

**Gastrointestinal and Hepatobiliary Surgeon,
Professor Richard Stubbs**

**A Report by the
Health and Disability Commissioner**

Case 09HDC01870



Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Overview

This complaint relates to the adequacy of the information provided by Professor Richard Stubbs to Mr A prior to surgery at a private hospital on 4 December 2007, and the quality of the care provided following the surgery. Mr A (aged 64) had colorectal cancer with liver metastases,¹ and chemotherapy was no longer effective. He was referred to Professor Stubbs for consideration of Selective Internal Radiation Therapy (SIRT) and Hepatic Artery Chemotherapy. On 4 December 2007 he underwent an anterior resection of the rectum, a cholecystectomy, and an insertion of a hepatic artery port-a-cath for SIRT. He made a slow recovery and, on 17 December 2007, a chest X-ray and CT scan indicated the development of an anastomotic leak or other viscus perforation within the abdomen. He was transferred to the public hospital for surgery and discharged home on 18 January 2008. Mr A did not undergo the SIRT and died two months later.

Complaint and investigation

On 24 July 2008 the Health and Disability Commissioner (HDC) received a complaint from Mrs A about the services provided by Professor Richard Stubbs to her husband, Mr A. An investigation was commenced on 2 September 2008 into the appropriateness of the care provided by the private hospital, Professor Richard Stubbs and a district health board (Hospital 2).

On 18 February 2009, HDC decided that DHB representatives should meet with Mrs A. No further action was proposed in relation to the private hospital.

On the basis of expert advice obtained from Professor Bryan Parry, HDC referred Professor Stubbs to the Medical Council of New Zealand with a recommendation that a competence review be performed. The Medical Council decided not to carry out a review, but asked Professor Stubbs to report back to them in six months' time.

On 18 March 2009, Professor Stubbs requested that HDC re-open the file to give him an opportunity to comment on Professor Parry's advice, with which he disagreed. He stated that he had expert advice supporting his view available from three colorectal surgeons.²

HDC obtained further information from Mrs A and Mr B, Mr A's son-in-law.

After a review, HDC concluded that, as new information had become available, the overall justice of the situation required that the matter be reconsidered.

The investigation was re-opened on 1 September 2009.

¹ Secondary cancers.

² In due course, Professor Stubbs submitted expert advice only from Dr Richard Perry.

The following issue was identified for investigation:

- *The appropriateness of care provided by Professor Richard Stubbs to Mr A, including the adequacy of the information provided.*

The parties directly involved in the investigation were:

| | |
|--------------------------|-----------------------|
| Mrs A | Consumer's wife |
| Mr B | Consumer's son-in-law |
| Professor Richard Stubbs | Surgeon/Provider |
| The private hospital | A private hospital |
| Hospital 2 | A public hospital/DHB |

Information was reviewed from Mrs A, Mr B, Professor Stubbs, the private hospital and Hospital 2.

Independent expert advice was obtained from general and hepatobiliary surgeon Dr Peter Johnston (attached as **Appendix A**) and colorectal surgeon Professor Bryan Parry (attached as **Appendix B**). Professor Stubbs obtained expert advice from colorectal surgeon Dr Richard Perry (attached as **Appendix C**). Professor Parry was asked to comment on Professor Stubbs' response to my provisional opinion and Dr Perry's advice. Professor Parry's further expert advice is attached as **Appendix D**.

Key events

Treatment at Hospital 1

In June 2006 Mr A was diagnosed as having a colorectal cancer with liver metastases and the primary recto-sigmoid tumour in situ. He was treated at the nearest public hospital (Hospital 1) with first line chemotherapy³ using a Folfex regimen, which had good initial effects for some months. However, his disease began to progress and he was commenced on second line chemotherapy with Folfiri, to which he had a poor response.

Around August or September 2007 he developed symptoms of subacute bowel obstruction related to his primary bowel tumour, which was managed non-operatively with high dose steroids. He took dexamethazone⁴ for relief of his obstructive symptoms. Mr A was advised that there was no further systemic chemotherapy available to him.

A medical oncologist at the hospital referred Mr A to Professor Stubbs for consideration of Selective Internal Radiation Therapy (SIRT) and Hepatic Artery Chemotherapy (HAC) to treat his extensive liver metastases originating from a primary tumour at or close to the recto-sigmoid junction of the bowel.

³ Treatment with anti-cancer drugs that are injected into a vein or muscle, or are taken orally. These drugs enter the bloodstream and reach all areas of the body. They can destroy not only the cancer cells but also affect healthy cells.

⁴ Dexamethasone is a corticosteroid.

Consultation at the private hospital

On 18 November 2007, Mr A attended his first appointment with Professor Stubbs, accompanied by his son-in-law, Mr B. Professor Stubbs advised that clinical examination of Mr A revealed a grossly enlarged liver from metastatic disease, which was shown by the CT scan performed at Hospital 1. Rectal examination and sigmoidoscopy⁵ confirmed the presence of a tumour 12cm from the anal margin.⁶ Mr A indicated that he was keen to pursue any option that might extend his life. Professor Stubbs told him that SIRT followed by HAC was a possibility that had a good prospect of controlling his liver disease, at least for a period of time.

Professor Stubbs explained to Mr A that it would be necessary to remove his bowel tumour because he already showed symptoms suggestive of incipient bowel obstruction, although the symptoms had been largely controlled by the use of high dose steroids. Professor Stubbs proposed an operation in which an anterior resection of rectum would be performed to remove the primary tumour, with probable primary anastomosis plus cholecystectomy,⁷ and insertion of a hepatic artery port-a-cath⁸ for the purposes of SIRT delivery of yttrium microspheres⁹ via the hepatic artery¹⁰ and subsequent HAC.

Information provided to Mr A

Professor Stubbs says that he discussed the SIRT option in some detail, and the risks of the procedure were thoroughly outlined to Mr A. Prior to seeing Professor Stubbs, Mr A had read his patient information booklet on the subject of liver cancer, which explained the SIRT treatment. Professor Stubbs apparently indicated to Mr A that the benefits of this approach would only be gained if there were no major complications from his bowel surgery and he obtained a good response from the SIRT. In relation to the risks of the operation itself, Professor Stubbs says that he explained the difficulties resulting from the position of the bowel tumour at about 12cm from the rectum, which made the procedure more difficult than a tumour higher in the bowel:

⁵ Sigmoidoscopy is the medical examination of the large intestine from the rectum through the last part of the colon.

⁶ The anal canal goes from the rectum to the anal margin where the canal meets the outside skin at the anus.

⁷ The surgical removal of the gall bladder.

⁸ A "port-a-cath" is an access port introduced under the skin over the right lower rib cage. "The port is attached to a fine catheter or tube which is placed in the hepatic artery as it goes into the liver. The port is either used each month for chemotherapy or it needs to be flushed, to stop it clotting off, which would mean it could no longer be used. Even if the port is no longer being used there is usually no need for it to be removed." Ref: "*Liver Cancer: A Guide to Diagnosis and Treatment.*" Richard S Stubbs, August 2007, p 24.

⁹ The microspheres become trapped in small blood vessels feeding the tumour and remain radioactive for a total of three weeks. The microspheres are specially prepared for the patient in a nuclear reactor in Sydney, Australia, and despatched to the private hospital. The microspheres must be ordered eight days before delivery, because their half-life is 2.6 days, and there is little opportunity to delay upon delivery without the dose falling to levels that make it less useful.

¹⁰ An artery that distributes blood to the liver, pancreas and gall bladder as well as to the stomach and duodenal portion of the small intestine.

“I also explained that there were significant risks attached to anterior resection of rectum, including the possibility of a leak leading to peritonitis and the need for further surgery. I judged this risk to be around five percent or greater particularly because of his high dose steroid therapy and his relatively advanced state of metastatic disease. Both of these circumstances are known to be associated with a high rate of failure of healing at the anastomosis.”

He told Mr A that his chance of dying from the surgery was 1%.

