Surgeon

A Report by the

Health and Disability Commissioner

(Case 00/07593)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Mrs A	Consumer
Dr B	Surgeon
Dr C	Consumer's General Practitioner

Expert advice was obtained from Professor Iain Martin, an upper gastrointestinal and laparoscopic surgeon, and Associate Professor Charlotte Paul, an epidemiologist, health researcher, and ethics committee member.

Complaint

On 25 July 2000 the Commissioner received a complaint from Mrs A about the standard of care provided by Dr B. The complaint is that:

Dr B did not provide health services of an appropriate standard to Mrs A. In particular:

- *On 20 April 1999 and 15 February 2000 Dr B conducted a liver biopsy during the performance of other procedures, although he did not advise Mrs A of this or obtain her informed consent prior to either biopsy.*

- *Following surgery on 15 February 2000 when Mrs A telephoned Dr B complaining of severe pain and bruising and having developed a haematoma, Dr B failed to advise her to come in for an examination. Instead, Dr B told Mrs A that he would fax the chemist a prescription for stronger pain relief for her.*

- *Dr B collected data from the liver biopsies and completed questionnaires during consultations with Mrs A for his own information without Mrs A's knowledge and informed consent.*

Information reviewed

- Letter of complaint from Mrs A
- Response from Dr B including a copy of his clinical records
- A private hospital medical records
- A public hospital medical records
- ACC correspondence

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

Information gathered during investigation

On 20 April 1999, 44-year-old Mrs A had a Silastic Ring Gastric Bypass operation performed by Dr B, at a private hospital.

In February 2000 Mrs A had several episodes of abdominal pain. Dr C, her general practitioner, referred Mrs A to Dr B, who diagnosed gallstones and advised her to undergo a cholecystectomy.

On 15 February 2000, Mrs A had a laparoscopic cholecystectomy performed by Dr B at a private hospital. Mrs A stated that after the operation she was seen by Dr B, who told her that her operation had been straightforward and that he had performed a liver biopsy, which was normal. Mrs A stated that she was surprised that a liver biopsy had been done as this had not been discussed or consented to. When she asked Dr B why he had done the biopsy, he said that it was "to compare with previous data from the last biopsy".

Mrs A was unaware that a liver biopsy had been done at the time of the Silastic ring surgery and stated that she had not consented to the procedure at that time or when a further biopsy was taken at the time of the laparoscopic cholecystectomy. Dr B commented on the failure to obtain specific consent as follows:

> "It was not my habit at that time to notify patients of that particular procedure, which I saw as a relatively trivial extension to a major operation. …
>
> I personally continue to believe there should be no need to advise a patient that a liver biopsy is being obtained at the time of gastric bypass because any risk associated with this is tiny compared with the risk of the surgical procedure itself. However, based on my experience with [Mrs A], it has become routine practice to inform patients that a biopsy will be performed."

Following the laparoscopic cholecystectomy, Mrs A suffered considerable pain. According to the medication record the following pain relieving medication was administered postoperatively: Tramadol 100mgs given twice on the day of surgery, intramuscular morphine at 12am on 15 February and 10am on 16 February, and Panadeine approximately every four hours until discharge on 17 February.

When Mrs A returned home on 18 February she noticed a large "dark red wine" coloured bruise on her abdomen. She tried to contact Dr B but was unable to speak to him until 19 February when he advised that "these things happen sometimes and that it would be better eventually, but might take a bit longer than initially suggested". Mrs A continued to have severe pain and on Monday 21 February she rang Dr B, who advised that he would fax her "chemist a prescription for stronger pain relief". Mrs A's pain was so severe that on 23 February she was admitted to a public hospital after attending the an After Hours Medical Centre.

According to the hospital clinical record Mrs A was "in mild distress" on admission and an 11cm sub-hepatic haematoma (collection of blood) was identified as the cause of the pain. Mrs A stated that she asked the registrar if the haematoma could have been caused by the liver biopsy and he said it was very likely but was unwilling to put this on the ACC form.

Dr B stated that, in his view, the haematoma formed as a result of bleeding from a number of possible points "including a division of some adhesions at the time of surgery to obtain access to the gall bladder rather than from the liver biopsy site itself".

Mrs A was concerned that Dr B took two liver biopsies without her consent and that there seemed to be no clinical reason for performing the biopsies. Mrs A was also concerned that Dr B might be undertaking research, since he told her he had been comparing the results with previous data.

