IRISH HAEMOPHILIA SOCIETY

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TRIBUNAL OF INQUIRY

(Into the Infection with HIV and Hepatitis C of Persons with Haemophilia and Related Matters)

PROCEEDINGS: Tuesday 3rd April 2001 - Day 113

The Chairperson commenced proceedings by congratulating Mr Martin Hayden S.C., for the I.H.S., on his elevation to Senior Counsel, and wished him well in his practice at the Inner Bar.

Mr John Finlay examined Sister Frances O'Hora. Sister O'Hora was sister in charge of the surgical ward at the national Children's Hospital from November 1985. Children with haemophilia admitted to the National Children's Hospital were by preference admitted to the surgical ward. Sister O'Hora dealt with both in-patient and out-patient children with haemophilia.

Sister O'Hora described the procedure whereby a child would be admitted for treatment for a bleed and be treated by the doctor. Sister O'Hora said the doctor would decide which treatment was appropriate, and the doctor would administer the treatment. The sister would record the treatment on a printed form which would then be supplied to the National Haemophilia Treatment Centre at St. James's Hospital. Sister O'Hora said that when she arrived at the National Children's Hospital it slowly began to dawn on her that there were children being treated who were HIV positive.

Mr Finlay referred Sister O'Hora to a study entitled *HIV Infection in the Irish Paediatric Haemophilia Population to May 1989*. Sister O'Hora said she did not know who prepared this study. Of 34 children with severe haemophilia attending the National Children's Hospital, 16 were infected with HIV, 14 of whom had haemophilia A and two of whom had haemophilia B. Of the 16 infected with HIV, seven were asymptomatic, five had symptoms of AIDS, and four had HIV symptoms. One child had died by the end of 1988.

Sister O'Hora said children with HIV were treated in the same manner as other children, except when it was necessary because of their illness to isolate them. Universal precautions were taken and in this way all children were treated the same.

Sister O'Hora told Mr Finlay that from time to time product would be recalled to St. James's Hospital from the NCH. She did not however specify when this had happened.

Sister O'Hora was cross-examined by Mr Jim McCullough for the Irish Haemophilia Society. Sister O'Hora said the doctor who would administer factor VIII and factor IX would be either a doctor who was assigned to Prof. Temperley, or the doctor on house. Sister O'Hora said the doctor on duty would administer the factor VIII and factor IX and would sign the treatment form and the forms would be returned to St. James's Hospital. Sister O'Hora said she was never formally told about HIV. No procedure was in place for identifying those patients who had become infected with HIV. Sister O'Hora said she became aware of the children who were infected with HIV during the course of her duties. She said in dealing with the parents of such children, they would discuss the presenting illness but would not discuss the issue of HIV. Sister O'Hora said they would use whatever product was supplied to them by St. James's Hospital. There was no discussion on the relevant merits of the product.

PROCEEDINGS: Wednesday 4th April 2001 - Day 114

Mr Gerry Durcan for the Tribunal, examined Dr Paule Cotter.

Dr Cotter is consultant haematologist at Cork University Hospital. She took up her post on 1st October 1979. Dr Cotter explained to the Tribunal that home therapy became possible when concentrate became available in and around 1973. Until the advent of factor concentrates Dr Cotter said the life expectancy of people with haemophilia was around 16 years. Dr Cotter said in 1979 she compiled a register of her 38 haemophilia patients. Also in 1979 a home treatment programme was established for people with severe haemophilia. The object of the programme was to prevent the effect of haemophilia such as joint deformities witnessed previously. Patients and parents, where appropriate, were trained in the administration of home therapy, which was viewed as a beneficial process at the time. Dr Cotter said it allowed normal life to proceed with some families going on holiday for the first time ever.

Mr Durcan asked Dr Cotter to describe any downside of home therapy treatment. Dr Cotter said hepatitis was a constant danger with respect to treatment with concentrates. However, she said patients were well informed. The I.H.S. educated its members, she said, at this time HIV was not known. Dr Cotter said that all blood products posed a risk of hepatitis. There was a slightly increased risk in using concentrate. Dr Cotter said that NANB hepatitis was regarded as a relatively mild condition at this time. Those exposed to treatment on a regular basis with concentrate were almost certain to get hepatitis, she said. Dr Cotter said that all treatment is a matter of balancing benefit against risk. She said in the early 1980's, the dangers of concentrate treatment were not apparent, whereas the benefits were obvious. The consequences of using concentrate were not clear in 1980 and 1981, said Dr Cotter.