Mr A’s son-in-law, Mr B, who was present at the consultation, recalls the information disclosed about the risks and likely success of the SIRT treatment as follows:

“Professor Stubbs advised the SIRT treatment would offer [Mr A] an extension to his life of up to one year of comfortable and symptom free living. He outlined that with the cancer being advanced and the fact that [Mr A] had already had two courses of chemotherapy, the likelihood of success for the SIRT was reduced from around 90% success to around 2/3rds (66%) success. He also warned [Mr A] that if the SIRT was not successful then his life would be shortened and he would suffer a painful last few months. That was made clear.”

...

“... [T]here was then some discussion about the need for a bag. Professor Stubbs advised that he would take the option of not using a bag for [Mr A’s] procedure (I can’t quite recall the reasons why he decided that). The second part of the conversation was around the risks of the operation to remove the tumour, remove the gall bladder and insert the catheter into the liver for the SIRT treatment. This was a conversation along the lines of any conversation a doctor would give to a patient before a major operation. The risks here appeared to [Mr A] and me to be no greater than usual. We discussed this after the consultation.”

Mr B stated that Professor Stubbs mentioned a risk of a major complication of around 1%, which he thought sounded like the normal thing said by a surgeon to a patient when discussing risks.

Professor Stubbs then went on to talk about the cost of the operation, \$40,000–50,000, which Mr A said he was willing to pay. They then discussed proposed dates for the surgery.

Clinical notes

Professor Stubbs recorded the following in the clinical notes:

“Keen to do what he can.

— rationale of SIRT / HAC explained

— rationale of resection of 1° explained

Risks of anterior resection

- leakage 5% / peritonitis
- Port placement) 1% mortality
- SIRT) risks / uncertainties / results
- Not curative —
- relies on good recovery — 65%
- relies on no complications from bowel surgery.”

Surgery at the private hospital

Mr A was admitted to the private hospital on 3 December 2007. He consented to an anterior resection of the rectum, a cholecystectomy, and an insertion of a hepatic artery port-a-cath for SIRT. The operation was performed on 4 December. The plan was to deliver the SIRT on 14 December, which allowed a 10-day interval between the surgery and the SIRT. Professor Stubbs allowed a longer time than the usual three to seven days because of his concern about Mr A’s recovery from bowel surgery, and because he did not want to deliver high dosage radiation into Mr A’s liver until he was happy that the bowel anastomosis had healed. During the intervening period it was planned to reduce Mr A’s dose of steroids.

The operation proceeded satisfactorily and was completed in three hours 14 minutes. Five units of blood in total were given during and after the operation to correct Mr A’s pre-existing anaemia and replace an estimated blood loss of 700–800 mls.

Postoperative progress

Mr A showed reasonable clinical progress over the first few days after surgery. His clinical records show a relatively normal pulse, temperature, satisfactory blood pressure, normal respiratory rate and normal urine output. However, he became oedematous¹¹ and his abdomen became distended.

Mrs A, who was present with her husband during his hospitalisation, recalls that the doctors discussed with Mr A the need for him to pass flatus,¹² as this was an indicator of successful surgery. Because it was emphasised as being important, the family asked Mr A about this issue every day. They believe he did not pass flatus. Mrs A stated, “My recall of this is very clear because it was so acutely important that it became almost a joke that we all asked him constantly if he had passed flatus and laughed about it.” Professor Stubbs states that bowel sounds commenced at an early stage and Mr A passed flatus by day three postoperatively. The clinical record for 6 December 2007 has a notation made by Professor Stubbs’ registrar, “passed flatus”, and this is supported by the nursing record.

¹¹ Excessive accumulation of fluid in the body tissues.

¹² Wind.

A chest X-ray was taken on 7 December and a further chest X-ray with erect and supine abdominal films on 10 December, because of continuing abdominal distension. Neither of the X-rays showed signs of free gas to suggest an anastomotic leak. The abdominal X-rays taken on 10 December showed slightly prominent loops of large bowel, but no convincing evidence of obstruction. Professor Stubbs advised that these were not unexpected at this stage. Until 17 December he was reassured that there was no major problem requiring further surgery, as there was no tachycardia, elevated temperature or elevated blood count to suggest developing infection. He stated, “We anticipated gradual improvement in his condition with the passage of time.” Professor Stubbs reassured Mr and Mrs A that his slow progress was not unexpected in view of his large burden of metastatic disease.

Mrs A, who is a registered nurse, recalls that her husband was deteriorating daily, although the hospital staff assured her that he was progressing. She saw no signs of progress from the third day after surgery, and she was concerned about his levels of pain.

SIRT delayed

The original plan was that Mr A would undergo SIRT on 14 December 2007 but it was delayed for one week until 21 December. Professor Stubbs said that the need to delay the SIRT in light of his slow recovery coincided with a production problem of the yttrium microspheres in Sydney, which mandated a delay of one week. Mrs A is very clear that the nursing staff were embarrassed and distressed that the treatment was delayed solely because of a faulty batch of yttrium microspheres, rather than Mr A’s condition.

16 December 2007

On Sunday 16 December Mrs A became distressed about Mr A’s condition and believed he was dying. She requested that arrangements be made for him to be flown home. The private hospital nurses telephoned Professor Stubbs and he came in. The hospital notes refer to low oxygen saturations. Mrs A recalls Mr A’s extreme pain, grey colour and that he was cold and clammy. Mrs A said that Professor Stubbs “told me that he was at home and that family time was important to him”.

Mrs A recalls:

“[R]ather than assess [Mr A’s] condition Professor Stubbs maintained he just needed to eat more and exercise which was obviously well beyond his means. [Mr A] did say to me on one occasion, ‘get me up for this bloody walk then, fat lot of use it will do’, and he could barely get the words out; we got as far as the door to his room and we had to give up as it was so clearly impossible for him to do ... this was a man so close to dying that the request to eat and exercise were totally unrealistic and Professor Stubbs should have absolutely known this from professional experience.”

Professor Stubbs noted in the medical record, “Slow progress but no obvious complication from bowel surgery. Oedema limb/trunk/genitals an issue —

complicated by surgery, metastatic load, low protein, steroids.” He recorded, “May or may not tolerate SIRT — delay of a week is a shame, but not available.”

Professor Stubbs recorded that he had a “full frank discussion with [Mr A], his wife and daughter. He is very keen to receive SIRT otherwise would die in next three to four weeks. May do so anyway.” Professor Stubbs ordered albumin infusions and frusemide in an effort to improve Mr A’s serum albumin and reduce his oedema. He encouraged fluids and food intake and commenced Mr A on oral morphine for his pain.

17 December 2007

On the morning of 17 December Mr A developed nausea and vomiting and had an elevation of his pulse rate to 110. He was seen by another doctor as Professor Stubbs was in another city that day. A chest X-ray revealed a large pneumoperitoneum,¹³ which indicated the development of an anastomotic leak or other viscus perforation within the abdomen. The doctor arranged for a CT scan, which showed extensive intra-peritoneal free gas and fluid. This suggested a viscus perforation. The doctor discussed the options for treatment with Mr and Mrs A. The options were either to do nothing other than provide support and palliative care, or to reoperate to treat the peritonitis and presumed anastomotic leak.

The decision was made to move Mr A to the nearest public hospital (Hospital 2) for surgery. Professor Stubbs stated that the decision to proceed to surgery was “largely on the basis of Mr A’s determination to get through to have the SIRT and HAC which he had originally sought”. Mrs A stated that “the reason we made the decision to move him was not about wanting the SIRT treatment to extend his life, but rather about ensuring he didn’t have a painful death, as explained by [the doctor] to [my daughter]. So again, we were really realistic about what was happening to [Mr A].”

In his response to the complaint, Professor Stubbs said that the perceived advantages of a transfer to the public hospital were that Mr A would need a level of intensive care over and above that provided at the private hospital, given his poor general status. Mr A was uninsured, and the cost of further surgery and intensive care may have been prohibitive. In addition, it was expected that the private hospital would be winding down for Christmas and closing for a period after Christmas.

On 17 December Mr A underwent a laparotomy, washout, division of colorectal anastomosis and end colostomy. The operation note records: “Large (1cm) defect posterior part of staple line at colorectal anastomosis.” He was grossly oedematous from his waist to his feet, with pitting.