Mrs A advised me that Dr B "would always fill out a thing like a questionnaire where he could circle options" rather than write in notes when she went to see him. Mrs A considered that Dr B appeared to be unduly interested in improvement in her asthma subsequent to her gastric bypass and that this annoyed her because she had only mild asthma and did not believe it was related to her size.

Mrs A stated that Dr B's nurse told her that he kept the data for his own personal quality assurance. However, when Mrs A requested her medical notes, the questionnaires were not included.

Dr B advised me that he has kept detailed personal records on all of his patients since about 1990 and that a questionnaire is completed on the occasion of each follow-up visit with a patient. A detailed database has been compiled from information from each patient's detailed personal record. Dr B has used this information to publish internationally and to make improvements and modifications to his procedures. Dr B' nurse and a senior scientific officer assist him in maintaining the patient database and collating the data in preparation for scientific meetings, both nationally and internationally, and for his many publications over the years.

In relation to the liver biopsies, Dr B stated that in his practice this has been a routine part of gastric bypass surgery. He considers the risk to the patient to be trivial and notes that important information about associated liver abnormalities, common in morbid obesity, can be gained. In Dr B's view, which he said is shared by many undertaking gastric bypass surgery, it is important to document the state of the liver prior to surgery.

Dr B stated that the opportunity to gain further information about the liver is afforded by any subsequent upper abdominal surgery in such patients, with minimal additional risk. Although in the past he did not seek specific consent for the biopsy, Dr B has since changed his practice and now obtains consent. Dr B provided a dissertation on gastric bypass surgery and stated that the improvements in procedures have resulted from the collection of data such as that collected by him. Dr B stated that he believed the particular surgery he

performed to be "very close to an ideal operation for the management of the otherwise unmanageable problem".

Dr B advised me that obesity surgeons struggle to gain acceptance in the international community and that this will only change with collection of supportive data. Dr B stated that Mrs A had had an "excellent result" from her Silastic Ring Gastric Bypass, a particular technique that he developed following data collection and modifications to his earlier practice.

Response to provisional opinion
Dr B provided the following response to my provisional opinion:

"1. Severe obesity is associated with a very high frequency of liver abnormalities, in particular fatty liver. This may range from mild steatosis, through to severe steatosis with steatohepatitis with or without cirrhosis. While in most circumstances there are no clinical consequences for the patient, on occasions there may be practical advice which should be given in order to prevent deterioration in the state of the liver, e.g., avoid alcohol in the event that there is existing cirrhosis.

2. Liver biopsy under direct vision at the time of surgery carries only a tiny risk of any complication. For myself, I am a liver surgeon and specialist as well as regularly practising obesity surgery. In my view, my patients may reasonably expect a higher level of specialist advice from me in the event that they have coexisting liver problems, such as cirrhosis. I accept that in 2002 the taking of liver biopsies at the time of gastric bypass necessitates informed and written consent. I do not, however, accept that it constitutes research, any more than performing a glucose tolerance test prior to surgery to detect and document the existence of impaired glucose tolerance or diabetes, which is very common in the obese population. The fact that some practitioners may choose to do these tests and others not is no different from the normal clinical environment in which some doctors will request more tests and investigations in the course of evaluating a particular patient or diagnosis than others. Some of these tests may even entail procedures which carry small risks (e.g. endoscopies and some radiological procedures).

3. In [Mrs A's] case, she was found to have a minor abnormality in the liver at the time of her gastric bypass. I sought to determine whether the situation was improved, the same, or worse after weight loss. It is not inconceivable that the state of the liver might have been worse, even though the liver function tests were normal prior to the second procedures. Cirrhosis can and often does exist in the presence of normal liver function tests (i.e. the routine blood tests). I accept that I should have obtained [Mrs A's] consent prior to taking the liver biopsy, but I believed that the information to be gained by the biopsy was of potential value to [Mrs A], although it proved not to be so.

4. I would like to note that all the actions taken by me in [Mrs A's] case were carried out in good faith, and with the best of intentions for [Mrs A]."

ACC
The Accident Compensation Corporation accepted [Mrs A's] claim for medical mishap on the basis that bleeding requiring readmission following laparoscopic cholecystectomy is rare and would occur in less than 1% of cases.