Dr Cotter said the first reports of HIV infection emerged in late 1982 with respect to infections among the homosexual population in the United States. She said she first became aware of the threat of HIV from a report of a baby contracting HIV from a blood transfusion. She said this was in and around late 1982.

With respect to Dr Cotter's state of knowledge in 1983, Mr Durcan summarised it as being that HIV was blood-borne, that concentrate carried a risk, that it was a U.S. problem, and that the BTSB was supplying U.S. concentrate. Dr Cotter said the haemophilia treaters in Ireland took their lead from Prof. Temperley, who followed the guidelines of the UK Haemophilia Centre Directors.

Given the knowledge that HIV was blood-borne, Mr Durcan asked Dr Cotter, in what way did her practice change in the spring of 1983? Dr Cotter said they attempted to implement the guidelines. Dr Cotter said in mid-1983 the policy was to follow the protocols drawn up by the National Haemophilia Treatment Centre. Dr Cotter agreed that these protocols no longer existed as they had been updated. Dr Cotter said there was a protocol in 1983 along the lines suggested by MASAC. Dr Cotter said this was contained in the UK Haemophilia Centre Directors Guidelines. She said that these guidelines were distributed to junior doctors, but she was not assured of compliance with them. Mr Durcan asked Dr Cotter, was it the case that there was a protocol but she was not sure that everyone adhered to it? Dr Cotter said, to the best of her knowledge the policy was adhered to.

Mr Durcan asked Dr Cotter, did she tell her patients that the risk of using concentrate was increasing, particularly during 1983. Dr Cotter said she was reassured by the document from the UK Haemophilia Centre Directors, and from the words of Prof. Bloom, that while there was a risk there was no indication that she should stop using concentrate.

On 22nd December 1983 Prof. Temperley published guidelines which were copied to Dr Cotter. Dr Cotter agreed that these guidelines were drafted following Prof. Temperley's visit to the UK Haemophilia Centre Directors. Dr Cotter said protocols in existence prior to this were treatment protocols.

Mr Durcan asked Dr Cotter if, by the end of 1983 and the start of 1984, did a considerable risk arise from using concentrates, and should it not therefore have been used if at all possible? Dr Cotter said she did not think the risk was considerable. She said that the UK Haemophilia Centre Directors were not describing it as considerable. It was known there was a risk but the impression was not one of considerable risk. In discussions she had with her patients there was no mention of considerable risk.

Dr Cotter agreed with Mr Durcan that by the autumn of 1984 the risk attendant on the use of concentrates had become much clearer. She said she had come to this view following her attendance at the World Federation of Hemophilia conference in Rio. She also said she had come at this stage to realise a problem existed in the UK and Ireland.

Mr Durcan referred Dr Cotter to the case of Louis, a child with mild haemophilia who was treated for a laceration to his head in November 1982. Dr Cotter said Louis continued to bleed, even with treatment for his bleed. She said he did not respond to tranexamic acid. The wound was oozing and she had to consider that internal bleeding was a possibility. She made a decision to administer concentrate. Dr Cotter said that DDAVP was not approved until mid-1983 by the FDA. She said she made her decision as a clear clinical decision, having weighed the benefits and the risks.

Mr Durcan referred Dr Cotter to a letter written to Louis's general practitioner on 10th January 1984. The letter points out to the doctor that the present policy is to treat the boy with cryoprecipitate rather than commercial concentrate, should he need haemophilia cover. However, early in 1984 it is noted that in respect of the prospect of dental work, Louis would be treated with Hemofil if necessary. Dr Cotter said that a dental extraction was a very serious matter for a person with haemophilia, especially a child. Mr Durcan put it to Dr Cotter that in early 1984 it would have been reasonably clear that there was a considerable risk of transmission of HIV virus through a dose of Hemofil. Dr Cotter said that on balance she thought that the correct clinical course to take was to administer concentrate. She said this was the case even though the risks of the virus were certainly becoming clearer.