On 21 December, Professor Stubbs reported to Hospital 1’s medical oncologist and suggested that if Mr A was well enough he could receive yttrium in January. However, he thought Mr A’s condition would continue to deteriorate and he would require only palliative care. He stated, “It is always difficult and potentially

¹³ A pneumoperitoneum is air or gas in the abdominal (peritoneal) cavity.

problematic when patients come with such advanced disease when they still face significant surgery such as anterior resection of the rectum.”

Professor Stubbs’ involvement with Mr A ended at the point of his transfer to Hospital 2, although he did visit him there on at least one occasion following his surgery.

Discharge home

After a slow recovery from the surgery, Mr A was discharged home on 18 January 2008. Professor Stubbs spoke to Mrs A on the telephone on 5 February and again on 11 February. Professor Stubbs stated:

“We agreed that his general condition was not sufficiently good for him to be considered for SIRT. It seems [Mr A] himself had by this time become resigned to not ever receiving the SIRT he originally sought. I left it with his wife that they were free to contact me if his condition rallied sufficiently that they wished that decision to be reconsidered. At that stage I refunded to him the \$15,000 that he had advanced for SIRT therapy prior to his admission to [the private hospital].”

In contrast, Mrs A recalls that in February 2008 Mr A decided not to have the SIRT treatment because he did not want to have further treatment from Professor Stubbs and felt he had gone through enough. She disputes that he was too debilitated for the SIRT treatment and states that he recovered to some extent. She believes he was physically able to tolerate the SIRT treatment but he did not wish to deal with Professor Stubbs again. Mrs A also disputes Professor Stubbs’ comment that he willingly returned the \$15,000 they had paid for the SIRT treatment. She said that the refund was made only after they were asked by the private hospital to pay their bill and Mr A said he would not pay until Professor Stubbs had refunded the SIRT treatment money, which until then he had failed to do.

Mrs A recalls a telephone conversation in February 2008 where “Professor Stubbs told me the treatment would have been much more successful had [Mr A] not had chemotherapy and steroids. Yet this was not made clear prior to [Mr A] going to [Hospital 2] [for the surgery]. I do feel we were misled ... [Mr A] felt ripped off by the process, he had every risk factor that indicated the surgery wasn’t advisable yet he was persuaded by Professor Stubbs (and others) and his inaccurate information to pursue the treatment.”

Death

Mr A died two months later.

Complaint

Mrs A complained to HDC about Mr A’s treatment at the private hospital and at Hospital 2. With regard to the treatment provided by Professor Stubbs, she complained that Mr A was aware of the 65% success rate of the SIRT treatment but not of the high risks of the bowel surgery for a person with his risk factors, and that this information might have made a difference to their decision to proceed with SIRT.

Her husband talked only about the benefits of the SIRT treatment, and she does not believe that he was made aware of the risks of the surgery.

Mrs A also complained about the lack of response from Professor Stubbs to Mr A's deteriorating condition following the surgery and, in particular, the lack of pain relief provided to her husband. In addition, they were not given accurate information after the surgery, as they were told that it had been straightforward and had gone well, but discovered later that blood replacement was required for significant blood loss.

Mrs A and her family feel that Professor Stubbs acted unprofessionally and without real regard for Mr A's quality of life.

Professor Stubbs' response

Professor Stubbs advised that SIRT has been offered at the private hospital for over 12 years for the management of advanced hepatic malignancy, and has been given to well over 200 patients. The private hospital is the only centre in New Zealand offering this treatment. He stated, "The treatment options and their value are fully discussed by me in my patient information booklet which is given to all prospective patients usually before they see me for their first consultation."

Professor Stubbs acknowledged that SIRT treatment is more difficult if major bowel surgery is required as well as treatment for the liver tumour, and said that "[Mr A] was made aware of the importance to his treatment program of an uncomplicated course in relation to his rectal cancer surgery. Regrettably, complications were encountered; this was unfortunate but the possibility was foreseen and taken into account."

Professor Stubbs said that while at the private hospital Mr A was generally seen by members of his medical team twice a day, and was always seen daily and more frequently if required. Mr A showed good clinical progress for the first few days after surgery and had a relatively normal pulse rate, normal temperature, satisfactory blood pressure, normal respiratory rate and normal urine output. Mr A became oedematous, which is virtually universally seen in those undergoing major surgery in the presence of major metastatic disease and/or nutritional deficiency. Mr A's slow progress was not entirely unexpected in view of his large burden of metastatic disease. There were no grounds to believe that an anastomotic leak with peritonitis had occurred until 17 December, when it was revealed by the chest X-ray and CT scan.

Professor Stubbs disputed the opinions of my expert advisors, Dr Johnston and Professor Parry, because he considered they both wrongly considered that Mr A had a bowel obstruction, whereas he had an elective bowel resection and underwent elective bowel preparation the day before surgery. He explained that the comment in the operation notes that there was "a degree of obstruction" related the degree of dilatation proximal to the tumour, and did not mean there was an acute bowel obstruction. He also believed my experts misunderstood the level in the rectum at which the anastomosis was performed, and were under the impression it was a low anterior resection. Professor Stubbs emphasised that the surgery involved a high anterior resection.

Opinion: Breach — Professor Stubbs

Mr A was terminally ill and wanted to pursue treatment that had the potential to extend his life. In such circumstances, a reasonable patient considering innovative and expensive treatment needs to be given balanced information about the merits of the procedure, to enable them to make decisions with their eyes wide open. As noted by Joanna Manning:¹⁴

“Patients who are extremely ill or facing terminal or incurable conditions where the standard treatment is ineffective or has failed pose particular difficulties in balancing patient autonomy and protection from harm. Arguably, it may be justifiable to submit a patient to a greater degree of risk than minimal with fully informed consent in such circumstances.”

When an experimental or innovative procedure is involved, particular care is required to ensure patients are fully informed and aware of the risks.

Appropriateness of surgery

In June 2006, Mr A was diagnosed with colorectal cancer affecting the recto-sigmoid junction. Treatment with chemotherapy was reasonably successful for 18 months, but the cancer then began to progress. He was referred to gastroenterology and hepatobiliary surgeon Richard Stubbs in his private practice for an assessment of treatment options.

On 18 November 2007, Professor Stubbs had a consultation with Mr A, who was accompanied by his son-in-law, Mr B. A clinical examination revealed a grossly enlarged liver from metastatic disease, and rectal examination and sigmoidoscopy confirmed the presence of a tumour 12cm from the anal margin.

Mr A indicated that he was keen to pursue any option that might extend his life. Professor Stubbs explained that SIRT followed by HAC had a good prospect of controlling the disease in his liver for a period of time but was not curative. He explained that it would be necessary to remove Mr A’s bowel tumour, as he already showed symptoms suggesting incipient bowel obstruction.

Professor Stubbs proposed an anterior resection of the rectum to remove the tumour, with a probable primary anastomosis plus a cholecystectomy and insertion of a hepatic artery port-a-cath for the purposes of SIRT and subsequent HAC. He explained that, in his experience, a good response to SIRT could be expected in approximately 65% of people in Mr A’s circumstances, so long as there was good recovery from the surgery. He told Mr A there was a 5% chance of an anastomotic leak and that the overall risk of mortality from the surgery was 1%.

My expert advisor, general and hepatobiliary surgeon Dr Johnston, advised that the decision to offer surgery was reasonable in light of Mr A’s request for active

¹⁴ Manning J, “Determining Breach of the Standard of Care” in Skegg & Paterson (eds), *Medical Law in New Zealand* (Brookers, Wellington, 2006) ch 4, p 139.

treatment, although it needed to be recognised that the treatment proposed was at the very limit of what could be done surgically for him.

Risk of anastomotic leak

Dr Johnston was concerned that a primary bowel anastomosis was fashioned in the presence of an apparent bowel obstruction, because of the risk of leakage. He suggested that HDC seek further expert advice as to whether this operation was appropriate in Mr A's circumstances, particularly his degree of obstruction, metastatic disease and steroid administration.

