) have taken this case to heart and reviewed their practices accordingly.
>
> … The significant issue — that of proceeding without waking the patient — could not be the subject of a successful prosecution in the light of the expert opinions."

The private hospital
The private hospital accepts that it was a nurse's responsibility to report blood result abnormalities to the medical staff. However, the private hospital submitted that the failure to advise Dr E of the abnormal LFTs prior to Mr A's anaesthesia was only a mild deviation from practice, and therefore did not warrant a finding that the Code of Health and Disability Services Consumers' Rights (the Code) was breached.

In support of this submission, the private hospital provided advice obtained from Philippa Pringle, Director of Nursing at Mercy Hospital, Dunedin. Ms Pringle stated:

> "In my opinion the nursing staff were remiss in not following their own policy for notifying consultant staff of [Mr A's] abnormal LFT on the evening prior to his surgery and thereby ensuring that [Dr E] had an opportunity to discuss options with [Mr A]. Taking all the circumstances into account, I believe this particular aspect of [Mr A's] care to be only a mild deviation from the expected standard of care as I believe there was still an option available to the surgeon to not operate on [Mr A] until he had investigated further."

The private hospital added that, if HDC considered that a breach of the Code was warranted, it should not be held vicariously liable for the failure of "one [private hospital] nurse who did not follow [the] policy requiring nurses to advise consultants of abnormalities".

The private hospital advised that [Mr A's] discharge summary was completed by [Dr E's] practice nurse, Ms L (who is not an employee of the private hospital); however, it has decided to review the quality of discharge information.

Further expert advice

Professor van Rij reviewed my provisional opinion, [Dr E's] response, and the advice from Associate Professors Dixon and Gane. Professor van Rij advised:

"…

Post operative [care]
… The pre-eminence of an expert here does not distract from the facts provided in the account of a patient who became jaundiced and passed dark urine associated with elevated plasma bilirubin following the operation.

Documentation
… My comments about research were not intended as gratuitous at all. This group led by [Dr E] has an international reputation for their research in these patients. Research work of this calibre is dependent on excellent documentation. [Dr E] reports on his quality outcomes also in his reports to the HDC — it is therefore reasonable to have expected similar levels of documentation in the clinical record.

[Other responses by [Dr E] fail to acknowledge the need for written documentation of what happened to the patient. Verbal [instructions] alone are insufficient and provide no basis for recounting the delivery of care. It is perhaps gratuitous to suggest that [I have] little understanding of documentation in the private hospital sector. I have practiced in the private sector including bariatric surgery for more than 20 years and am well aware of that context. It is my concern that what is being argued is that in the private sector sound written documentation of the patient's progress is not required."

Code of Health and Disability Services Consumers' Rights

The following Rights in the Code of Health and Disability Services Consumers' Rights are applicable to this complaint:

RIGHT 4

Right to Services of an Appropriate Standard

(1) Every consumer has the right to have services provided with reasonable care and skill.

(2) Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.

…

(5) Every consumer has the right to co-operation among providers to ensure quality and continuity of services.

RIGHT 6

Right to be Fully Informed

(1) Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including —

…

(b) An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; …

RIGHT 7

Right to Make an Informed Choice and Give Informed Consent

(1) Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.

Other relevant standards

"Good Medical Practice — A Guide for Doctors" (Medical Council of New Zealand, 2005):

> "Domains of competence:
>
> …
>
> 3. In providing care you must:
>
> …
>
> - keep clear, accurate, and contemporaneous patient records that report the relevant clinical findings, the decision made, the information given to patients and any drugs or other treatment prescribed."

Opinion: Breach — Dr E

Introduction
I have no doubt that the decisions Dr E made in relation to Mr A were made with the best possible intentions, and there is no evidence that the operation itself was not performed competently.

Although I comment below on a number of aspects of Dr E's care of Mr A, the central issue in this case is Dr E's responsibility in relation to obtaining fully informed consent.

Informed consent
The principle of informed consent is at the heart of the Code of Health and Disability Services Consumers' Rights (the Code). The key issue for determination is whether [Dr E] complied with his obligations under the Code to fully inform Mr A and obtain his informed consent prior to his gastric bypass surgery.

In the context of a liver function test that was (in his own words) "grossly abnormal" and indicative of quite serious cirrhosis of the liver, Dr E decided to proceed with surgery "with the full knowledge that the risks were increased", but without discussing the increased risks with Mr A. Dr E calculated that the risk of dying was five times greater than originally advised to Mr A when he signed the consent form (5% rather than 1%), and the risk of major complications was also increased (15% rather than 5–10%).