Mr Durcan asked Dr Cotter did she explain to the child's mother about the risk. Dr Cotter said that in May 1984 the risk was still theoretical, and did not amount to a considerable, risk. Mr Durcan put it to Dr Cotter that by May of 1984 the risks of Hemofil and the risks of concentrates, and the risks of getting HIV from concentrates was very clear indeed. Dr Cotter said that this may be the case retrospectively, but she was not sure she could be that certain in May of 1984.

Mr Durcan asked Dr Cotter, could she remember telling Louis' mother that risks attached to the use of Hemofil. Dr Cotter said she did not recall. Mr Durcan put it to Dr Cotter that, while it was not clear that the suggested dental surgery did in fact take place, in the circumstances Louis would have been fortunate if it didn't; particularly as heat-treated product would become available within six weeks of the suggested use of Hemofil in late 1984. Dr Cotter agreed.

Mr Durcan referred Dr Cotter to the case of Tim, a boy with mild haemophilia who was treated with factor concentrate on 30th may 1983 for cover of teeth extractions. Dr Cotter said he had a previous bleed from the mouth and bled excessively. 250ml of factor concentrate was administered because of the small volume, the ease of administration, and to prevent serious complications. Dr Cotter said DDAVP was not licensed until April 1984. Cryo was unsuitable for this patient, she said, due to its large volume, his small veins, she said it was easier to treat him with concentrate.

Mr Durcan asked Dr Cotter were Tim's parents informed as to the risks of concentrate? Dr Cotter said she was not sure what patients were told at this time.

Mr Durcan asked Dr Cotter if the treatment afforded to Louis and Tim suggested that the protocols were being followed? He noted that both were classified as mild haemophiliacs and were being covered for dental extractions by concentrates. Dr Cotter said she did not think the treatments afforded to these patients suggested the protocols were followed. She said that patients sometimes behave in a clinical manner that is unexpected.

Mr Durcan asked Dr Cotter would it not have been possible to use cryo as the first option, and revert to concentrate only if the cryo did not prove suitable to cover the projected treatment? Dr Cotter agreed that this could have been done.

With respect to seeking heat-treated products from Armour in December 1984 on a named-patient basis, Dr Cotter explained that this was necessary because heat treated product was unlicensed in 1984. She did not consider seeking heat treated commercial factor IX at the same time. Dr Cotter said that BTSB supplied factor IX from Irish voluntary donors. The same considerations which applied to the use of heat-treated factor VIII did not apply to factor IX.

Mr Durcan asked Dr Cotter if she took any steps to get heat-treated commercial factor IX product for her patients in the early months of 1985 while waiting from BTSB to heat treat its products? Dr Cotter said she was aware there was a small risk from BTSB unheat- treated factor IX in use by the Cork centre in 1985. Mr Durcan asked Dr Cotter why, during 1985, she had taken no step to ensure that her patients got safer heat treated factor IX? Dr Cotter said, "Looking back now, perhaps I certainly should have". Dr Cotter said it was not always possible to get everything she required, and 1984 was a very difficult period for the health services.

Mr Durcan put it to Dr Cotter that since she had not actually looked for heat treated factor IX, financial constraints could not have come into play because if she didn't look for the product she could not have looked for the money for the product. Dr Cotter said she would accept that.

Mr Durcan referred Dr Cotter to the issue of testing patients for HTLV-III in December 1984/January 1985. Dr Cotter said there was considerable delay in the test results being returned from the VRL. She said she got a list of test results in June 1985. Results came back piecemeal and Mr Martin of the Blood Transfusion Unit, compiled a list updating it as results came in. Dr Cotter said patients were told at the time of the test that it was for HTLV-III.

Mr Durcan referred Dr Cotter to the case of Fred, whose medical record notes he refused to have a HIV test in 1990. The 1985 list of test results notes that Fred's HIV test is negative. Dr Cotter said she could not be certain that Fred had not been told he was negative. Mr Durcan put it to Dr Cotter that those tested would have been anxious to know their test results. She said they may have been. Dr Cotter said that the initial results were kept in a drawer in her office.