Further expert advice was obtained from Professor Bryan Parry, consultant colorectal surgeon, who advised that the risk of anastomotic leakage in this case was significantly higher than 5% because of the risk factors, which included Mr A's male gender, significant comorbidities, liver metastases, high steroid usage, and obstructed colon. Professor Parry assessed the cumulative odds ratio of increased risk of an anastomotic leak at over 20%.

Professor Parry acknowledged the divergence of opinion within current colorectal practice about the pros and cons of a defunctioning ileostomy¹⁵ and said that, in light of Mr A's advanced disease, a surgeon might choose not to do an ileostomy on the grounds of preserving Mr A's quality of life. However, Professor Parry stated that the patient would have to be made aware of this and be in full agreement:

“... [T]his would need to have been discussed with the patient prior to the operation and [Mr A's] informed consent obtained for either policy. Not doing so would be a departure from appropriate standard of care of medium severity in my view.”

Professor Stubbs responded that the advice provided by Dr Johnston and Professor Parry was based on incorrect facts, as both believed Mr A had a bowel obstruction. Professor Stubbs advised that he recorded in his notes “a degree of obstruction” to refer to the degree of dilatation proximal to the tumour. This should not be interpreted as meaning an acute bowel obstruction was present. He also said there had been a misunderstanding about the level in the rectum at which an anastomosis was performed. This was a high anterior resection, not a low anterior resection, and the anastomosis was above the peritoneal reflection.

HDC sought further expert advice from Professor Parry in light of this information. He responded that the fact that the rectal resection was not low meant there was a lesser risk of anastomotic leaks, but the other risk factors were still operative and were “summative or cumulative” in their effects on risk. He pointed out that the operation note had given him new insight that it was a difficult dissection due to the state of the tissues, perhaps resulting from previous chemotherapy. Professor Parry considered that this was a further and independent factor that increased the risk of a leak and, in

¹⁵ A defunctioning ileostomy is a surgically created opening of a loop of terminal ileum brought up through the surface of the skin, usually in the right iliac fossa. The stoma will divert faecal waste away from the anastomotic site.

his view, added to the case for a defunctioning loop ileostomy. He referred to the operation notes, which state that “bowel preparation was imperfect” and that there was “a degree of obstruction upstream and some dilatation of the bowel”. Professor Parry stated that the additional information did not change his original conclusions.

Professor Stubbs responded with further explanation of his reasons for telling Mr A the risk of an anastomotic leak was 5%. He stated:

“How one can possibly expect to precisely attribute a risk to an *individual patient* under these circumstances defies credibility. This brings me to the question how should estimates of risk be related to patients, given the impossibility of bringing any precision to the art. Many doctors, recognising these limitations, prefer not to nominate specific percentages when they speak of risk. Those of us who do, do so not in order to indicate any precision, but rather to demonstrate approximate order of risk. The point I made to [Mr A] was that he was a higher than usual risk of a leak, and that if a leak should occur it would be unlikely that we would be able to proceed with his SIRT, and in that event he would gain no benefit from his/our efforts. I gave a figure of around five percent to indicate the risk was greater than usual (i.e. double). The truth is, patients in his situation do not decide to proceed or not based on differences of two and five percent or even five and ten percent, or for that matter ten and twenty percent ... I submit that even had I told him of a 20 percent (which I simply do not accept applied), he would still have opted for surgery, hoping for subsequent SIRT.”

Professor Stubbs submitted that it is impossible to attribute a specific risk of a particular outcome to a given individual and that this is not what patients seek or can expect, as the best that can be done is to give patients an indication of the nature of the risks they face and, perhaps, an estimate of their risk. He stated, “The nominating of a figure is fraught with problems, and dispute around the figure should not, except in extreme and probably very obvious circumstances, be a basis for determining the adequacy or otherwise of the informed consent process.”

Professor Stubbs obtained expert advice from colorectal surgeon Dr Richard Perry regarding the risk of an anastomotic leak. Dr Perry acknowledged that “estimation of the risk of leakage from a colorectal anastomosis is not an exact science”. He reviewed published literature and concluded:

“If a quantification of risk is to be given, I do not think Professor Stubbs erred far from the mark when he described a 5% risk of anastomotic leak.”

However, he qualified this as follows:

“It is very difficult to take a literature based quantum statistic for risk of anastomotic leakage and apply it to an individual patient undergoing high anterior resection. There are aspects of the consent process which are much more important and helpful to the patient than a fraught analysis of the quantitative risk of an anastomotic leak.”

In response, Professor Parry noted:

“It is problematic for all patients, for all surgeons, for all operations, for all times because of the essentially stochastic nature of surgical complications. Nevertheless it is the best we have and underpins all quality and audit endeavours to optimise patient outcomes. Nihilism serves no useful purpose except as a refuge.”

Discussion

Professor Stubbs’ legal counsel observed, in his letter of instructions to Dr Perry, that “there is a major philosophical difference between [HDC], who has a liking for reasonably precise percentages of risk in assessing warnings to be given when obtaining informed consent and Professor Stubbs ... particularly when performing the more advanced and rare surgery which he offers ...”.

This is to mischaracterise the issue at the heart of the case. It is not a matter of philosophy but of law. Patients are entitled to the information that a reasonable patient, in their circumstances, would expect to receive, including “an explanation of the options available including an assessment of the expected risks, side effects, benefits, and costs of each option”.¹⁶

What were Mr A’s circumstances in November 2007 when he consulted Professor Stubbs? He had incurable bowel cancer that had metastasised into his liver. His oncologist had referred him to Professor Stubbs at his private practice in another centre, for consideration of innovative treatment (SIRT and HAC) not available anywhere else in New Zealand. The treatment was expensive and Mr A had no health insurance. He was keen to pursue any option that might extend his life. He needed to have an anterior resection of the rectum with probable primary anastomosis (plus cholecystectomy and insertion of a hepatic artery port-a-cath) before the SIRT and HAC could proceed.

A patient in these circumstances would certainly expect to be told about any risks that the surgery itself might worsen his overall condition. I agree with Professor Stubbs’ point that patients do not expect mathematical precision. But there is a major difference between a 1 in 20 (5%) risk and a 1 in 5 (20%) risk.

I accept that an individual surgeon may choose to disclose his own track record, eg, “This risk has eventuated for 5 of 100 patients on whom I have performed the operation.” But in my view, a responsible surgeon must (1) contextualise his personal track record by reference to well recognised, published risk data (eg, “Other surgeons report that this risk eventuated for 5–20 of 100 patients”) and (2) adjust the estimate of risk based on the individual patient’s circumstances.

Dr Perry does not think that Professor Stubbs “erred far from the mark when he described a 5% risk of anastomotic leak”. In contrast, Professor Parry considers the “minimal 5% risk is much too low in this case” and estimates that Mr A’s risk was in excess of 20%.

¹⁶ Right 6(1)(b) of the Code of Health and Disability Services Consumers’ Rights.

As Professor Stubbs' legal counsel notes, "it is within [the Commissioner's] remit to decide between differing opinions and frame [the] final report accordingly".

In my view, Professor Stubbs underestimated the cumulative risk factors relevant to Mr A's situation, including his male sex, his high comorbidity because of extensive cancer, his liver metastases, and his preoperative steroid use (which Dr Perry recognised probably increased Mr A's risk of anastomotic leak "a little" and "perhaps by a few percentage points").

Dr Perry noted that the overall risk in published studies depended on the make-up of the group and questioned whether it was valid to add these risk estimates cumulatively. But the stepwise increase in risk referred to by Professor Parry, based on the Auckland City Hospital experience, was from a baseline risk, not an overall risk. The baseline low-risk subgroup (0–1 risk factors) had a risk of 3.1%; the risk increased cumulatively to 14.7% with two risk factors, and to 33.3% with three risk factors.

Nor do I accept Professor Stubbs' justification that "even had I hold him of a 20% [risk], he would still have opted for surgery, hoping for subsequent SIRT". It is no answer to a failure to provide adequate information to claim that the patient would have opted for the surgery no matter how high the risk. The patient is still entitled to the information before making a decision.