Although I accept that waking a patient from anaesthesia should not be undertaken lightly, in my view Dr E should have taken this action. Mr A was undergoing major elective surgery. The original risk disclosure had occurred over five months earlier (during the August 2005 consultations) and Mr A's risk profile had increased significantly following the LFT results on the eve of the operation. He should have been woken and Dr E should have discussed with him the significantly increased risks associated with the abnormal LFT results, and proceeded only after a full discussion, with fresh consent from Mr A. It was Mr A's life that was potentially on the line, and the decision whether to run the elevated risks was his alone to make.

It is irrelevant whether other surgeons would have proceeded without waking the patient.[23] The test is not what other reasonable surgeons would do, but rather what a reasonable patient, in the particular patient's circumstances, would expect to be told. Mr A's circumstances included the fact that he was a patient who took a cautious approach to proceeding with surgery, as indicated by the two consultations with Dr E in August 2005.

This was not an emergency operation, and Mr A could have been woken and the blood results discussed with him. Even though a surgeon may have "accepted knowledge of a risk that the patient is unaware of" (in the words of Associate Professor Dixon), that does not satisfy the requirement for the patient to have accepted the risk. What to a surgeon may seem an acceptable risk may be seen in an entirely different light by the patient.

I note that Dr Ed Gane, Dr E's second expert, stated that Mr A's predictive postoperative risk of death (taking into account the LFT results) was "at least 20%". While I am satisfied that Mr A should have been consulted about the 5% risk of death, Dr Gane's advice is sobering; by his reckoning, Mr A had at least a 1 in 5 chance of dying within 90 days of the operation. No one other than he could decide if that was a risk he wanted to run.

Dr E took the risk that Mr A's cirrhosis of the liver was attributable to NASH, as he apparently more commonly encounters this as a cause of abnormal liver function, and this abnormality may be alleviated by weight loss. Dr E concedes that, had he known that Mr A's abnormal liver function was due to alpha-1 antitrypsin deficiency, he would have been unwilling to proceed with the surgery.[24]

In the leading Canadian case of *Reibl v Hughes*,[25] the risks from surgery were a 4% risk of death and a 10% risk of stroke, risks that bear a striking resemblance to the risks faced by Mr A in the surgery Dr E was about to perform (5% risk of death; 15% risk of major complications). The Supreme Court held that a reasonable patient in

[23] In any event, as noted by Associate Professor Dixon, "there is no … unanimous opinion" amongst surgeons.

[24] As Dr E stated in his letter of 23 May 2007 to Mr A's sisters.

[25] *Reibl v Hughes (*1980) 114 DLR (3d) 1 (SCC).

these circumstances would want to know of these risks in order to make an informed decision whether to submit to the operation. There is a consensus around the common law world that *Reibl v Hughes* provides an illustration of a case in which the risks were so obviously necessary to an informed choice on the part of the patient that no reasonably prudent doctor would fail to disclose them, notwithstanding the practice of the profession.[26]

The legal position is clear in New Zealand, where Right 6(1) of the Code is based on the prudent patient test adopted by the High Court of Australia in *Rogers v Whitaker*.[27] As noted by Mason CJ in that case:[28]

> "Because the choice to be made calls for a decision by the patient on information known to the medical practitioner but not to the patient, it would be illogical to hold that the amount of information to be provided by the medical practitioner can be determined from the perspective of the practitioner alone or, for that matter, of the medical profession …"

It is no answer to the lack of informed consent to say that Mr A made no complaint when he was told postoperatively about the LFT results and Dr E's decision to proceed with surgery. Even by Dr E's own account, Mr A was "a little perturbed". It seems unlikely that in the immediate aftermath of surgery Dr E advised Mr A that he faced a 5% risk of death and a 15% risk of complications as a result of his operation. In any event, the inadequate preoperative consent could not be cured retrospectively.

Mr A had signed a consent form that said, "I … can share in making decisions about treatment". He was denied the opportunity to do so by Dr E's decision, without consultation with Mr A, "to proceed with surgery with the full knowledge that the risks were increased".

Dr E breached Right 6(1)(b) of the Code by failing to give Mr A an updated assessment of the expected risks of the operation. It follows that Mr A did not give informed consent to the surgery, and Dr E also breached Right 7(1) of the Code.

Preoperative assessment

Although liver function tests were omitted by error in the preoperative workup, a blood test done on the afternoon prior to surgery was available in the early evening. The result was sent by facsimile to the gastroenterology clinic (which is in the same building at the private hospital as the wards), arriving at 5.17pm. However, it was not sent to Mr A's ward until 10.27pm, some time after his preoperative reviews by Dr F and Dr E.

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[26] See Lord Bridge in *Sidaway v Bethlem Royal Hospital Governors* [1985] AC 871, p 900; *Pearce v United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118, p 124 (Woolf LJ).

[27] *Rogers v Whitaker* [1992] HCA 58.

[28] Ibid, para 14.