Mr Durcan asked Dr Cotter who would inform people of their HIV test results. Dr Cotter said it would be her or a member of the haematology staff. She also said that counselling in respect of test results was on offer from Mr Evans, the infection control nurse. Dr Cotter said that in early 1985 the significance and natural history of the HIV condition was unknown. She said that the I.H.S. and the Cork AIDS Alliance made facilities available and were active and helpful at the time. Mr Durcan put it to Dr Cotter that this was a less than satisfactory situation. Dr Cotter said that this was the case.

Mr Durcan referred Dr Cotter to the case of Mr Gerard Healy, whose January 1985 test was returned as "negative – below cut-off. Please repeat". Mr Durcan asked Dr Cotter was the January test repeated? Dr Cotter said that the January sample was re-tested. This test was not carried out until November of 1985. A fresh test was then conducted in December of 1985, however Dr Cotter said that a test may also have been carried out in May of 1985. In any event, Mr Durcan put it to Dr Cotter that a repeat of the January test being delayed until November of 1985 was unsatisfactory and undesirable. Dr Cotter indicated that she would have to have access to her notes before she could fully ascertain whether or not a test had been conducted in May.

Mr Durcan then referred Dr Cotter to the case of Noel. Noel was tested for HIV in January 1985. Dr Cotter said she was sure he was told later that year that the test results were positive. A letter written by Dr Cotter in1992 refers to the fact that Noel did not appear to realise that he was HIV positive. Dr Cotter said this may just have been his impression. She believed he was told in late 1985 of his HIV positivity, but there was no record of this. Dr Cotter said that efforts were made to contact Noel while he was in England, where he had emigrated in1988. Such efforts were directed at ensuring that Noel received adequate follow-up treatment for his HIV, said Dr Cotter, not for the purpose of giving him his test results. While it appeared from the medical record that Noel did not know of his HIV positive status until 1992, Dr Cotter said that when people got bad news they sometimes went into a state of denial. Evidence to this effect had been already adduced to the Tribunal by the social worker for St. James's Hospital, she said.

Dr Cotter's evidence was interrupted by a brother of Noel, Fred, who was in attendance at the Tribunal. He said he was the brother of Noel who had died in 1999. Fred then left the Tribunal.

Following a short adjournment, Mr Durcan indicated that Fred apologised to the Tribunal for his intervention. He realised that such intervention was inappropriate.

Mr Durcan referred Dr Cotter to the case of Garret. Dr Cotter informed Garret's GP in 1985 that he was HIV negative. In fact Garret was HIV positive. Dr Cotter's view was based on a hand written list containing a result for Garret. The list was inaccurate. Dr Cotter said she accepted that this was an unsatisfactory situation. Garret discovered he was HIV positive when he read correspondence addressed to his parents which mentioned his positive status. It also emerged that Garret's mother had not been told of Garret's HIV positive status until 1990. Garret's mother learned of her son's HIV positive status when she met Dr Cotter by chance at Cork Regional Hospital in 1990 prior to her son's departure on a holiday to France. Garret's mother had been at the hospital to collect factor concentrate for him. Dr Cotter said she was of the view that Garret's parents knew of his HIV positive test shortly after she had got the result. Dr Cotter said she could not remember the exact circumstances of informing Garret's mother of his HIV positive status.

PROCEEDINGS: Thursday 5th April 2001 - Day 115

Mr Durcan continued his examination of Dr Paule Cotter.

Mr Durcan referred Dr Cotter to the case of Andrew. Andrew is a severe factor IX deficient haemophilia B patient. From the early 1980's Andrew and his brother attended the Cork centre for prophylactic treatment. Dr Cotter agreed with Mr Durcan that in 1985 Andrew and his brother continued to be treated with unheat-treated BTSB factor IX. Dr Cotter agreed that the Cork centre did not have a supply of commercial heat-treated factor IX at this time, so no question arose of treating Andrew with heat-treated factor IX.