Independent advice to Commissioner

Surgical advice
The following independent expert advice was obtained from Professor Iain Martin, an upper gastrointestinal and laparoscopic surgeon:

> "This report relates to the treatment given by [Dr B] to [Mrs A], between January 1999 and February 2000. This report has been prepared by myself, Professor Iain G Martin, Med MD FRCS FRACS using copies of hospital notes and clinical records provided by the Office of the HDC.
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> This report will comprise 4 parts:
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> a) A chronological summary of the events between January 1999 and February 2000.
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> b) My interpretation of said events.
>
> c) Answers to specific questions raised by the Office of the Heath and Disability Commission.
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> d) My opinion on the standard of care in this case.
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> **Section 1: Chronological summary of the relevant events**
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> - 19th January 1999. [Mrs A] was seen by her general practitioner, [Dr C]. She was noted to be overweight, depressed and suffering from hypothyroidism. Following this consultation, [Mrs A] was referred to [Dr B] for consideration of gastric bypass surgery. It was recorded in the referral letter that [Mrs A] had in the past seen [Dr B] to discuss such surgery but at that stage she had declined to go ahead with the operation.
>
> - 8th February 1999. [Mrs A] was seen by [Dr B] in his rooms. She was noted to be overweight with a weight of 116kg and a body mass index (BMI) of 42.6 kg/m^2, putting her in the 'clinically morbidly obese' category. Such patients are prone to many of the obesity related conditions; [Mrs A] had one such condition, reflux oesophagitis. Following this consultation [Mrs A] decided she wished to pursue the surgical approach. The risks of the procedure were clearly mentioned,

but pertinent to the questions later raised by [Mrs A] no mention was made of the plan to biopsy the liver.

- 19th April 1999. [Mrs A] was admitted to a public hospital in for the planned surgery to be performed the following day.

- 20th April 1999. [Mrs A] underwent a Silastic Ring Gastric Bypass (the Fobi operation). The operation was performed by [Dr B] and proceeded uneventfully. A liver biopsy was taken from the left lobe of the liver.

- 20th-24th April 1999. [Mrs A] made an uneventful recovery from the operation and was discharged home on the 25th April 2000.

- 3rd June 1999. [Mrs A] was reviewed by [Dr B] in his rooms. She was making satisfactory progress and her weight had fallen to 104kg.

- 4th August 1999. [Mrs A] was again reviewed by [Dr B] in his rooms. Her weight had fallen to 95kg and she was noted to be pleased with the results of surgery.

- 8th November 1999. [Mrs A] reviewed by [Dr B]. Weight had fallen to 83kg.

- 7th February 2000. [Mrs A] reviewed by [Dr B] in his rooms. Her weight had fallen to 79kg. She was noted to have had several episodes of abdominal pain and an ultrasound scan had demonstrated gallstones. In view of this pain, [Mrs A] was advised to undergo cholecystectomy. It was noted that this procedure would be carried out laparoscopically but that there was a risk of conversion to open operation. No mention was made of a liver biopsy.

- 15th April 2000. [Mrs A] was admitted to the private hopital under the care of [Dr B]. That day she underwent a laparoscopic cholecystectomy using a very standard technique. The operation seemed uneventful. A biopsy was taken from the right liver using a 'Trucut' needle.

- 15th-17th April 2000. [Mrs A] recovered from her operation. The notes indicate that she made an uneventful recovery. [Mrs A] reports that she had significant pain. [Mrs A] was discharged on the 17th April.

- 24th April 2000. [Mrs A] was admitted to a public hospital having presented to the emergency department with abdominal pain. On examination she was noted to be tender in the right upper quadrant. Her haemoglobin was noted to be 93g/l on admission. It was suspected she had a post operative collection or haematoma and arrangements were made for an abdominal ultrasound scan. The ultrasound examination was

performed that day and demonstrated a 10x11cm collection in the gallbladder bed area. It was thought to most likely represent a haematoma.

- 24th-26th April 2000 [Mrs A] was managed conservatively with pain relief and discharged home on the 26th April.

Section 2: Interpretation of above events.

[Mrs A] was a 45-year-old lady when seen by [Dr B] in 1999. She had clinically morbid obesity, with a BM1 of 42.6 kg/m^2. In addition she had significant gastro-oesophageal reflux, a well-recognised complication of obesity. There is no doubt for such patients that obesity surgery can play a valuable role in such patients' management and I would support fully the use of such surgery. This is not merely cosmetic surgery as is often believed. Gastric bypass in one of its several variants is recognised as probably the best operation currently available in terms of a balance between effective weight loss and side effects. Although I do not use the Silastic band variety of this operation, gastric bypass is also my favoured operative approach. The Silastic ring gastric bypass is a well described and validated operation and I enclose a photocopy of a recent book chapter detailing the results obtained by the originator of the operation. The risks of the operation were fully explained to the patient and the operation was performed in a very satisfactory manner. The only issue is that of the liver biopsy and I will return to this issue later.