Dr E stated that the blood results were not available at the time of his assessment. This is incorrect, as they had been available since 5.17pm, and would also have been available had he contacted the laboratory. However, although the previous blood results taken in the preoperative clinic visits had indicated potential problems (INR, insulin resistance, low platelet count, ferritin level), Dr E incorrectly believed he had no reason for concern, and he did not look out for the LFT results.

Dr van Rij described a number of "cues" that should have alerted Dr E and his clinical team to the abnormal LFTs, including Dr F's earlier assessment indicating "fatty liver", the abnormal blood tests taken in the earlier preoperative stage, and a clinical examination that should have shown jaundice. Dr van Rij advised that these cues should have been spotted, and the failure to act on them was a severe lapse from professional standards.

Dr E, however, submitted that these "cues" were not unusual for the patients on whom he operated. This may be true, but in my view Dr E should have ensured that he obtained LFT results for Mr A preoperatively. It was an important element of Mr A's preoperative picture which Dr E failed to obtain.

Although Dr van Rij advised that Dr E's personal responsibility was a mild departure from standards, I consider that as leader of the team, he must accept overall responsibility for this failure. Dr E was the clinician who should have ordered the LFTs in the preoperative clinic, but he failed to do so, and failed to note his omission. Dr E was also the doctor who requested LFTs once Mr A was admitted, yet he failed to take note of the results.

By failing to review Mr A's LFTs prior to anaesthesia, Dr E did not provide Mr A services with reasonable care and skill, and therefore breached Right 4(1) of the Code.

Postoperative care

Although Mr A appeared to recover well in the few days after the operation, his condition partly obscured deteriorating liver function. Dr E stated that there were no signs of postoperative deterioration in liver function, yet Dr van Rij advised that such a statement is "quite incorrect".

Dr van Rij commented on Dr E's statement that "there was no sign of post-operative deterioration in liver function" following surgery, and prior to discharge. Dr van Rij advised:

> "It is hard to concur with the statement made. As commented above there was a significant understatement of what was happening in the recollections given by [Dr E]. … This is an example: A change of bilirubin from 103 to 208µmol/L, yellow sclera and dark urine, and platelets having dropped to 62b/L, even though the raised enzymes remained just as raised, is hardly the picture of a straight-forward bariatric procedure."

Dr E stated that the intent was to perform further investigations after Mr A's discharge. However, there is no record of this intention in the clinical record, the discharge summary, or the letter to Mr A's GP. In fact, the only record of the intention to investigate further Mr A's liver function was set out in a letter written to his GP, dated the day *after* his death. (I comment below on Dr E's correspondence with the GP.)

It appears that Mr A's liver function deteriorated in the period after surgery, yet he was discharged home with no plan to investigate the cause of the abnormal liver function. Dr E was on notice on the day of Mr A's surgery that he had significant liver disease — in Dr E's own words, "gross cirrhosis". In addition, the result of the biopsy taken during the operation was returned on or soon after 8 February, indicating the possibility of a serious diagnosis (alpha-1 antitrypsin deficiency), yet Dr E took no action following receipt of this information.

Dr E provided a report by Dr Gane which stated that Mr A's liver function did not deteriorate "markedly in the early postoperative period". However, I also note Dr Gane's advice that most postoperative deaths occur between days 7 and 30. Dr E set in place no specific post-discharge care beyond a repeat of the LFTs six weeks after discharge.

Dr E should have taken more care in the postoperative stages to monitor Mr A's liver function, and ensure that appropriate care was provided after discharge. In the days after surgery, clues pointing to worsening liver function were recorded in the clinical notes (jaundice, bilirubin stained urine, increasingly abnormal blood tests), yet this deterioration was seemingly not noted by Dr E, and no action taken or planned.

I note that Dr E advised Mr A's sisters after his death that a diagnosis of alpha-1 antitrypsin deficiency meant that "almost certainly Mr A would have gone into liver failure and died in the next 12 months". Having knowledge of such a prognosis would have allowed Mr A to delay the surgery (assuming he wished to proceed) to put his affairs in order. As Mr A's partner noted, his family and friends "would at least have had time to make the most of time we had left together". Mr A was denied this opportunity.

By failing to respond to the clues pointing towards Mr A's deteriorating liver function, and in particular to order further investigations after discharge, Dr E did not provide Mr A services with reasonable care and skill, and therefore breached Right 4(1) of the Code.

Documentation

It is a professional and legal requirement for a practitioner to maintain a clinical record for each patient in accordance with professional and ethical standards. It is essential that all relevant information, including appointments, examinations, and test requests and results, is accurately recorded to guide future management and ensure continuity of care.

The Medical Council of New Zealand publication *Good medical practice, A guide for doctors* (2005) sets out the responsibility of a doctor to keep clear, accurate and contemporaneous records that report the relevant clinical findings, the decisions made, the information given to patients and any medication or other treatment prescribed.