Andrew was tested for HTLV-III in January 1985 and the test proved negative. Dr Cotter said Andrew was also tested in July of 1985, and that she had seen documents which indicated a result of this test was returned to Cork in September of 1985, giving a positive result. However, Dr Cotter was not able to direct the Tribunal to any documents in the medical record before it that would support her position. Mr Durcan told the Tribunal that the Virus Reference Laboratory would give evidence that no such tests were conducted on serum from Andrew in July 1985. Mr Durcan agreed that the documentation showed that a test had been dispatched to the VRL in July 1985, but does not indicate that it was returned in September.

Mr Durcan directed Dr Cotter to an extract from the Virus Reference Laboratory day book which indicates that a test sample from Andrew was sent to the Virus Reference Laboratory on 12th November 1985. The result of the test was positive and it was notified to Dr Cotter on 14th November 1985.

Mr Durcan referred Dr Cotter to a further extract from the VRL day book. A specimen dated 1st January 1985 received by the VRL on 3rd December 1985, confirmed negative. This meant that an aliquot from the earlier sample had been re-submitted in December and had been confirmed as a negative. Such confirmation was received by Dr Cotter on 5th December 1985. Dr Cotter agreed that the test taken in July, which proved positive, was confirmed positive in November 1985. With this information Dr Cotter agreed that the pattern of test results indicated that Andrew had seroconverted some time after January of 1985.

Prior to this there had been no haemophilia B seroconversions. Dr Cotter said that the huge significance of this did not impress upon her at the time. Dr Cotter said that the Cork centre was getting a whole series of tests back. They were getting negatives and positives. She also said that the BTSB withdrew product at this time, but it was only in December 1985 that she realised that a patient with haemophilia B who had been treated with home produced blood transfusion service board produced product had become positive. Mr Durcan asked Dr Cotter whom she contacted when she realised that her haemophilia B patient had seroconverted? Dr Cotter said she had no distinct recollection of contacting anyone in December of that year. Dr Cotter said she may have contacted the Department of Health. She may have contacted Prof. Temperley but had no distinct recall of telling Prof. Temperley in December. She had no distinct recollection of informing the BTSB. Dr Cotter said the BTSB had already withdrawn the batch so she presumed that they had done so for a reason. Mr Durcan asked Dr Cotter did she tell the BTSB that one of her patients had seroconverted while using their product? Dr Cotter said she had no recollection of doing so.

Mr Durcan asked Dr Cotter how she could have known which batch of BTSB product had caused the infection? Dr Cotter said she did not know which batch caused the infection, but assumed that since the BTSB had withdrawn a batch of product that this was the infected batch.

Mr Durcan referred Dr Cotter to a document from Mr McGrath of the Blood Transfusion Unit in Cork University Hospital, which outlined the usage of batch no. 90633 in 1985. The document accounts for 100 vials of factor IX dispatched by the BTSB to Cork in 1985, the batch number being 90633. Dr Cotter insisted that a withdrawal had taken place in October 1985 of BTSB factor IX. However, it would appear that all the vials of batch no. 90633 dispatched to Cork were used. Mr Durcan put it to Dr Cotter that it appeared to be the case that, after having discovered that BTSB factor IX had caused the seroconversion in her factor IX patient, that the same product continued to be used through the month of December 1985, the last of it being used on 19th December. Mr Durcan pointed out that not only was a BTSB product used, but the actual infected batch continued to be used up to two week after Dr Cotter had positive proof that it had caused the first recorded FIX serocoversion in this State.

Mr Durcan put it to Dr Cotter that, despite her knowledge that one of her patients had seroconverted due to unheat-treated BTSB factor IX, some of her patients continued to use that product after she was aware of her patient's seroconversion. Mr Durcan put it to Dr Cotter that, after she became aware of the seroconversion and after she became aware of the fact that it must be due to BTSB product, the situation was allowed to continue whereby the very product that had caused the infection continued to be used, and that she didn't take any effective step to stop the use of this product. Dr Cotter accepted that this was the case.