Following this operation, [Mrs A] was followed up entirely appropriately by [Dr B]. The use of standard audit questionnaires that I would interpret as research as opposed to audit, again a subject I will return to later.

Following the gastric bypass [Mrs A] achieved satisfactory weight loss and as not infrequently seen (up to 30% of cases) developed post operative symptomatic gallstones. Correctly, [Dr B] suggested that [Mrs A] undergo cholecystectomy which was performed laparoscopically using a standard technique. The only addition was again the performance of a liver biopsy, again this is dealt with later.

After the cholecystectomy, [Mrs A] developed a gall bladder bed haematoma. This is a recognised complication of cholecystectomy and it is impossible to say whether this occurred as a result of the cholecystectomy or the liver biopsy. I would argue strongly that this haematoma could not be ascribed to the liver biopsy either beyond reasonable doubt or in the balance of probabilities. This complication was managed non-operatively in [a public] hospital and this would be the normal outcome in such cases.

Section 3 answers to specific questions raised by the office of the HDC

a) Were [Dr B's] actions to treat [Mrs A] in April 1999 and February 2000 appropriate? My answer is an unequivocal yes in terms of the operations chosen and the way in which they were carried out.

b) Were [Dr B's] decisions to perform liver biopsies during both operations justified? I do not believe that liver biopsy is indicated clinically in most patients undergoing gastric bypass operations and in the absence of a specific liver abnormality is not indicated during laparoscopic cholecystectomy. I believe that the issues surrounding the liver biopsies are the only ones in this case that should be debated and I propose to return to these in a later section.

c) Was the data collection appropriate? As I have indicated above, I believe the questions raised on the questionnaires were all entirely appropriate ones to ask for a surgeon performing a rigorous audit of such operations. I do not believe that there is any debate in this area. I return later to the difference between research and audit which is the crux of the issues raised here.

d) Did [Mrs A] receive enough information from [Dr B]? I believe that [Mrs A] was fully informed about both operations and the relevant risks. [Mrs A] was not however informed about the liver biopsies and again this will be dealt with below.

e) Issues surrounding the care after the cholecystectomy? I do not believe that the care provided by [Dr B] was inappropriate or below acceptable standards. Clearly there is a discrepancy between [Mrs A's] recollection of the pain and that recorded in the hospital notes but I do not believe there are ground to suggest that care fell below acceptable professional standards.

f) How complete were the records? I found that the records were kept to acceptable professional standards and I was able to address the issues raised in this report from the records.

Section 4: Opinion as to the standard of care in this case

With the exception of the issue of the liver biopsies, I believe that the care provided to [Mrs A] by [Dr B] was of an entirely appropriate and professional standard.

I do however have some concerns about the liver biopsies. [Dr B] has argued that such biopsies form a very minor part of the operations and do not

contribute significantly to any increased risk. It is also argued that such biopsies are routine and are taken to audit the outcomes of such operations.

There are two issues here. Firstly, should a liver biopsy be regarded as a routine part of obesity surgery or any follow up operations? Secondly, does the collection of such data constitute research and hence require ethical approval?

…

I will deal with each of the liver biopsies separately as I believe that there are differences.

The first biopsy taken at the time of the gastric bypass was taken as 'routine' as indicated on the pathology request form. In fact there were potential clinical indications for such a biopsy in that [Mrs A's] liver function tests were slightly abnormal. The biopsy showed some mild abnormalities of fatty infiltration and inflammation, a condition very commonly found in obese patients. That having been said, I believe that most surgeons performing obesity surgery would not routinely biopsy the liver in this situation and personally if I planned to do it I would discuss the issue with the patient. The reason why most surgeons do not biopsy the liver is that these findings are very common indeed in this patient group and the findings of the biopsy do not generally alter management.