In *J v Director of Proceedings* (an appeal from a decision of the Health Practitioners Disciplinary Tribunal),[29] Baragwanath J stated that "[f]or the reasons expressed by the Tribunal meticulous record keeping is a fundamental obligation of the practitioner". The Tribunal had stated:[30]

> "Note-keeping should not be regarded as a minor matter. … Thorough note-taking is the cornerstone of safe and effective medical practice. Poor note-taking provides poor support for clinical practice for either [the practitioner] or any other person reviewing his notes and continuing or amending the treatment plan which has been prescribed."

When consultation notes are missing, it becomes difficult to confirm the facts of a case and casts doubt on any supplemental information provided. In the end, whatever is remembered at a later date, the written record is the most significant witness of a provider's actions. It is important for the provider's sake as well as the patient's that the record is clear and complete.

Dr E made no entries in Mr A's clinical record during his entire admission. There is no record of any of Dr E's postoperative discussions with Mr A, nor of the care prescribed, the rationale for that care, or subsequent plans for investigation or treatment. This is a severe departure from professional standards.

Dr E does not accept that his standard of documentation was lacking. In another case in which Dr E was found to have breached the Code because of a failure to document his care, I stated:[31]

> "[Dr E], as the clinician responsible for [the patient's] care, had a duty to ensure that his assessments, decisions and courses of treatment were recorded contemporaneously. … [Dr E] made no entries in the hospital records and did not ensure that his assistant made regular entries. I note that, in response to my provisional opinion, [Dr E] acknowledged the desirability of a better standard of note taking."

Despite his avowal in the earlier case, Dr E appears still not to appreciate the need for proper documentation.

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[29] *J v Director of Proceedings*, High Court Auckland, CIV-2006-404-002188, 17 October 2006, para 63.

[30] Health Practitioners Disciplinary Tribunal decision Med05/11D, para 14.

[31] See http://www.hdc.org.nz/complaints/casenotes?01HDC04847 (7 May 2003).

Dr E also appears to suggest that a different standard applies to private hospital medical notes. Whatever the differences in practice, I do not accept that there is any legal distinction between the standard of documentation required in the private and public sectors. In short, the professional requirement to "keep clear, accurate, and contemporaneous patient records" is applicable to both public and private sectors.

In this case, Dr E's documentation of Mr A's care fell short of the expected standard. Accordingly, Dr E breached Right 4(2) of the Code.

Communication with GP
After Mr A's surgery, Mr A's GP was sent a letter dated 9 February 2006, apparently written by Dr E's registrar, but sent in the name of Dr E. The letter contains no mention of any liver problems encountered (although the enclosed operation note refers to some abnormalities), and no reference to any need for further investigations.

As leader of the team, Dr E was responsible for ensuring that Mr A's GP was provided with adequate information on discharge. He failed to do so.

In a letter to Mr A's GP the day after Mr A's death, Dr E advised that "there was one relatively important piece of information that we did not mention" in the letter of 9 February, and proceeded to discuss Mr A's liver problems. Dr E added in his letter that Mr A "did not discuss with me any pre-existing liver problems or concerns".[32]

Dr E went on to advise the GP that it "will be important for Mr A to have blood tests for the gene studies" in relation to the diagnosis of alpha-1 antitrypsin deficiency.

Dr van Rij commented that some aspects of the letter of 9 February were "severely off the mark". By failing to adequately advise Mr A's GP of the problems encountered during his admission, Dr E failed to cooperate with a fellow health care professional to ensure quality and continuity of care. Accordingly, Dr E breached Right 4(5) of the Code.

Opinion: No further action — the private hospital

Staff communication
Dr E relied on nursing staff employed by the private hospital to support him in caring for Mr A. Dr van Rij advised that in a number of areas Dr E was let down by colleagues.

[32] I note that this is contrary to Dr E's statement to HDC:

> "I do recall [Mr A] mentioning that he had previously been noted to have abnormal liver function tests …"

Mr A's blood results were available to nursing staff at 10.27pm the night before surgery. The results were clearly abnormal, as was graphically reflected in the number of asterisks on the result form, yet they were not communicated to medical staff (ie, the anaesthetist, Dr F) until the next morning.

The private hospital accepts that it was the responsibility of the nursing staff to bring abnormal blood results to the attention of medical staff, and that it was remiss of staff not to notify Dr E of Mr A's abnormal LFT results the evening prior to surgery, to give the surgeon an opportunity to discuss options with Mr A.

In light of the private hospital's acknowledgement of the omission, and its offer of an apology for this, I do not consider that any further action is warranted.

Nursing care
Apart from the communication issue noted above, it appears that the nursing care provided to Mr A was of an appropriate standard. However, I note that although Mr A's weight was recorded on admission, his Body Mass Index (BMI) was not calculated. This was an omission, given the reason for his admission.