Mr Durcan put it to Dr Cotter that it must have been obvious to her that the BTSB product was dangerous because that product had infected one of her patients, and at this time she had very clear proof that this was the case. In those circumstances, said Mr Durcan, did she not feel that she should have contacted the BTSB and told it there was something wrong with one of its product, in that "it has infected one of my patients". Dr Cotter said, "I think in retrospect, yes, I would accept that. I should have done that." Mr Durcan pointed out to Dr Cotter that the batch in question continued to be used up until February of 1986. He also said that the BTSB could not have known it was infectious unless she told them that she had proof positive that their product was causing infection. Dr Cotter agreed that this was the case.

Mr Durcan referred Dr Cotter to a letter from Prof. Temperley in April 1986, where he asked Dr Cotter to repeat HTLV-III tests and said he would discuss the need for this later. Mr Durcan asked Dr Cotter, had she told Prof. Temperley about Andrew at this point? She said she believed she had. Mr Durcan put it to Dr Cotter that the tenor of the letter did not indicate that Prof. Temperley knew about the seroconversion of Dr Cotter's factor IX patient.

Mr Durcan referred Dr Cotter to an *Irish Times* article of 8th June 1986, containing a report on the seroconversion of people with haemophilia B as described by Prof. Temperley at a public meeting in UCD. Mr Durcan said it would appear that when Prof. Temperley wrote to the BTSB in April of 1986, he did not appear to know if the seroconversions had been caused by commercial factor IX or BTSB factor IX. They were still trying to figure it out. Mr Durcan put it to Dr Cotter that she knew for sure in 1985, and if she had told Prof. Temperley in 1986 of the BTSB seroconversion in Cork, he would not have been so uncertain in his UCD presentation or in his letters to her. Dr Cotter said things were not as clear then as now.

Mr Durcan put it to Dr Cotter that it was important for the BTSB to know that their product was infected due to the risk of infecting others that the continued use of the product presented. Dr Cotter should have informed the BTSB earlier, suggested Mr Durcan. Dr Cotter agreed she should have done so. She said it was an omission on her part not to have done so at the time.

On the issue of hepatitis C, Dr Cotter agreed that tests were available from 1991/1992 onwards. She said this was so, but they were wary of test results until PCR became available in 1994.

Mr Durcan asked Dr Cotter how did persons with haemophilia in Cork come to be tested for hepatitis C. Dr Cotter said some were referred to Dr Tobin in Dublin. Dr Power of the BTSB made testing available on a limited basis when the hepatitis C/anti-D hepatology unit was set up. Dr Cotter agreed that accurate testing was available in Dublin from 1992, however such testing was not available in Cork. Dr Cotter said some of the haemophilia population in the Cork group of 20-30 people had been tested. Those that had not been tested were eventually given the test in 1995 when local facilities were put in place, said Dr Cotter.

Mr Durcan asked Dr Cotter could those in need of testing not have travelled to Dublin to be tested. Dr Cotter said this could have been done but they needed a hepatologist to look after and counsel them following testing. Mr Durcan put it to Dr Cotter that the advantages of early testing would have been the availability of earlier treatment and the reduced risk of passing on infection. Dr Cotter agreed that these were significant advantages which had been foregone by not testing people with haemophilia for hepatitis C. In the event, a three year delay occurred in testing those with haemophilia in Cork for hepatitis C. Dr Cotter agreed that such testing could have been done, but she said that she was taking advice from her colleagues.

On the issue of the lack of an infectious diseases consultant in Cork, Dr Cotter agreed that the absence of an infectious diseases consultant meant that those infected with HIV were less likely to get a referral. They would suffer recurrent infections and their CD4 count would decrease. Dr Cotter said she herself prescribed AZT. She said that when triple therapy became available she referred people to Dublin. This occurred in September or October 1996.

Dr Cotter was then cross-examined by Mr Raymond Bradley for the Irish Haemophilia Society. Mr Bradley referred Dr Cotter to the case of Garret. He put it to her that he was instructed that Garret's mother was not informed of her son's HIV positive status until August of 1990. Dr Cotter said she would accept that Garret's mother came to know of his status in and around that time.

Mr Bradley then referred Dr Cotter to the case of Noel. In her evidence of the previous day, Dr Cotter had indicated that she thought she had informed Noel of his HIV status before he went to the UK in 1988. Dr Cotter indicated that she thought he had been informed sometime around November 1985. Dr Cotter said Noel had been informed of his HIV status but this was not recorded in his medical record as it was not her practice to record HIV status for reasons of confidentiality.