The second biopsy taken at the time of the cholecystectomy is slightly different. On this occasion the preoperative liver function tests were normal and the biopsy was used to gain information regarding the effect of the gastric bypass on the liver. In the absence of a specific abnormality then liver biopsy would not be regarded as part of routine clinical practice and … probably would be regarded as constituting research and not clinical audit. I believe that separate consent should have been sought for this. If it were held that this was research then ethics approval would be required. I fully take [Dr B's] point that the absolute risk of this biopsy did not add significantly to the risk of the operation but I would contend that this is not the major issue; even a simple blood test needs ethical approval and consent if the results are for research and not clinical management. I recognise that this point of view may be challenged and I think it would be advisable to seek an opinion from others with expertise in consent, ethics and research prior to making a definitive decision on this matter. A recent study from Australia (enclosed)[1] looking at abnormalities of liver function in morbid obese patients obtained specific informed consent for the study (which did include other tests as well). Other studies that I have been involved with

[1] Dixon, J.B., Bhathal, P.S. and O'Brien, P.E. Nonalcoholic Fatty Liver Disease: Predictors of Nonalcoholic Steatohepatitis and Liver Fibrosis in the Severely Obese. Gastroenterology 2001; 121:91-100.

which required taking a liver sample for reasons other than direct patient management have always required specific consent.

Summary
In summary I find that the standard of care offered by [Dr B] to [Mrs A] was appropriate. I do not believe that the haematoma following the cholecystectomy can, even using the test of balance of probabilities, be ascribed to the liver biopsy and its occurrence and management do not in my opinion raise any issues. The audit forms used and data collected were again entirely appropriate and broadly mirror those used in similar situations around the world. Such audit forms would not usually form part of the clinical record. The only issue that I have is with the liver biopsies, particularly the second one taken during the cholecystectomy. I believe that this was performed to gather new knowledge and not to alter management directly and hence would have required appropriate consent."

Ethical advice
The following independent expert advice was obtained from Associate Professor Charlotte Paul, an epidemiologist, health researcher, and ethics committee member:

"**My Professional Background and Experience**

I am qualified in medicine and public health and have a PhD in epidemiology. I am a Fellow of the Faculty of Public Health Medicine of the Royal Australasian College of Physicians. I have over 20 years experience in conducting research. I was a medical advisor to Judge Cartwright for the Cervical Cancer Inquiry. I have been a member of the Health Research Council Ethics Committee and have just been appointed to the National Ethics Committee.

I have been asked to give advice in the following two questions:

Q1. Whether in my opinion liver biopsy 1 (taken at the time of the Silastic Ring Gastric Bypass (SRGB) operation) was taken for the purposes of audit or research? Should [Dr B] have obtained specific informed consent of the patient and/or ethics committee approval for the liver biopsy 1.

Q2. Whether liver biopsy 2 (taken at the time of the laparoscopic cholecystectomy operation) was taken for the purposes of audit or research? Should [Dr B] have obtained specific informed consent of the patient and/or ethics committee approval for liver biopsy 2?

Before addressing the specific questions I would like to clarify some background issues.

(a) Is the distinction between research and audit relevant here?

My understanding of the complaint, and the questions I have been asked, is that there is an assumption that there are either legal and/or ethical implications in determining that the intervention in question was undertaken for the purposes of research versus audit. There may be legal implications in terms of the Code, but I do not consider that there are ethical implications if the intervention is called research or audit. I consider that the ethically relevant distinction is between an intervention undertaken for the purposes of clinical care and intervention undertaken not for the purposes of clinical care (be it research or audit).

(b) How do research and audit differ?

The NZ National Standard for ethics committees defines audit as 'examining practices and outcomes in a particular time and place to see whether they conform with expectations, with a view to informing and improving management rather than adding to general knowledge'.

Clinical research can be either observational or can involve an intervention which departs from the normal practice of clinical care (experimental research). Observational research uses data already collected or questionnaires or interviews. Experimental research involved interventions in clinical care which are determined by the investigator (see Report of the Cervical Cancer Inquiry, 1988, pp 62-63). Sometimes the research is mainly observational but may include specific research interventions (See Freedman et al.[2]).

In this case, the questionnaires could certainly be regarded as audit, while the liver biopsies, if not undertaken for the patient's clinical care, would be called a research intervention.

In the light of the above, I have revised the questions I have been asked to make them more relevant:

(1) Were the liver biopsies part of the clinical care of the patient or were they for research purposes?

The answer to this question is a clinical one. I can comment only on the information provided from [Dr B] and Professor Martin.