Discharge summary
Dr van Rij expressed concern that the discharge summary was completed by a member of nursing staff, rather than a doctor. The summary contains no information about Mr A's liver problems or intended investigations. Although it describes itself as "an important document", to be given to a doctor if Mr A needed any "medical assistance within the next 7 days", it omitted important information.

The private hospital advised that the nurse who completed the discharge summary was Dr E's practice nurse, and not an employee of the private hospital. However, the private hospital has undertaken to review the quality of discharge information, as recommended by HDC.

Referral to Director of Proceedings

The various omissions by Dr E in this case support my referring him to the Director of Proceedings to consider whether further proceedings are warranted. I note with concern that this is not the first time that Dr E has been sanctioned for failure to obtain fully informed consent.

In Opinion 01HDC05619[33] I found that Dr E breached Rights 6(1)(a) and 6(1)(b) of the Code by giving a patient "an unbalanced explanation of her condition that supported his own treatment preference". I also found that Dr E failed to provide "adequate information about the alternative of treatment in the public system".

[33] See http://www.hdc.org.nz/files/hdc/opinions/01hdc05619.pdf (31 July 2002).

In Opinion 00HDC07593[34] I found that Dr E breached Rights 6(1) and 7(1) of the Code as he failed on two occasions to inform a patient that he intended to take a liver biopsy for research purposes during surgery.

I also note that in another case, the Medical Practitioners Disciplinary Tribunal found that Dr E was guilty of "conduct unbecoming a medical practitioner" by virtue of his failure to adequately inform his patient about the possible adverse effects of a certain surgical procedure.

It is of concern that Dr E still appears not to appreciate the legal and ethical requirement of obtaining a patient's fully informed consent.

Recommendations

I recommend that Dr E take the following action:

- Apologise to Mr A's family for his breaches of the Code, the apology to be sent to HDC for forwarding.
- Arrange for an independent review of the quality of his documentation. The results of this review are to be sent to HDC by **19 December 2008**.

I recommend that the private hospital take the following action:

- Apologise to Mr A's family for the lapse in communication identified in my decision, the apology to be sent to HDC for forwarding.
- Review the quality of discharge summaries, and advise HDC of the results of the review by **19 December 2008**.

[34] See http://www.hdc.org.nz/files/hdc/opinions/00hdc07593.pdf (30 August 2002).

Follow-up actions

- Dr E will be referred to the Director of Proceedings in accordance with section 45(2)(f) of the Health and Disability Commissioner Act 1994 for the purpose of deciding whether any proceedings should be taken.

- A copy of this report will be sent to the Medical Council of New Zealand and the Royal Australasian College of Surgeons.

- A copy of this report, with details identifying the parties removed (except the experts who advised on the case), will be sent to the New Zealand Private Surgical Hospitals Association and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Addendum

The Director of Proceedings decided to lay a charge of professional misconduct against Professor Stubbs before the Health Practitioners Disciplinary Tribunal, which heard the matter in August 2009.

In a decision dated 21 December 2009 the Tribunal found Professor Stubbs guilty of professional misconduct and subsequently imposed the following penalties:

(a) Conditions on Professor Stubbs' practice including that he undergo:

(i) a mentoring programme to run for a minimum period of 18 months and a maximum of 3 years; and

(ii) a practice audit;

(b) Censure;

(c) A fine of $20,000; and

(d) 50% of costs of both the Director of Proceedings and the Tribunal.

Permanent name suppression was declined.

A copy of the Tribunal's decision can be found at http://www.hpdt.org.nz/Default.aspx?tabid=230

Appendix 1

Mr A's blood test results

Test	Normal range	9 Aug 05	1 Feb 06	3 Feb 06	4 Feb 06	5 Feb 06	6 Feb 06	7 Feb 06	16 Feb 06
Fasting insulin	10–80pmol/L	379							
Sodium	135–145mmol/L		138	141	139	136	136	135	132
Potassium	3.6–5.2mmol/L		4.4	4.2	4.1	4.6	4.3	4.2	4.5
Urea	3.0–8.4mmol/L			7.2	6.5	4.8	4.6	4.5	5.7
Creatinine	50–110µmol/L		77	79	79	71	67	66	
Total protein	60–83g/L		71	63	60	57	55	59	
Albumin (serum)	34–50g/L		35	32	30	28	28	28	
Globulins (serum)	20–35g/L		36	31	30	29	27	31	
Bilirubin (total)	0–20µmol/L		103	181	208	215	204	205	274
GGTP	0–61iu/L		274	231	207	180	170	167	248
Alk Phos	20–110iu/L		199	158	148	139	139	153	238
ALT	0–40iu/L		74	77	77	76	77	86	192
AST	0–35iu/L		149	176	181	172	171	185	338
INR	0.8–1.2	1.4		1.3	1.4	1.4	1.4	1.4	
Platelets	150–450b/L	86	86	78	58	65	62	62	143