Mr Bradley directed Dr Cotter to her statement, where she notes that Noel was contacted through his family with a view to having him attend for review. In Dr Cotter's supplemental statement she notes that Noel is to be advised re: follow-up. Mr Bradley put it to Dr Cotter that she did not mention in her statement or supplemental statement that she had informed Noel in 1985 of his HIV positive status. Dr Cotter agreed that there was no documentary evidence in the medical notes or elsewhere that Noel had been told he was HIV positive in and around 1985. However Dr Cotter said that the indications in the notes were that he had been told.

Mr Bradley asked Dr Cotter how she kept a record of those patients who had been informed of their HIV diagnosis. Dr Cotter said she kept most of it in her head and she knew from the type of recording in the notes that the patient had been informed.

Mr Bradley put it to Dr Cotter that the record in the medical notes stated in January 1992 that Noel was very upset in respect of his diagnosis as he did not realise he was HIV positive. Mr Bradley put it to Dr Cotter that he did not realise he was HIV positive because he had not been informed until 1992. Dr Cotter said her use of the word "realise" indicated to her that Noel been told previously of his HIV status and had either failed to grasp the information or had forgotten it. Mr Bradley asked Dr Cotter if this was

the case, why had she not instructed her Counsel to cross-examine Noel's brother Eoin on that basis on Day 10 of the Tribunal? Dr Cotter said she could not answer that question.

Mr Bradley asked Dr Cotter, was it her evidence that she sought Noel not to inform him of his HIV diagnosis, but to ensure that he received adequate healthcare and furthermore that he could pursue litigation. Dr Cotter agreed that this was the case. Mr Bradley asked Dr Cotter, was she seeking him out to pursue litigation in circumstances where she was likely to be one of the defendants? Dr Cotter said her primary reason for seeking him out was to ensure that he had medical follow-up, and also to inform him of the compensation available. She said whether she would be sued was a separate issue.

Mr Bradley referred Dr Cotter to the witness Ernie. Dr Cotter explained that Ernie first came to the Cork treatment centre following a hair transplant. Dr Cotter said following this procedure, he bled profusely and was admitted in a collapsed and shocked condition. Mr Bradley asked Dr Cotter, did she consider prescribing cryoprecipitate at this time, as Ernie was upon his admission a previously untreated patient with haemophilia? Dr Cotter said that this patient was collapsed, shocked, and had almost bled to death. She wanted to ensure that she gave him the most effective treatment to stop the bleeding, and the most effective treatment was concentrate. She said he also needed blood transfusions, which indicated the severity of the bleed. Mr Bradley asked Dr Cotter, was it normal practice to treat a patient with mild or moderate haemophilia with concentrate in the first instance? Dr Cotter said that this incident happened in December 1982. In her opinion the patient was shocked, he needed a blood transfusion and was bleeding to death, and she needed to stop the bleeding as a matter of urgency.

It is noted in Ernie's medical records that shortly after his treatment with concentrate he developed jaundice, indicating non-A, non-B hepatitis. On 7th March 1995, Ernie received a letter from the Blood Transfusion Service Board indicating he was hepatitis C positive. Mr Bradley asked Dr Cotter, as the treating consultant was she aware of the practice of informing patients of their hepatitis C positive status by post? Dr Cotter said that the letter in the medical record was a confirmatory letter; the patient would have already been seen in preliminary testing by the doctor.

PROCEEDINGS: Friday 6th April 2001 - Day 116

Mr Bradley continued his cross-examination of Dr Cotter, and referred Dr Cotter to the case of Ernie.

Mr Bradley asked Dr Cotter about health consequences in delaying the testing of those with hepatitis C. Mr Bradley put it to Dr Cotter that the risk of transmission of hepatitis C, and the health consequences for the person affected, meant that delay had a serious consequence for the patient. Dr Cotter said she had learnt a lot about hepatitis C over the last few years, and she was anxious that patients would get treatment. By delaying testing, Ernie was at risk for a considerable period. Dr Cotter said there was no PCR testing in Cork and it was not possible for her to have PCR done at an earlier stage.