(i) Dr B described his use of such liver biopsies, at the time of SRGB surgery and at subsequent upper abdominal surgery, as 'routine'. He states that Assoc.

[2] Freedman, B., Fuks, A., Weijer, C. Demarcating research and treatment: a systematic approach for the analysis of the ethics of clinical research. Clin Res 1992 Dec; 40(4):653-60.

Professor D also did liver biopsies as a routine at SRGB surgery. He gives the reasons as follows:

> … has provided very important information regarding the associated liver abnormalities which are so common in morbid obesity. In addition, some of the earlier forms of obesity surgery, in particular small intestinal bypasses, were implicated in the development of major liver problems and for that reason it has always been desirable, in my view and in the view of the many who perform the surgery, to document prior to any surgery the state of the liver. … The opportunity to gain further information about the state of troubles in the liver is readily afforded at the time of any subsequent upper abdominal surgery in such patients."

These reasons seem to me to be a mixture of clinical care and research purposes.

(ii) The information from Professor Martin, which I have been given, appears to address the question: were there clinical reasons in this case to do liver biopsies. He appears to reach the conclusion that there were clinical reasons for biopsy 1, but not for biopsy 2. This does not address the question of whether it is justifiable to do liver biopsies as routine for a patient such as this.

I cannot answer this question definitively one way or the other. To do so would require evidence of other surgeons' clinical practice, and whether knowledge of the results of liver biopsies could change clinical decisions. But from [Dr B's] own account I accept there are clinical care purposes, though not clearly stated. If so, the fact that biopsy results may also be used for research purposes is not relevant. Nor should ethics committee review have been required.

(2) Assuming that the liver biopsies were undertaken as part of clinical care, should separate informed consent have been sought?

The argument for seeking separate consent for the liver biopsies is that they carry risks over and above the main operation, even if they may also confer benefits. Again this is a question which required clinical knowledge of absolute and comparative risks. The balance may differ for biopsy 1 and biopsy 2.

(3) Are there any other issues arising from the supporting information?

From my limited perspective, one of the issues arising from this case is the need for clinicians to clearly distinguish clinical interventions from research interventions. As the helpful (but complex) paper from Freedman and colleagues states: 'The correct description of an action is critical for ethical evaluation'. [Dr B] appears to be undertaking observational research (or audit) of the outcome of his surgical procedures. For this he uses information

collected as part of his clinical care. This is an important contribution to the improvement in care for future patients and cannot harm the patients whose information is used anonymously. Yet clearly his patient formed a view that he was undertaking additional procedures, which were not indicated clinically, for his research. Had that been so, it was essential she knew this and consented. In future these matters should be clarified."

Further surgical advice

The following additional surgical advice was obtained from Professor Martin:

"Thank you for your letters of the 22nd and 26th March. I have considered the guidelines provided by your office and the advice provided by Dr Paul.

To answer the questions raised:

1) *Comments on the guidelines.*[3] This is a document produced following a review of the world literature in 1999. It is comprehensive and was authored by two doctors of very considerable international repute. I think it provides a very good baseline for an understanding of the issues involved. Whilst laparoscopic biopsies are mentioned, the document essentially deals with percutaneous liver biopsy.
2) *Are there any Australian or New Zealand Guidelines?* I am unaware of such a document.
3) *Comparison of open vs. laparoscopic vs. percutaneous liver biopsy?* I would expect that the risks of an open biopsy would be very much lower than that of a percutaneous biopsy. The biopsy site is visible and overall would add almost no risk to a major operation such as gastric bypass. Again I would expect the additional risks of a laparoscopic liver biopsy when added to a laparoscopic cholecystectomy to be lower than that of a percutaneous biopsy. I do not believe it would be possible to quantify such risks.
4) *Was biopsy two taken for research as opposed to clinical purpose?* I have considered this issue again and would conclude as I did at the first report that this biopsy was taken for the purpose of research rather than clinical need. There was no indication clinically for such a biopsy and such a biopsy would not be part of a standard cholecystectomy.
5) *Is it justifiable to do a routine liver biopsy in such patients?* As I have indicated I do not consider that there is clinical indication for routine liver biopsy in patients following bariatric surgery. In the absence of any indicators of poor liver function then there is consensus that liver biopsy will not provide useful clinical data (see BSG guidelines).

[3] Grant, A., Neuberger, J. Guidelines on the use of liver biopsy in clinical practice. International Journal of Gastroenterology and Hepatology 1999, Vol 45, Supplement IV.