Other blood test results on 9 August 2005

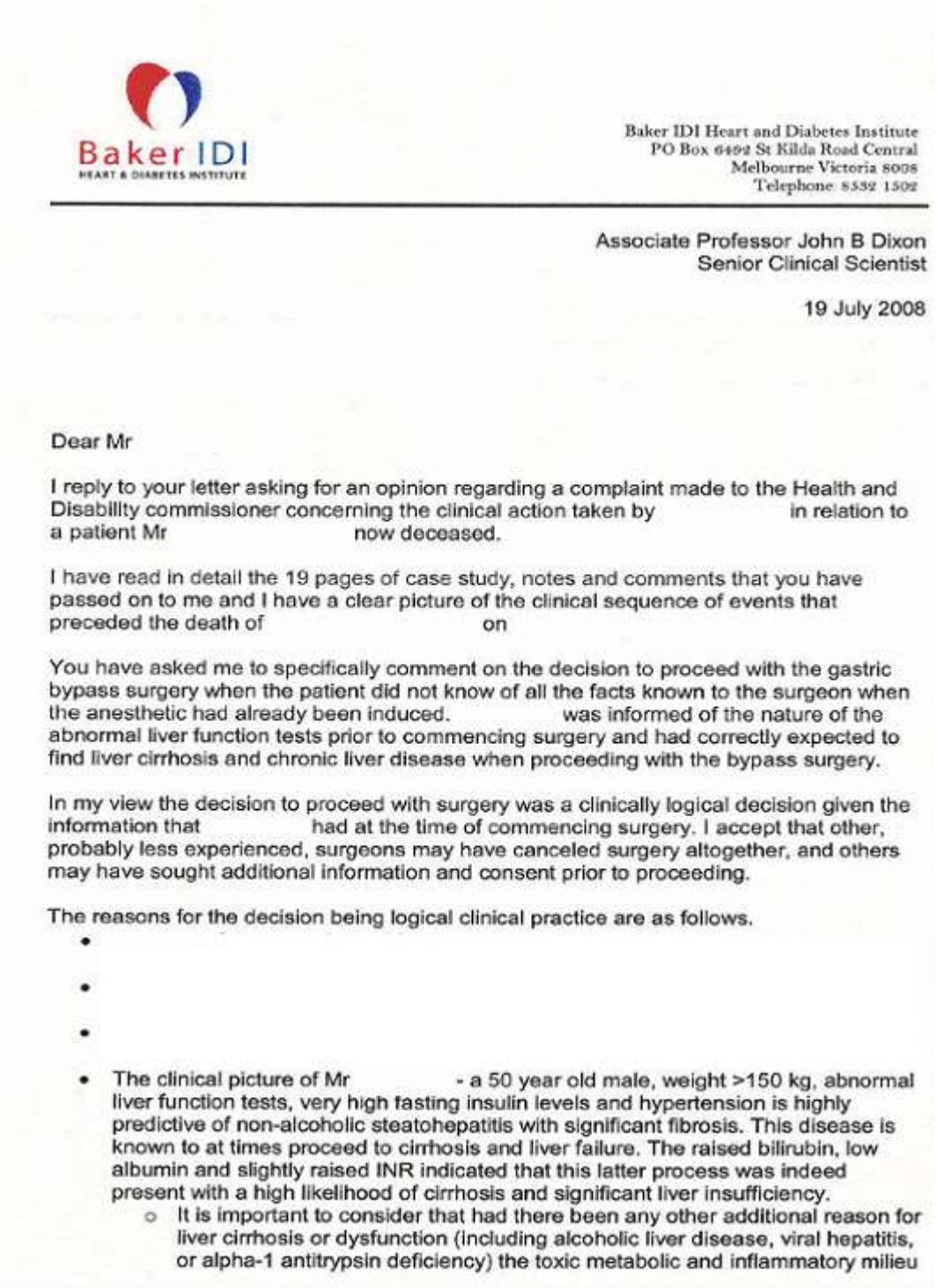
Serum ferritin:	775µg/L	(normal range 20–500ug/L)
Iron binding capacity:	39µmol/L	(normal range 40–75umol/L)
Iron saturation:	59%	(normal range 20–55%)

The report form for the serum ferritin result has an added comment:

> "Besides iron overload, serum ferritin is raised in inflammatory and malignant conditions and hepatocellular [liver] disease."

Appendix 2

Expert advice from Associate Professor John Dixon



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PO Box 6492 St Kilda Road Central
Melbourne Victoria 8008
Telephone 8532 1502

Associate Professor John B Dixon
Senior Clinical Scientist

19 July 2008

Dear Mr

I reply to your letter asking for an opinion regarding a complaint made to the Health and Disabillty commissioner concerning the clinical action taken by in relation to a patient Mr now deceased.