Patients in desperate circumstances, who are being encouraged to undergo innovative procedures, are particularly in need of full information that does not downplay any risks they face. The "more advanced and rare" the surgery (to quote Professor Stubbs' legal counsel), the greater the need to err on the high side when describing well recognised risks.

Defunctioning ileostomy

Mr B recalls that Professor Stubbs told Mr A that a "bag" was not recommended in his case, although he cannot recall the reasons for this. He does not recall any discussion of the pros and cons of a defunctioning ileostomy or that Mr A was given a choice about it. Professor Stubbs stated that other surgeons "would not have particularly advocated a defunctioning ileostomy in Mr A's circumstance, or been critical of non-use of a stoma". I accept the view of my expert, Professor Parry, that, in light of divergence of opinion about the matter, a reasonable patient would expect to be told about the option of a defunctioning ileostomy, and the effects that an ileostomy might have on his quality of life, and be given the opportunity to make a choice in light of that information.

Conclusion

Professor Stubbs went to some lengths to provide Mr A with information that he considered relevant about treatment options. However, in my view, in light of Mr A's particular circumstances, he was entitled to be told that he faced a risk in the order of 20% of an anastomotic leak, and about the option of a defunctioning ileostomy. I conclude that Professor Stubbs did not give Mr A adequate information, and breached Right 6(1)(b) of the Code.

Opinion: No breach — Professor Stubbs

Appropriateness of care

On 4 December 2007, Professor Stubbs performed surgery on Mr A at the private hospital consisting of anterior resection of the rectum, a cholecystectomy, and an insertion of a hepatic artery port-a-cath for SIRT. Mr A's progress for the first few days after surgery was slow, with abdominal distension and oedema, but no specific complication.

On 16 December Mr A's condition deteriorated and the private hospital nurses asked Professor Stubbs to review him. Dr Johnston considered that the anastomotic leak could have been recognised at this time rather than on 17 December, if Professor Stubbs had had a higher level of suspicion. The signs can be subtle in the early stages, but the risk of leakage was known to be higher because of Mr A's metastatic disease. Dr Johnston considered that Mr A's steroid use may have masked the signs of infection. However, he advised that earlier detection of the leak would probably not have changed the outcome.

Dr Johnston considered that, in general, the care was satisfactory. I conclude that Professor Stubbs did not breach the Code in relation to his standard of care.

Other comment

This is not the first time that Professor Stubbs has breached the Code by inadequate information disclosure. In two recent cases he has been reminded by HDC of the need to improve his informed consent practice. In case 07HDC11318, I stated:¹⁷

“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.

...

What to a surgeon may seem an acceptable risk may be seen in an entirely different light by the patient.”

Similarly, in case 09HDC00795, I noted:¹⁸

“On the basis of the information Dr Stubbs provided to them, Mr and Mrs B opted for oncological treatment, unaware that the vascular access device could fail and what the medical and financial consequences of this would be.

...

¹⁷ 07HDC11318 (17 October 2008) at page 32.

¹⁸ 09HDC00795 (15 September 2009) at page 11.

Information about the possibility of failure of the vascular access device was information that a reasonable consumer in Mr B's circumstances would expect to receive, in light of the medical and financial implications should this occur."

I repeat what I said in case 07HDC11318:¹⁹

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

The first of these cases (following HDC's breach finding and referral to the Director of Proceedings) led to Professor Stubbs being found guilty of professional misconduct by the Health Practitioners Disciplinary Tribunal (Decision No. 271/Med09/113D, 21 December 2009). HDC's breach finding in the second case was challenged unsuccessfully by Professor Stubbs in judicial review proceedings (*Stubbs v Health and Disability Commissioner*, High Court Wellington, CIV 2009-485-2146, 8 February 2010, Ronald Young J).

In my view, there is a public interest in this third adverse finding from HDC in relation to Professor Stubbs' informed consent practice being made public. Each of the HDC breach findings is moderately serious, and they have been made within an 18 month period. My decision to publicly name Professor Stubbs is therefore consistent with HDC's Naming Policy.²⁰

Accordingly, Professor Stubbs will be named in the version of this report placed on the HDC website, upon the expiry of the suppression order preventing publication of his name in the disciplinary proceedings cited above.

Recommendations

I recommend that Professor Stubbs:

- Apologise to Mrs A for his breach of the Code. This apology is to be sent to HDC and will be forwarded to Mrs A.
- Review his informed consent practice in light of this report.
- Advise HDC by 30 April 2010 what steps he is taking to improve his informed consent practice.

¹⁹ At page 38.

²⁰ "Policy Document — Naming Providers in Public HDC Reports", Health and Disability Commissioner, 15 July 2008, accessible at <http://www.hdc.org.nz/>

Follow-up actions

- A copy of this report will be sent to the Medical Council of New Zealand and the private hospital.
 - A copy of this report identifying only Professor Stubbs and the experts who advised on this case will be sent to the DHB.
 - A copy of this report with details identifying the parties removed, except Professor Stubbs and the experts who advised on this case, will be sent to the Royal Australasian College of Surgeons and 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 A

Independent advice to Commissioner — General and Hepatobiliary Surgeon Dr Peter Johnston

This report is given by Peter Stuart Johnston, MB ChB (1978), FRACS (1985). I have been asked by the Commissioner to provide expert advice on this complaint. My background in relation to evaluating this file is of practice in General and Hepatobiliary Surgery since 1986, in the last three years this being solely hepatobiliary, upper gastrointestinal and transplantation surgery. I have read and agreed to follow the Commissioner's Guidelines for Independent Advisors.

Information provided to me by the Commissioner includes:

- Complaint
- Notification letters
- Information from Dr Stubbs
- Information from [the private hospital] including clinical file, response from Mr Stubbs to HDC, operation record.
- Information from [Hospital 2] including clinical file and response from [Hospital 2] management to HDC

[At this stage, Dr Johnston sets out the questions asked by HDC, which have been omitted as they are repeated in the body of his report.]

1. Please comment generally on the standard of care provided to Mr A by Dr Stubbs

[Mr A] was referred to Mr Stubbs from [his home city] after a course of treatment with chemotherapy for colorectal cancer, with liver metastases and the primary recto sigmoid tumour in situ. Mr Stubbs discussed surgery to place an access port for intra hepatic radiation treatment ("SIRT") and excise the primary tumour. The risks of this surgery as noted by Mr Stubbs in his discussion with [Mr A] are in my view quite appropriate. In particular, an incidence of leakage of 5% from the colo-rectal anastomosis was discussed. At the time of the operation (4.12.2007), Mr Stubbs recorded that "there was a degree of obstruction upstream with some dilatation of the bowel and imperfect bowel preparation". Postoperative progress was rather slow, with abdominal distension and oedema which persisted. No specific complication was noted, and this course was evidently ascribed to the magnitude of the surgery in the presence of bulky metastatic disease. On 16.12.07, Mr Stubbs was asked to see [Mr A] by the nurses, the [private hospital] notes refer to low oxygen saturations, Mrs A in her letter to the HDC refers to extreme pain, grey colour, and his being cold and clammy. A chest X-ray to be done the following day was arranged, and a "full and frank discussion" was held with the family about delaying the proposed SIRT treatment.

The next day, [Mr A] had further deteriorated, the chest X-ray showed free intra abdominal gas consistent with perforation of the GI tract (most likely anastomotic

leakage); Mr Stubbs was away that day and [his colleague] became involved and transferred [Mr A] to [Hospital 2] for urgent surgery. Anastomotic breakdown was discovered and the bowel anastomosis converted to a stoma.

I believe that in general the care provided at [the private hospital] was satisfactory, with two reservations. [Mrs A] questions the responsibilities of the nursing staff when a patient is not making the expected progress, noting that it was she who alerted the nurses to call Mr Stubbs on 16.12.07. It is noted that Mr Stubbs had been in touch by phone the morning of that day. Other than the low oxygen saturation, which was obvious although of many possible causes, the clinical situation was evidently not clear enough to alert Mr Stubbs to a major problem when he reviewed [Mr A] at 1600 that day; an experienced nurse will sometimes spot a problem before medical staff notice it, but not necessarily so. I do not think the nursing staff were at fault here.