With respect to the case of Oliver, Mr Bradley noted Oliver was assayed with a 50% range of factor VIII. Dr Cotter agreed that someone with this level of factor VIII would not normally need treatment. However, she said that sometimes the level assayed does not correlate with the extent of the bleeding.

It would appear that Oliver was treated with concentrate on 18th May 1982. Oliver was referred for hepatitis C screening at his own behest in 1997. Mr Bradley asked, how could a person such as Oliver, who had been treated with concentrate, have been overlooked in compiling a list of those who should be tested for hepatitis C even as late as 1995 when hepatitis C testing became available? Dr Cotter said that the records of the Cork centre were not satisfactory. It was not possible to trace each person who may have got concentrate. In relation to Oliver's late hepatitis C diagnosis, Dr Cotter said that the records at the time were not as complete as they are now, nor was there a record of treatment schedules to say that he had been given factor VIII. Due to these facts Oliver was lost in the follow-up, said Dr Cotter.

Dr Cotter said that Oliver should have been tested with other people with haemophilia, but he seems to have slipped through and was not tested in that way. No treatment database existed at this time, said Dr Cotter, patient records were compiled manually and it was therefore not possible to trace each patient who had received factor concentrate.

Mr Bradley put it to Dr Cotter that, by looking at the treatment record, the patient register or the medical record of the patient, she could have ascertained that he had received concentrate and was in need of a hepatitis C test. Dr Cotter said she obviously was not successful with this particular patient. Mr Bradley put it to Dr Cotter that the consequence of this for Oliver was that he was at risk of transmitting hepatitis C, and that his health was deteriorating during the period in which he went undiagnosed for hepatitis C? Dr Cotter accepted that this was the case.

With respect to Mr Gerard Healy, a person with mild haemophilia A, Dr Cotter said that the use of concentrates significantly improved quality of life for such patients.

Mr Bradley also referred Dr Cotter to the medical records of Eoin, Fred and Noel. With respect to the medical records of Dominic, Mr Bradley noted that Dominic discovered his hepatitis C status when he read a referral letter from a Dublin-based physiotherapist describing his case to a fellow medic. Dr Cotter said no clear line of communication existed at the time.

With respect to the patient Louis, a two year old child with a factor VIII level of 50 per cent, who was treated with factor VIII on 24th November 1982, the records show that Louis was admitted to hospital on 21st November 1982 and was given concentrate on November 24th, Asked why concentrate was given, Dr Cotter said she was concerned that the bleed suffered by Louis was continuing to ooze. She feared an intra-cerebral bleed danger. The patient's condition was serious and distressful. In these circumstances

she determined that concentrate was an appropriate treatment. Mr Bradley asked Dr Cotter was any effort made to administer cryo as opposed to concentrate. Dr Cotter said she could not recall.

With respect to the treatment of Andrew and other factor IX deficient haemophilia B patients in Cork in December of 1985, Dr Cotter agreed that the contaminated factor IX supplied by the BTSB was administered to four patients up to a month after Dr Cotter learned that the BTSB factor IX had caused seroconversion in Andrew. The four haemophilia B patients received contaminated BTSB factor IX on 8th, 13th and 19th December 1985. Andrew's brother was among this group. Dr Cotter received confirmation of Andrew's HIV positive status on November 14th 1985.

Dr Cotter was cross-examined by Mr Ian Brennan for the Department of Health. Mr Brennan asked Dr Cotter, had she ever informed the Department of Health of the seroconversion of her patient in November of 1985. Dr Cotter said she was under the impression that the Department of Health was so informed by the VRL. She agreed with Mr Brennan that she had attended a meeting on 13th December 1984 with Department of Health officials, at which the issues concerning HIV infection and the use of heat-treated blood concentrates was discussed.

Dr Cotter was cross-examined by her own Counsel, Mr Angus O'Brolchain. Dr Cotter said the delay in responding to test results was partly because the positive test result for Andrew was contained within a number of other results arriving at the same time. She also said the issue of confidentiality and the hysteria surrounding AIDS, created a problem in dealing with the results.

The Tribunal adjourned until 24th April, 2001.
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