I have read in detail the 19 pages of case study, notes and comments that you have passed on to me and I have a clear picture of the clinical sequence of events that preceded the death of on

You have asked me to specifically comment on the decision to proceed with the gastric bypass surgery when the patient did not know of all the facts known to the surgeon when the anesthetic had already been induced. was informed of the nature of the abnormal liver function tests prior to commencing surgery and had correctly expected to find liver cirrhosis and chronic liver disease when proceeding with the bypass surgery.

In my view the decision to proceed with surgery was a clinically logical decision given the information that had at the time of commencing surgery. I accept that other, probably less experienced, surgeons may have canceled surgery altogether, and others may have sought additional information and consent prior to proceeding.

The reasons for the decision being logical clinical practice are as follows.

-
-
-
- The clinical picture of Mr - a 50 year old male, weight >150 kg, abnormal liver function tests, very high fasting insulin levels and hypertension is highly predictive of non-alcoholic steatohepatitis with significant fibrosis. This disease is known to at times proceed to cirrhosis and liver failure. The raised bilirubin, low albumin and slightly raised INR indicated that this latter process was indeed present with a high likelihood of cirrhosis and significant liver insufficiency.
    - It is important to consider that had there been any other additional reason for liver cirrhosis or dysfunction (including alcoholic liver disease, viral hepatitis, or alpha-1 antitrypsin deficiency) the toxic metabolic and inflammatory milieu

Names have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

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generated by his obesity related condition would have aggravated his liver damage and contributed to cirrhosis and ultimately liver failure.

- Significant weight loss through appropriate bariatric surgery was likely to provide the only real possibility of a "lifeline" to improve his ailing liver function. Reversing the toxic inflammatory and metabolic milieu, as has been demonstrated with significant weight loss with bariatric surgery, was an opportunity to reduce the stress on his liver despite the inherently greater risk of operating on a seriously ill man. It is important to consider that bariatric surgery should be considered in very ill people if the condition being treated is likely to be responsive to weight loss.
- Less experienced surgeons would reasonably seek the help of an expert such as when confronted with this situation.

In my research work that has focused on the health outcomes of weight loss, and in particular bariatric surgery. I attend many international conferences and courses each year regarding bariatric surgery. The clinical dilemma that was presented with is commonly presented for discussion and experts asked for their opinion on proceeding with surgery. There is usually no unanimous opinion, but more experienced surgeons especially those with a good knowledge of the effects of weight loss on serious fatty liver disease recommend proceeding with the bariatric surgery if it is technically feasible, that is if there is no major evidence of portal hypertension with varacies in the region of the gastro-esophageal junction. Surgeons may see a cirrhotic liver at the time of surgery and most would recommend proceeding with the bariatric procedure while confirming the nature of the disease with a liver biopsy. Clearly before proceeding with the surgery they have accepted knowledge of a risk that the patient is unaware of.

The two most commonly used forms of bariatric surgery, Roux-en Y Gastric Bypass and the Laparoscopic Adjustable Gastric Band surgery, have both been shown to improve liver function. More extreme forms of surgery such as Bilio-Pancreastic Diversion under some circumstances aggravate liver disease and would not be recommended under these circumstances. Bariatric surgery has been used both before and after liver transplantation. If Mr were to have needed liver transplantation for his chronic liver disease then weight loss and reduction in the toxic environment provided by insulin resistance and obesity related steatohepatitis would have been prerequisites.

In conclusion, made the decision to proceed with surgery with the knowledge and expertise that indeed the risks were high, but that he was able to provide one of a few procedures that may truly make a difference to the natural history of a very serious disease.

Appendix 3

Expert advice from Dr Ed Gane

New Zealand Liver Transplant Unit
(10th Floor) Auckland Hospital
Auckland, New Zealand
09 307-4949
6560
09 375-4345

EMAIL : edgane@adhb.govt.nz
FAX: 09 529 4061
Mobile: 021 548 371(LIVER 1)

24th July 2008

Dear Mr

Re: Medical report for complaint investigated by the Health and Disability Commissioner in respect of and his management of

I was asked to assess the medical management of who died on 2 weeks after bariatric surgery performed by in on 2006, in particular to comment on the following issues:

1. Significant deterioration in liver function in the 6 days following surgery (until discharge from hospital)

This man already had advanced cirrhosis prior to surgery. Although he was jaundiced, the other parameters of liver synthetic function were well preserved and his is CTP (Child-Turchotte-Pugh) score was 7 –i.e. Class B and MELD (Model of End-stage Liver Disease) prognostic score was 16. Both the CPS and the MELD prognostic models have been shown in large published studies to be reliable predictors of survival following elective abdominal surgery (see http://www.mayoclinic.org/meld/mayomodel9.html) .