The first reservation about the [private hospital] care which arises is that the anastomotic leakage problem could perhaps have been recognised on 16.12.07 if a higher level of suspicion had been present. Admittedly the signs of this can be very subtle at first, but in this situation the risk of leakage was known to be higher because of the metastatic disease. Not referred to in Mr Stubbs' commentary is the steroid drug use: it is well known that the usual features of infection such as fever and elevation of the white blood cell count are often masked by steroid drugs. The oxygen desaturation, combined with the slow progress against this background could have been viewed with more suspicion, and more urgent investigation carried out on that day. The outcome would probably not have been different, however, and it is difficult to be certain that earlier recognition was possible.

Related to this is my second reservation, that a primary bowel anastomosis was fashioned in the presence of apparently obstructed bowel, with the additional risk factors noted above. Anastomosis in the presence of obstructed bowel is known to have a higher leakage rate; this problem (or at least its severity) can be averted by adding a protective ileostomy upstream of the join, or an on-table washout of the colon to reduce the faecal load if leakage did occur, or both. Practice in colorectal surgery changes over time and as I no longer practise regularly in the area of colorectal surgery I would suggest the Commissioner requests an opinion of a colorectal surgeon on this specific point, i.e. was a primary anastomosis of the bowel without covering stoma an appropriate operation in [Mr A's] circumstances, noting the degree of obstruction, metastatic disease and steroid administration.

2. If not commented on above, please comment specifically on the management decisions made by Dr Stubbs

The decision to offer surgery was reasonable in light of the patient's strong request for active treatment, although it needed to be recognised that the treatment proposed was at the very limit of what could be done surgically for [Mr A]. It appears that Mr Stubbs' discussion of the risks and benefits was realistic. The other important management decisions have been discussed above, namely the details of the operation and the recognition of the anastomotic leak.

Another, more general comment can be made on Mr Stubbs' response. He extends his commentary to include the role of palliative care services in patients undergoing cancer surgery. It appears he was not asked specifically to comment on this, but does so in discussion of the whole complaint which includes the role of palliative care. Although there was not a clear role for palliative care services to assist [Mr A] and his family at [the private hospital], Mr Stubbs' comments do give rise to concern. He states that discrepancies in approach between the surgical and palliative care philosophies may give rise to "distress and confusion in the minds of the patients and their families", and for this reason tries to avoid combining the two approaches. I think this is an extreme view in 2008; I believe that while a conflict in approach may arise, this is a necessary conflict, with which the patient and family need to engage. The input of an experienced clinician who does not have a subconscious attachment to the success of the surgery can be invaluable in management decisions, and to deny this input, if applied as a regular practice, would deny some patients access to appropriate options. As stated above, I do not think this was the case in [Mr A's] stay at [the private hospital].

3. Please comment generally on the standard of care provided to Mr A by staff of the private hospital

I have touched on this above, and regard the care as satisfactory.

[This section has been excised because it relates to a provider who is not the subject of this investigation.]

Appendix B

Independent advice to Commissioner — Consultant Colorectal Surgeon Professor Bryan Parry

Initial advice

I am Bryan Ronald Parry, Professor of Surgery at the University of Auckland and a Consultant Colorectal Surgeon at Auckland City Hospital. I am vocationally registered with the New Zealand Medical Council, No. 7011, and am a Fellow of the Royal Australasian College of Surgeons as well as a member of the Colorectal Surgical Society of Australia and New Zealand. I am a practising colorectal surgeon with a strong general surgical background, and am the Clinical Director of the Nutrition Support Service at the Auckland City Hospital.

I acknowledge the receipt of photocopies of clinical notes of [Mr A's] stay at [the private hospital] and subsequently during the time of his stay at [Hospital 2]. In addition I have received a copy of a report [from Hospital 2] in response to a request by Rae Lamb the Deputy Commissioner of HDC. Furthermore I have a copy of Mrs A's original letter to the Health and Disability Commissioner of 24 June 2008 with her complaint as well as two letters from Dr Richard Stubbs answering the queries requested by the Deputy Commissioner of HDC.

Pertinent to your request of me, I have an extract of the report previously requested by yourself of Dr Peter Johnston highlighting the key issue for which you require my advice:

Whether it would have been appropriate for Dr Stubbs to have done a defunctioning loop ileostomy at the time of operating on the 4 December 2007 to either reduce the chance of anastomotic leakage or make it less risky to the patient's condition if it had occurred.

Dr Peter Johnston points out that:

“A primary bowel anastomosis was fashioned in the presence of apparently obstructed bowel, with additional risk factors noted above. An anastomosis in the presence of obstructive bowel is known to have a higher leakage rate; this problem (or its severity) can be averted by adding a protective ileostomy upstream of the join, or an on-table washout of the colon to reduce the faecal load if leakage did occur, or both. Practice in colorectal surgery changes over time and as I no longer practise regularly in the area of colorectal surgery I would suggest the Commissioner requests an opinion of a colorectal surgeon on this specific point, i.e. was a primary anastomosis of the bowel without covering stoma an appropriate operation in the patient's circumstances, noting the degree of obstruction, metastatic disease and steroid administration.”

I will attempt to answer this question under the following headings:

Risk factors for anastomotic leaks

The following risk factors for anastomotic leakage after colorectal anastomosis have been recognized by various authors: male gender²¹, previous abdominal surgery²², low rectal anastomosis²³, liver metastases²⁴, preoperative radiation²⁵, occurrence of intra-operative technical surgical problems²⁶, preoperative steroid use²⁷, long duration of operation²⁸, contamination of the operative field²⁹, and patient high ASA score (measure of co morbidity)³⁰.

These data provide a framework in which to consider [Mr A's] case. He was male gender, had high co morbidity because of his extensive cancer, had liver metastases, had preoperative steroid use, as well as having undergone a long operation. I note that blood loss was estimated to be approximately 800ml — which is quite high for this sort of operation and therefore I wonder whether intra operative difficulties were encountered accordingly but not annotated.

Additionally this man had an obstructed colon — an additional factor not addressed by the above literature series as all of them were in the elective setting.

Leak rates in rectal anastomosis

The Auckland Hospital experience revealed an overall leak rate of 7.4% for colorectal anastomosis but the incidence went up stepwise according to the number of risk factors present. In our particular study these were male gender, previous surgery, low anastomosis, and inflammatory bowel disease diagnosis. However this stepwise escalation of leak rate would apply to the other papers quoted above.

Therefore a risk of anastomotic leak rate of 5% as quoted to [Mr A] by Dr Stubbs was, in his circumstance, likely to be too low in my opinion.

Does defunctioning loop ileostomy help?

Matthiessen et al in their randomised control trial of using defunctioning ileostomy found no difference in preventing a leak with a use of temporary stoma per se. Nevertheless Chude et al showed both a reduced incidence of anastomotic leak and a better outcome for those patients in which a defunctioning ileostomy was made.

²¹ Lipska et al, ANZJ.Surg 2006, 76:579–85; Matthiessen et al, Colorectal Dis. 2004:462–9.

²² Lipska et al, ANZJ.Surg 2006, 76:579–85.

²³ Lipska et al, ANZJ.Surg 2006, 76:579–85; Matthiessen et al, Colorectal Dis. 2004:462–9; Buchs et al, Int J Col Dis 2008 23:265–70.

²⁴ Lipska et al, ANZJ.Surg 2006, 76:579–85.

²⁵ Matthiessen et al, Colorectal Dis. 2004:462–9.

²⁶ Matthiessen et al, Colorectal Dis. 2004:462–9.

²⁷ Konishi et al JM Col Surg 2006 202:439–44.

²⁸ Konishi et al JM Col Surg 2006 202:439–44; Buchs et al, Int J Col Dis 2008 23:265–70.

²⁹ Konishi et al JM Col Surg 2006 202:439–44.

³⁰ Buchs et al, Int J Col Dis 2008 23:265–70.