> In summary the opinion provided by Dr Paul has not altered the opinion that I expressed in my initial report that the second liver biopsy was taken not for clinical purpose but for what is probably best termed research. As I also indicated it is impossible to state whether the complication suffered by the patient after the cholecystectomy was caused by the liver biopsy."

Further ethical advice following response to provisional opinion
Further independent expert advice was obtained from Associate Professor Charlotte Paul, following [Dr B's] response to the provisional opinion:

> "My understanding is that in your latest provisional opinion you have accepted Professor Martin's conclusion that the second liver biopsy would not be regarded as part of routine clinical practice and hence would constitute a research intervention.
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> In my first report I accepted [Dr B's] own account that there were clinical care purposes in the second liver biopsy, when I had not been shown the full report from Professor Martin.
>
> In my second report I acknowledged Professor Martin's view that the second liver biopsy was a research intervention. I pointed out that this conclusion implied the need for ethics committee review.
>
> The new information I have now been sent is a further letter from [Dr B] (dated 2.7.02). In this letter [Dr B] restates his position that the second liver biopsy was part of his normal clinical care, even though it might be more than others would recognise as routine.
>
> Previously, I indicated that the judgement about whether the second liver biopsy could be seen as part of clinical care depended on evidence of other surgeons' practice and whether knowledge of the results of such biopsies could change clinical decisions. This is a clinical judgement which Professor Martin is in a position to make, but which I am not.
>
> The only extra point I would add is that the judgement may also depend on the intentions of [Dr B]. Previously, in my first report, I accepted [Dr B's] account of his own intentions. He has since reiterated that his intentions were to undertake the procedure as part of clinical care."

Further surgical advice following response to provisional opinion
Further independent expert advice was obtained from Professor Iain Martin, following [Dr B's] response to the provisional opinion:

"Thank you for supplying the file and further information in this case. I have read through the provisional report and [Dr B's] response together with the further response from Dr Charlotte Paul.

There remains a difference of opinion between [Dr B] and myself regarding the second liver biopsy. It is clear that [Dr B] believed that he was genuinely acting in the best interests of the patient in re-biopsying the liver. There is agreement that specific consent should have been sought for this procedure but disagreement between us on the clinical indications for such a procedure. [Dr B] argues that because there is disagreement between clinicians on the need for a test that [is] an additional test, it does not constitute research if such a test is performed by some clinicians and not others. I would support [Dr B's] viewpoint completely with one caveat and that is the reason behind the test. If the investigation is performed in a systematic manner to gather new information and such an intervention would not be performed in the normal treatment of a patient in that situation then it could be argued that this is research. The interpretation of whether an intervention / investigation is research depends not on the magnitude of the intervention / investigation but on the reasons behind the decision for its performance.

I am prepared to concede that in this case, matters were not absolutely clear and that a degree of doubt does exist. I have placed my interpretation on matters but would concede that others, including [Dr B], could interpret events differently. I certainly remain of the opinion that specific consent should have been sought for the second liver biopsy.

Dr Paul's opinion also reflects the notion that the biopsy must be interpreted in the context of routine clinical practice and here [Dr B] and I disagree. I have not been able to find a clear answer to this question from the published literature and therefore this question will remain a matter of opinion of what is routine clinical practice."

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.

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 –

…

d) Notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval; …

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.

…

6) Where informed consent to a health care procedure is required, it must be in writing if

a) The consumer is to participate in any research; …

Opinion – Breach

Rights 6(1) and 7(1)

Dr B took biopsies from Mrs A's liver first during a Silastic Ring Gastric Bypass operation in April 1999 and secondly during a laparoscopic cholecystectomy in February 2000. Mrs A was not aware that the liver biopsies had been taken as this had not been discussed or consented to on either occasion. Dr B said that he saw the biopsies as inconsequential extensions of major operations and therefore he was not in the habit of seeking consent.

Mrs A was concerned that Dr B may have been carrying out research, as she did not think there was any clinical reason for the biopsies he had taken from her liver. Dr B stated that in his view, shared by many surgeons who perform gastric bypass surgery, it is important to document the state of the liver prior to any surgery. Dr B explained that his reason for doing the first liver biopsy at the time of the gastric bypass surgery was that some earlier forms of obesity surgery, in particular small intestinal bypasses, were associated with major liver problems. Mrs A's liver function tests were slightly abnormal and the biopsy did show "mild abnormalities of fatty infiltration and inflammation". My surgical advisor noted that

the liver biopsy taken at the time of the gastric bypass operation might have been justified on clinical grounds; however, most surgeons doing obesity surgery would not biopsy the liver, as such findings are common in obese patients and do not alter the management. I accept that Dr B may have had clinical reasons for requiring a liver biopsy at the time of the gastric bypass surgery.