Using the older prognostic model (see Friedman. Hepatology 1999; 29: 1616-23), based on this man's preoperative Child-Turchotte-Pugh status, his 90 day post-operative mortality is 30%

Using the newer prognostic model (see The et al. Gastroenterology 2007; 132: 1261-69, and also http://www.mayoclinic.org/meld/mayomodel9.html) based on this man's preoperative MELD score, his predicted 7 day, 30 day and 90 day post-operative mortality was 3.3%, 12.8% and 20% respectively.

Therefore, this man's predicted post-operative mortality is at least 20%.

The best laboratory markers of this man's liver synthetic function in the post-operative phase will be serum bilirubin, albumin and INR. Although the increased bilirubin level and reduced albumin level may reflect reduced liver synthetic function, these changes can also be attributed to other factors in patients with severe illness or following major surgery.

The increase in serum bilirubin in the immediate post-operative period may represent resorption of surgical bleeding and haemolysis of transfused stored blood. The decrease in the serum albumin level during the immediate post-operative period may reflect dilution (from crystalloid solutions infused perioperatively), catabolism from increased metabolic demands following major surgery and reduced dietary intake. Of note, this man's INR did not change, which would indicate preserved liver synthesis of coagulation factors. Also, he never developed clinical evidence of decompensation such ascites, oedema, or encephalopathy. Therefore, his liver function did not deteriorate dramatically in the first few post-operative days. However, as the MELD prognostic model above indicates, most post-operative deaths due to cirrhosis do not occur within the first week but between day 7 and day 30.

2. Rarity of alpha-1-antitrypsin deficiency causing isolated cirrhosis

It is not clear whether the diagnosis of alpha-1-antitrypsin (α1-AT) deficiency has indeed been confirmed in this man. The presence of PAS-positive, diastase-resistant globules may be observed in liver biopsies from patients with normal α1-AT phenotype with other chronic liver diseases. I would be suspicious that in the absence of any family history of emphysema or cirrhosis (in siblings rather than parents as this is an autosomal recessive condition), that it is more likely that this man's cirrhosis is secondary to non-alcoholic fatty liver disease rather than α1-AT deficiency. I note that he underwent liver biopsy in Hospital in 1995. It would be interesting to learn whether the histologic features in this biopsy were those of non-alcoholic fatty liver disease or chronic hepatitis (which would be consistent with PIZZ α1-AT deficiency)..

The diagnosis of α1-AT deficiency should be based on the confirmation of the PIZZ phenotype rather than histology. Has this been performed? Note that serum concentrations of α1-AT protein are also not helpful as they may be low in any patient with decompensated liver disease because of reduced protein synthesis.

If indeed this man had alpha-1-antitrypsin deficiency, then this is indeed a rare condition, with an estimated incidence of homozygous PIZZ α1-AT deficiency in Caucasians of 1:1800. Of people with homozygous PIZZ α1-AT deficiency, only a minority will ever develop liver disease, which is usually diagnosed in the neonatal period as persistent jaundice. Only 15% of people with homozygous PIZZ α1-AT deficiency ever develop liver dysfunction in adulthood and only a minority of these will develop cirrhosis, usually in association with heavy alcohol use. Therefore, the incidence of cirrhosis due to homozygous PIZZ α1-AT deficiency in the general population is very low– approximately 1:200,000.

3. Smooth postoperative recovery

As mentioned, this man's liver function did not deteriorate markedly in the early post-operative period- his INR remained stable and he did not develop any of the usual complications of decompensated cirrhosis such as ascites, gastrointestinal bleeding, or encephalopathy. I note that he developed peripheral oedema, requiring frusemide diuresis. Fluid retention is a common problem in cirrhotic patients, following administration of a salt load, because of a reduced ability to clear salt due to hyperaldosteronism and portal hypertension - this man received several litres of intravenous saline in the perioperative period. It is remarkable that he did not appear to develop ascites, which usually manifests post-operatively as large fluid losses through the laporotomy incision.

Also, the frusemide was stopped after only a few days and he did not require regular any ongoing diuretic therapy. These two observations suggest that the fluid retention was largely due to the large salt load administered at the time of surgery rather than further decompensation of his established cirrhosis.

4. Relationship between the perforated duodenal ulcer (cause of death) and the gastric bypass

Both this man's cirrhosis and the recent surgery are recognised risk factors for developing peptic ulcer disease. The incidence of peptic ulcer disease in cirrhotic patients is increased more than 10-fold than that in the general population (see *Phillips et al. Gastroenterology 1975;68:171*). Also, the death rate from peptic ulcer disease in cirrhotic patients is 5 times higher than in the general population (see *Bonnevie et al. Gastroenterology 1977;77:1000*). The incidence of acute peptic ulceration is also increased during periods of physiological stress such as following major surgery, renal failure or other critical illness (so called stress ulcers). Both associations are attributed to increased acid secretion and also reduced mucosal integrity, possibly via reduced prostaglandin production.

Kind regards
Yours sincerely