In my view I think a defunctioning loop ileostomy would have been helpful in reducing the impact of an anastomotic leak in this ill patient, and might have reduced its likelihood too. Certainly that would have been the approach taken with this patient in the Colorectal Unit at Auckland City Hospital based on our own data alluded to above.

It has to be said for the sake of balance however that, on a case-by-case basis, the surgeon may choose not to do a loop ileostomy (the risk notwithstanding) in someone like [Mr A] with advanced disease on quality of life (QoL) grounds. A stoma would reduce the QoL in the remaining (short) time of the patient's life expectancy. The patient would have to be made aware of this and be in full agreement however. I am not aware this was done in [Mr A's] case: Dr Stubbs' admission note for [Mr A] on 3 December contains no mention of preoperative stoma siting in preoperative preparation order list.

Summary

1. The risk of anastomotic leakage in this man was significantly higher than 5% in this man's case because of his risk factors including male gender, significant comorbidities, liver metastases, high steroid usage, and an obstructed colon. Extrapolating from the quoted studies, his cumulative odds ratio of increased risk of anastomotic leak would conservatively make it in excess of 20%.
2. A defunctioning ileostomy was advisable and might have reduced the impact of the leaked anastomosis on [Mr A's] clinical course.
3. Despite the evidence cited, there is a divergence of opinion within current colorectal practice about the pros and cons of defunctioning ileostomy. However this would need to have been discussed with the patient prior to the operation and [Mr A's] informed consent obtained for either policy. Not doing so would be a departure from an appropriate standard of care of medium severity in my view.

Further advice

Thank you for inviting me to consider my advice in the light of the three documents enclosed in your letter of 30 June 2009:

- Letter Professor Stubbs 26 Mar 2009
- Professor Stubbs' Operation Note 04 Dec 2007
- My report 14 Jan 2009

1. The operation note clarifies for me that the rectal resection was "high" (or at least "mid") and not "low". I agree the level of resection here has a lesser risk of anastomotic leak than when situated "low" per se, but the other risk factors were still operating, and these are summative or cumulative on their effect on risk.
2. The operation note also provides new insight that it was a difficult dissection due to the state of the tissues perhaps resulting from previous chemotherapy. This is a further

and independent factor in increasing the risk of leak, in my view, and adds to the case for a defunctioning loop ileostomy here.

3. Furthermore the operation note clearly states that the “bowel preparation was imperfect” and that there was “a degree of obstruction upstream and some dilatation of the bowel”.

4. The discursive content of Professor Stubbs’ letter regarding leak rate risks was addressed in my earlier report supported by key literature. In summary, independent risk factors are summative or cumulative in their effect, therefore the nominal 5% risk is much too low in this case.

5. My three conclusions set out at the end of my report dated 14 Jan 2009 remain my assessment of this case.

Appendix C

Expert advice provided by Dr Richard Perry to Professor Stubbs

My name is Richard Edward Perry, MBChB, DipObs, FRACS. I am a New Zealand registered Medical Practitioner and vocationally registered General Surgeon. I studied at the University of Otago Medical School, trained in General Surgery in Christchurch, and specialised in colorectal surgery at Creighton University in Omaha Nebraska and at the Mayo Clinic in Rochester Minnesota, USA. For the past 19 years, I have been in private practice as a Colorectal and Endoscopic Surgeon in Christchurch where I am currently Director of Intus Ltd Gastrointestinal Health at the Oxford Clinic. I am Chairman of the Australian & New Zealand Surgical Skills Education and Training Committee of the Royal Australasian College of Surgeons, and I was a member of the Council of the Colorectal Surgical Society of Australia and New Zealand for 9 years until 2008.

This opinion relates only to the single aspect requested: the content of Professor Parry's summary paragraph 1 which led to HDC criticising the consent process followed by Professor Stubbs.

This paragraph states:

“The risk of anastomotic leakage in this man was significantly higher than 5% in this man's case because of his risk factors including male gender, significant comorbidities, liver metastases, high steroid usage, and an obstructed colon. Extrapolating from the quoted studies, his cumulative odds ratio of increased risk of anastomotic leak would conservatively make it in excess of 20%.”

I do not have the full report of the Health and Disability Commissioner, and I have been provided with limited correspondence upon which this opinion is based:

- A letter of request from Professor Stubbs' lawyer.
- A letter from HDC to Professor Stubbs, dated 18 February 2009, advising of his decision to refer him to the MCNZ
- Report from Professor Stubbs about [Mr A] dated 30 October 2008
- Report by Peter Stuart Johnston dated 10 December 2008
- Report from Professor Bryan Parry dated 6 January 2009
- Letter from Professor Stubbs to HDC dated 26 March 2009
- Further letter from Professor Parry to HDC dated 29 July 2009
- A copy of the original Operation note dated 4 December 2007

At the core of the issue under scrutiny are three questions:

1. What is the risk of anastomotic leakage (leak from the join between two ends of bowel) after high anterior resection of the rectum?
2. What was the risk of anastomotic leakage following this operation on [Mr A]?

3. How should this risk best be conveyed to the patient during the consent process?

1. What was the risk of an anastomotic leak after high anterior resection of the rectum?

- 1.1. [Mr A] had a “high anterior resection”. This means a “high” anastomosis was created between the colon and the rectum, in the abdominal cavity (“above the peritoneal reflection”) and between 10cm and 15cm above the anus.
 - 1.1. Estimation of the risk of leakage from a colorectal anastomosis is not an exact science.
 - 1.2. In a recent (2007) publication of his own data, Australian colorectal surgeon Professor Cameron Platell stated that “it is surprisingly difficult to obtain current and accurate data on anastomotic leak rates from the literature”.¹
 - 1.3. Two key factors in anastomotic leak are:
 - 1.3.1. Skill and experience of the Surgeon. A landmark study demonstrated a variation in anastomotic leak rates from 0% to 25% among surgeons.²
 - 1.3.2. Distance of the anastomosis from the anus. Low anastomoses have a higher risk of leaking.
 - 1.4. Leak rate statistics are derived from a surgeon’s personal audit and/or from published case series: analysis of tens or hundreds of similar (but not identical) cases. Figures vary widely due to variations in patient population and case-mix, experience and specialisation of surgeon and surgical staff, institutional and environmental factors, the location of the anastomosis, evolution and improvements in surgical and perioperative management techniques (which have been significant over the past decade).
 - 1.4.1. For example, of Parry’s Auckland Hospital series of 160 patients undergoing anterior resection between 1992 and 2002, 9% had an anastomotic leak.³ This is a teaching hospital environment where the operating surgeon may be a trainee, or may not be a specialist colorectal or gastrointestinal surgeon.
 - 1.4.1.1. When this figure was refined according to location of anastomosis, the rates were 7.6% for a low (<5cm from anus) anastomosis, 4% for mid (6–10cm from anus) and 14% for high (10–15cm) anastomoses. [Mr A’s] anastomosis was high, so at first glance at Parry’s figures, one might anticipate a 14% risk of anastomosis, had he undergone his operation at Auckland Hospital between 1992 and 2002. However this would not be an accurate estimate because of the patient case-mix. Further review of Parry’s figures reveals that the higher leak rate in the high anterior resection group was due to the high proportion of those patients who had diverticular disease: their leak rate was 26% compared with 5% for cancer patients (p=0.004).

In other words, they had a different underlying disease process and different indication for the operation.

1.4.1.2. Furthermore, the leak rate after high anterior resection was 19% when the inferior mesenteric artery was ligated high (which is done for some cancer cases but not for diverticular disease), and 5% when it was ligated low ($p=0.02$). The latter group is likely to have included most or all of the diverticular disease patients, so the leak rate for patients (such as [Mr A]) with low ligation and high anastomosis for cancer was probably a lot less than 5%. Such is the complexity that the exact rate in this series cannot be extracted from the data given.

1.4.1.2.1. This range of figures from Parry's study alone illustrates the difficulty in quantifying an exact percentage risk of anastomotic leak in an individual patient. There are too many confounding variables.

