ROYAL INFIRMARY OF EDINBURGH
Little France, Old Dalkeith Road, Edinburgh EH16 4SA

SCOTTISH LIVER TRANSPLANTATION UNIT
Secretary 0131- [redacted]
Fax No. 0131- [redacted]
Email: [redacted]

Consultant Physician - Dr A J MacGilchrist
Secretary - 0131 [redacted]

1 March 2011

Ms Tracey Turnbull
Senior Solicitor
Central Legal Office
NHS National Services Scotland
Anderson House
Breadalbane Street
Bonnington Road
EDINBURGH
EH6 5JR

Dear Ms Turnbull

I enclose my report on the Reverend Black as requested. It is my view that the hepatocellular carcinoma from which he died seven years after his original transplant is more likely to be a de novo tumour rather than a recurrence of the tumour present in his explant. Our records indicate that the Reverend Black's transplanted liver came from a male donor. With donor and recipient the same gender, we cannot utilise Dr Mutimer's suggestion to determine the source of the tumour.

Either myself or Dr Bathgate would be more than happy to meet with Reverend Black's family to discuss all this if they so wish. Please do not hesitate to get in touch if you require more information.

Yours sincerely

A J MACGILCHRIST
Consultant Physician

Medical report on David Black (010537)

I, Dr Alastair MacGilchrist, MD, FRCP, have been employed as a Consultant Hepatologist in the Scottish Liver Transplant Unit since it opened in 1992. I have prepared this report for Ms Tracey Turnbull, Senior Solicitor in the Central Legal Office, in response to an enquiry from the relatives of the Reverend David Black which has arisen from reports prepared for the Penrose Inquiry.

The Rev David Black received a liver transplant to treat his hepatitis C related cirrhosis on the 21st April 1996. He developed recurrent hepatitis C in his transplanted liver which progressed to recurrent cirrhosis. In May 2003 he was diagnosed with hepatocellular carcinoma in the transplanted liver. This progressed rapidly and he died in Strathcarron Hospice on the 31st October 2003.

The subject of this report is the information provided to the Rev Black's family regarding his HCC. I suspect that this does not relate to the diagnosis of HCC in his transplanted liver in 2003, which I am confident will have been discussed in detail with the patient and his family, recognising that that was the cause of his fatal illness. Instead, I think the question will relate to the fact that HCC was also found in his original cirrhotic liver removed at the time of his transplant in 1996. The reason for his liver transplant was liver failure, and his pre-operative investigation had not revealed evidence of a tumour. However when the liver removed at the time of transplant (referred to as the explant) was examined, the pathologist found at least 8 nodules of HCC within the explant, the largest of which was 4 cm in diameter.

On reviewing his records, neither the handwritten in-patient notes during his hospital stay following his transplant, nor the many letters relating to his clinic visits following his transplant comment on this finding of multifocal HCC within the explant. I therefore speculate that this finding was somehow overlooked by the medical team which would explain why it was not discussed with the Rev Black's family (and by implication with the Rev Black himself).

The risk of tumour recurrence following liver transplantation is proportional to the size and number of tumours present within the liver at the time of transplant. Where this is diagnosed by imaging prior to liver transplant, only patients with a limited size and number of tumour nodules are considered suitable for transplant, reflecting the high risk of recurrence where multiple large tumour nodules are present. In 1996, routine pre-operative imaging only involved ultrasound scanning, and the Rev Black's ultrasound scan at the time of assessment for liver transplant did not show any focal lesion to suggest a tumour.

Where patients are transplanted with HCC present, either recognised prior to the transplant or discovered in the explant, the question of routine scanning to detect tumour recurrence post-transplant arises. However experts are divided on whether or not this is necessary or useful, since patients will only be transplanted with a low risk of recurrence, and if unlucky enough to develop recurrent tumour, it is almost invariably incurable. In 1996 our policy was to carry out ultrasound scans and serum alpha feto protein (AFP) measurements (a serum marker for HCC) every six months. It soon became apparent that the detection rate of asymptomatic tumours was vanishingly small and we have since changed our practice to a CT scan at six months and one year post-transplant, thereafter only if clinically indicated.

The Rev Black's first post operative ultrasound was in 1998 when he was being investigated for abnormal liver function tests. That ultrasound showed no evidence of tumour, and a liver biopsy showed that the abnormal liver function tests were due to recurrent hepatitis C. The handwritten notes from that admission in 1998 do mention the tumour in his explant two

years earlier. The notes do not state whether this was discussed with the Rev Black himself then or at any other time.

When he developed his HCC in his transplanted liver in 2003, i.e. seven years after his transplant, the question arose as to whether this was a recurrence of his original tumour or a new (so called *de novo*) tumour within his transplanted liver which by this stage had developed cirrhosis due to recurrent hepatitis C. I do not have any documentation regarding that discussion, but my consultant hepatology colleague Dr Bathgate recalls raising this very question with a senior colleague at another transplant centre because this was such an unusual development. Because of the very long interval from the time of transplant to the development of the tumour, it was concluded that this was most likely to be a *de novo* tumour rather than a recurrence. I agree with that conclusion.

Our current routine practice is that if an unexpected tumour is found in an explanted liver, this will be discussed with the patient. The timing of that discussion will vary according to the circumstances, either during their in-patient recovery period, or at an early clinic visit soon after discharge from hospital. In most cases tumours discovered in this manner will be small and have no adverse effect on the outcome of the transplant, particularly given the more extensive pre-transplant imaging which takes place nowadays. Although I do not think that we will have had a formal policy on such cases in 1996, the discovery of such extensive multifocal carcinoma in the explant would have been considered significant because the risk of recurrence, given the size and number of the nodules, would have been deemed considerable, and I would expect this to have been discussed with the patient. This is why I am surprised that there is no mention of the tumour in the correspondence, hence my suspicion that the medical team caring for Rev Black during the early post transplant period, both as an in-patient and at his initial clinic visits, were unaware of the explant findings.

I cannot deduce from his records how (or whether) this presumed gap in communication occurred. Pathology reports are initialled prior to filing in the notes, and the pathology report in question has been so initialled by one of the transplant unit registrars. The discharge summary relating to his transplant admission and the first two post-operative clinic letters are written by another of the registrars. The transplant unit operates a team approach to patient care: a consultant surgeon and consultant physician together look after all in-patients for a week at a time; each out-patient clinic is run by a consultant physician on a rotational basis, who will discuss every patient at that clinic. Thus several surgeons and physicians will have looked after the Rev Black during the post-operative period when one would expect the issue of the HCC in his explant to have been discussed.

On behalf of the liver transplant unit, I would like to take the opportunity to apologise to the Rev Black's family for any distress that this new information has caused. Whilst regretting the circumstances, I am confident that more explicit recognition and discussion of the multifocal HCC in the explant in 1996 would not have altered his subsequent clinical course. I would be more than happy to meet with the family to discuss this further if they so wish.

A J MACGILCHRIST

1st March 2011