In regard to the second liver biopsy taken at the time of the laparoscopic cholecystectomy, my surgical advisor stated that, in the absence of a specific abnormality, liver biopsy would not be considered routine clinical practice. Mrs A's pre-operative liver function tests were normal. My surgical advisor noted that "in the absence of any indicators of poor liver function then there is consensus that liver biopsy will not provide useful clinical data (see BSG guidelines)".

In response to my provisional opinion, Dr B said that severe obesity is associated with liver abnormalities and that knowledge of such abnormalities can afford the opportunity to advise the patient on preventative measures. Further, some practitioners will elect to do a liver biopsy in evaluating a particular patient. Mrs A was found to have a minor liver abnormality at the time of the first biopsy and Dr B sought to determine the effect of weight loss on this abnormality by taking the second biopsy. He believed that the information he obtained was potentially valuable to Mrs A and that his actions were carried out in good faith and with the best of intentions.

My expert surgical advice is that the additional risks from liver biopsy did not add significantly to the risk of either of Mrs A's operations. However, in my opinion the reasonable patient would want to be told that his or her surgeon proposes to perform a non-standard procedure such as a biopsy that most surgeons would not perform. Right 6(1) of the Code gives patients the right to receive "the information that a reasonable [patient], in that [patient's] circumstances, would expect to receive". Information about risks and participation in research are notable examples of information that must be disclosed, but information about proposed non-standard procedures must also be disclosed. Dr B failed to inform Mrs A, prior to both the first and the second liver biopsy, that they were non-standard procedures and did not obtain her specific consent. In these circumstances Dr B breached Rights 6(1) and 7(1) of the Code.

I note that Dr B advised me that he has changed his practice and seeks specific informed consent for all liver biopsies.

Other comment

Where a clinician performs tests or procedures that are not regarded as a routine or necessary part of clinical management by a responsible body of the relevant speciality, and that clinician admits that he collects data from such non-standard tests or procedures for research and publication purposes, the test or procedure is properly classified as a research

intervention. I do not accept that a clinician can cite his own minority opinion that the intervention is clinically appropriate so as to establish that the intervention was not research and therefore did not need specific consent and ethical approval.

Dr B himself appears to recognise that the second biopsy was in a different category since he advised me (in response to my provisional opinion) that he accepts he "should have obtained Mrs A's consent prior to taking the [second] liver biopsy". If the second biopsy was, like the first, simply part of his normal clinical practice and carried only a tiny risk, it is hard to see why it (and not the first biopsy) necessitated specific consent.

The fact that few clinicians would perform a liver biopsy as part of a standard cholecystectomy, and that Dr B was engaged in research on liver abnormalities in obese patients, inclines me to the view that he was seeking to gather new information unrelated to specific clinical management of Mrs A.

Accordingly, notwithstanding my surgical and ethical advisors' view that the second biopsy can be accepted as part of clinical care if Dr B genuinely believed it was in Mrs A's best interests to re-biopsy the liver, I consider that the biopsy was probably undertaken for purposes of research.

In these circumstances Dr B should also have informed Mrs A that he was undertaking research and obtained her written consent, as required by Right 6(1)(d) and 7(6)(a) of the Code.

Opinion – No Breach

Right 4(1)
My surgical advisor noted that a gall bladder bed haematoma is a recognised complication of cholecystectomy and, on the balance of probabilities, cannot be attributed to the liver biopsy. Such complications are usually managed non-operatively. I accept that Mrs A was experiencing considerable pain at the time of her admission to a public hospital. However, I am satisfied that Dr B responded appropriately by ensuring that Mrs A received stronger pain relief, and did not breach Right 4(1) of the Code.

Action

- I recommend that Dr B apologise to Mrs A. A written apology is to be sent to my Office and will be forwarded to Mrs A.

Further Actions

- A copy of this opinion will be sent to the Medical Council of New Zealand.

- A copy of this opinion, with identifying features removed, will be sent to the Royal Australasian College of Surgeons, the National Ethics Committee, and the Health Research Council Ethics Committee, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.