1.4.2. Another, similar study from Europe looking only at cancer cases had a 4% incidence of anastomotic leak for high anterior resection, 11% for mid, and 24% for low anterior resection.⁴

1.4.3. A prospectively collected personal series published recently of 243 anterior resections performed by two specialist colorectal surgeons showed an overall leak rate for all levels of colorectal anastomosis of 2.5%.⁵

1.4.4. Professor Platell's series from an Australian colorectal surgical unit had anastomotic leaks in 2.3% of high anterior resections for cancer (vs 7% for low anterior resection).¹

1.4.5. A recent large series from Shanghai had a 0.9% leak rate for high anterior resection (vs 5.9% for low anastomosis). Bowel surgeons performed significantly better than General surgeons (3.9% vs 11.3% leak rate over all levels of anastomosis).⁶

1.5. **In Summary**, in experienced hands, there is good, recent evidence that the anastomotic leak rate should be between 0.9% and 5% for a cohort of patients undergoing the same operation as [Mr A]. Note that there is an order of magnitude of difference between these figures.

2. What was the risk of anastomotic leakage following this operation on [Mr A]?

2.1. It is important to note that all the above series contain a heterogeneous group of patients. Individually, they will all have had their own risk factors. The 0.9 to 5% statistic includes all of these risk factors in all of these patients.

2.2. It is common practice to attempt to refine the risk estimate for an individual patient based on their unique risks. It is not valid to add these risk estimates cumulatively to the group statistic described in paragraph 1. The more frequently the risk factor occurs, the more reliably it will have been already

- accounted for in the group statistic. The less frequently it occurs, the less accurate the unique risk statistic will be.
- 2.3. There are factors, in addition to those outlined above, which are more likely to be present in patients who develop an anastomotic leak. It would be almost impossible to classify and study enough patients to resolve the quantum of risk directly attributable to each of these factors.
 - 2.4. There is almost universal agreement that the following factors are statistically significantly associated with anastomotic leakage: male gender, diabetes, cigarette smoking, low pre-operative albumin, prolonged operation, and excessive intraoperative blood loss.
 - 2.5. I will deal with two other risk factors separately because they were raised by Professor Parry:
 - 2.5.1. **Acute colonic obstruction** is a risk factor for anastomotic leakage. However, this risk factor was identified in patients presenting with acute fulminant colonic obstruction requiring emergency operation. In this situation an anastomotic leak is more likely to occur because the patient has many additional compromising factors, including fluid and electrolyte imbalance, impaired colonic perfusion, and gross colonic distension causing inflammation. [Mr A] did not have an acute colonic obstruction and I do not consider that the reference made in the operation note describes clinically significant obstruction that would significantly increase the risk of anastomotic leak.
 - 2.5.2. **Preoperative steroid use** has been identified as a risk factor because steroids impair wound healing.
 - 2.5.2.1. As difficult as it is to put a meaningful figure on the general risk of anastomotic leak, it is even more difficult to ascribe a quantitative risk increment to the use of steroids.
 - 2.5.2.2. The duration of steroid therapy and the dose received over the few days prior to the operation are probably also important factors.
 - 2.5.2.3. Steroid use appears inconsistently in the list of risk factors in published studies. Steroid use is generally a marker of another underlying disease process. In many cases, it is these processes (rather than or in addition to the steroids per se) that contribute to the additional risk of anastomotic leak.
 - 2.5.2.4. This is well illustrated in two excellent recent papers from USA and from France, where the authors set out to try to refine our understanding of the risks of anastomotic leakage. In their univariate (single factor) analysis, both studies showed an increased risk of anastomotic leak in patients on steroids. However, this increased risk did not persist on multivariate analysis, which allowed for the underlying conditions being treated with steroids, such as inflammatory bowel disease. These conditions are therefore

at least as relevant as steroid use itself when assessing the risk from steroid use.^{7,8}

- 2.6. **In Summary**, [Mr A's] risk of anastomotic leak was probably a little increased by his preoperative steroids, but there is no data upon which this can be quantified. From the description of the obstructive element in the operation note, I do not think it materially affected the risk of anastomotic leak.

3. How should the risk of anastomotic leak best be conveyed to the patient during the consent process?

- 3.1. Leak rate figures describe a statistical risk: What they say is that if 1000 patients have a high anterior resection, it is very likely that between 9 and 50 of them will develop an anastomotic leak.
- 3.1.1. Each one of those 1000 patients will have other factors that may influence the outcome of the operation for them. The impact of these factors cannot be quantified.
- 3.1.2. Surgical expertise is a factor too.
- 3.1.3. Therefore, it is very difficult to assign an accurate numeric value to the risk in any individual patient. The most meaningful statistic would come from the surgeon's personal experience. This is particularly so when the surgeon is highly specialised, so that his patient series will be sufficiently large and more homogeneous with regard to other risk factors than would be a series from a less specialised unit or from a teaching hospital.
- 3.2. It is reasonable, and common practice in obtaining informed consent, to try to give a patient a tangible concept of their risk of an anastomotic leak (amongst other things). The best a surgeon can do in that regard is to offer that by his estimate and experience, when he performs the operation in question on 100 patients, a few will leak (say 2–5). He might estimate that due to steroid use or other comorbidities, the likelihood of a leak is increased, perhaps by a few percentage points. Ultimately, we do not really know how much more likely any individual is to leak because they are on steroids, and we don't know whether that particular patient will be the unlucky one.
- 3.3. The heterogeneous basis from which the anastomotic leak rate statistics are derived make it a nonsense to argue about variations in relative risk of a few percentage points, or even of a low order multiple. Leak rate data can do no more than give a rough guide as to the order of magnitude of a risk.
- 3.4. **In Summary**, it is very difficult to take a literature based quantum statistic for risk of anastomotic leakage and apply it to an individual patient undergoing high anterior resection. There are aspects of the consent process which are much more important and helpful to the patient than a fraught analysis of the quantitative risk of anastomotic leak. If a quantification of risk is to be given, I do not think that Professor Stubbs erred far from the mark when he described a 5% risk of anastomotic leak. There is no scientific basis upon which the cumulative risk from [Mr A's] comorbidities can be extrapolated to a 20% risk of anastomotic leak.

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Appendix D

Further independent advice to Commissioner — Consultant Colorectal Surgeon Professor Bryan Parry

Thanks for your invitation to comment on this ongoing file. I acknowledge the attached documents from [Professor Stubbs' lawyer] and Richard Perry both of which I have considered.

1. Richard has provided information gleaned from the published literature of risk of anastomotic leak (AL) after anterior resection. In brief, he argues that the application of statistical risk of AL from diverse reports of heterogeneous groups of patients to that of an individual patient such as [Mr A] is problematic. However, it is problematic for all patients, for all surgeons, for all operations, for all times because of the essentially stochastic nature of surgical complications. Nevertheless it is the best we have and underpins all quality and audit endeavours to optimize patient outcomes. Nihilism serves no useful purpose except as a refuge.
2. He contradicts my assessment of AL in [Mr A's] case by selecting a different set of papers than mine. Fair enough, and theoretical discussion needs to be open and comprehensive. However the study from Auckland in which I took part is arguably closer to the environment in which [Mr A] underwent surgery than elsewhere particularly overseas. I therefore have confidence in the rigour of our study and its applicability to his case.
3. Richard has overlooked that risk factors are derived from studied independent variables revealed by multiple regression analysis. The independent variables or risk factors are *additive* and ramp up any particular individual's risk of AL alarmingly if he/she has multiple co-morbidities. That is why my estimate is 4 times higher than his in [Mr A's] case.

Turning to the nub. If, at the regular Audit Morbidity and Mortality Meeting in my institution my colleagues sought explanations of me about such a case, I would expect an uncomfortable time. Not to have done, or at least discussed, a defunctioning stoma with the patient would likely be received with surprise and even incredulity. It would be regarded with moderate opprobrium.

In fairness, as I said in a previous submission, not to do a temporary stoma *is* an option when considering quality of life issues in terminal patients when the risk might be deemed worthwhile. However the patient's informed views are paramount and the discussion needs to be had.

My opinion remains unchanged.