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INFECTED BLOOD INQUIRY

EXHIBIT WITN2287040

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Dear Roseanna

I am writing in response to your letter of 19 April on the decision of the Health Committee to call for a full judicial inquiry into infection with Hepatitis C through NHS treatment, with a particular focus on the efficacy of the 'look-back' exercise.

I have put on record on a number of occasions our sympathy for those who have contracted Hepatitis C through NHS treatment. This has had serious consequences for the lives of many people, and we do not underestimate or minimise these consequences. As you and your Committee know well, it is for this reason that the Scottish Parliament and Scottish Ministers took the lead in ensuring that payments were made under the Skipton Fund to those patients affected to recognise the suffering and hardship involved. The creation of a UK payments scheme has been a significant achievement and step forward.

I recognise the concerns which the Committee continue to have about some of the issues in relation to Hepatitis C, and I will deal in this letter with the key issues which were raised in the discussion and papers presented on 18 April.

Look-Back Exercise

Concerns have been expressed by the Committee that some patients did not know for long periods that they had been infected with Hepatitis C, in particular through blood transfusions, and that there should have been a more thorough and comprehensive strategy for tracing and counselling patients.

As my earlier letter explained, a UK look-back exercise was started in 1995 to trace as many patients as possible who had contracted Hepatitis C through blood transfusions. This exercise was agreed by UK Ministers on the basis of medical and scientific advice, and the different options for carrying out the look-back were carefully considered. I set out below the detail of how the look-back exercise was developed and the basis for the decisions taken. These were decisions taken by the UK Government, based on advice from the relevant professional advisory committees, before devolution. I do not think there can be any strong basis for seeking to reopen these issues, and revisit these decisions now, ten years later.

The look-back was a complex exercise which involved linking the records of blood donations and recipients of transfusions, and was a comprehensive and innovative public health approach to tracing individuals who might have become infected through blood. The look-back exercise was based on the methodology of a pilot exercise which was carried out by the Scottish National Blood Transfusion Service (SNBTS) in south-east Scotland. The results of that pilot were published in 1994. Given the encouraging results from this study, the decision was taken to conduct a look-back exercise throughout the UK.

The options for a more comprehensive approach to look-back, looking at either all blood donors or all archived samples of blood donations, were considered. The professional advice to Ministers was that the work involved in these alternative options would be disproportionate to the benefit because of the very large number of donors and blood donations involved, but in cases where an individual who had given blood requested a test this should be made available.

Testing and counselling of partners and relatives of the deceased would also have raised difficulties in tracking individuals and where they were living, often after some lapse of time. The risks of transmission of Hepatitis C through sexual relations is low although it can occur. The evidence indicates a 3% life-time risk of transmission (there is no risk of Hepatitis C transmission through everyday social contact). Seeking to trace partners and relatives would therefore have been in practical terms a very difficult exercise for a group of people where there would be a relatively low chance of identifying any transfusion-related infection.

The look-back exercise was carried out between 1995 and 1997, and covered all donors who tested positive for the Hepatitis C virus from the date of introduction of testing in 1991. For each donor who was found to be positive, the frozen archived samples of the previous donations were tested. Where these were positive, hospitals were asked to trace every recipient of each donation. In some cases this involved transfusions that had taken place a long time in the past. This included looking at manual hospital records where these were available. However, the recommendation at that time was that hospital blood bank records should be retained only for 11 years. Records were often incomplete, and could not necessarily be used to trace patients.

For these reasons the look-back exercise did not extend to all potential recipients of infected blood transfusions. It was estimated in 2001 in work by Dr Kate Soldan that 3,500 recipients may have received blood transfusions or tissue infected with the Hepatitis C virus. However, many of these will have died from their underlying conditions within a relatively short time after transfusion. Work for the Lord Ross Expert Group in 2003 projected on the basis of this estimate that about 800 recipients were still alive at that time.

I attach details of the timescale for the UK look-back exercise. This was announced on 11 January 1995 through a PQ, press release and press conference. The Scottish National Blood Transfusion Service also issued a press release to ensure awareness of the exercise in Scotland. The press releases included a UK helpline number for any member of the public who was concerned about the risk of Hepatitis C from a blood transfusion. Anyone at risk contacting the helpline was advised to consult their GP. Information on the look-back exercise and the helpline was also circulated to all hospital consultants and GPs.

The CMOs in England and Scotland also issued a letter and advice to all doctors on how to advise any patient who requested a test for Hepatitis C, and how to go about the process of getting the test results. This ensured that no group of doctors which needed to be included was left out of this important exercise.

It is important to note that anyone who had a blood transfusion prior to 1991, and is concerned about the risk, is able to consult their GP and to request advice and testing. If a test proves positive, SNBTS will carry out an investigation to trace any other recipients from any donors involved. Similar look-back work was carried out in other countries on a similar timescale. The results of a look-back study in Amsterdam were published in 1995. Denmark, Canada and the US started to carry out look-back exercises between 1995 and 1998. The results of these were broadly similar to experience in the UK.

There was a review of progress with the look-back exercise in January 1996. There was some concern that this was slower in achieving its objectives than had been predicted because of problems in identifying patients and medical records. The professional advice, however, was that: "it was important to continue with the present strategy. This had been carefully designed to identify and offer counselling and treatment to recipients of blood transfusion units implicated in the Look-Back in a structured way that would maximise benefits to them."

This conclusion was endorsed by Ministers who agreed that the look-back strategy should continue.

An important factor also in the timing of the look-back exercise was the licensing from 1994 of alpha interferon for treatment of chronic Hepatitis C. This meant it was possible to offer treatment to those who tested positive for Hepatitis C as a result of the look-back exercise. In the absence of an effective treatment option, there could have been concerns about whether it was appropriate to take pro-active steps to trace and test people who could be infected with Hepatitis C. If people who were unaware of their situation were informed that they had Hepatitis C, but no effective treatment could be offered, this would simply cause distress and anxiety without any benefit.

Where new Hepatitis C positive donors now come forward, or any new cases of infection arise where a link with blood transfusion is suspected, these will be investigated in a similar way to the look-back exercise. Since 1998 SNBTS has investigated 32 transfusion-transmitted infections related to Hepatitis C. In half of these cases it was possible to rule out transfusion-related transmission. In six cases a blood transfusion received before testing for Hepatitis C started in 1991 was identified as the possible source of infection and appropriate follow-up action was taken to trace any other recipients from the donor involved. The remaining cases could not be resolved because the necessary records were not available. This evidence confirms that some new and previously unknown cases of Hepatitis C infection from blood continue to come forward, but that these now represent very limited numbers.

Communication with patients

It has been suggested that there are cases where the professionals knew that a patient was infected but the patient was not informed. I think it would certainly be regrettable if this had occurred. The issue of how patients are informed that they have an infectious disease is essentially a matter for the professional relationship between the clinician and the patient. There is specific GMC guidance on this issue which I referred to in my letter to the Committee of 20 February (para 19). Doctors are expected to obtain consent from patients before testing for a serious communicable disease. Where a patient is diagnosed with such a disease, the doctor should explain to them the nature of the disease, and its medical, social and occupational implications, and ways of protecting others from infection.

Testing for Hepatitis C

Committee members raised a number of issues in relation to the introduction of testing for Hepatitis C, and whether testing should have been introduced earlier.

It was stated that there was a non-specific test which would have identified non-A, non-B Hepatitis in the period before 1991. It is not correct to say that the test in question - the ALT test - would have done this. The test detects evidence in the blood that may indicate that there has been some damage to the liver. ALT test results are raised temporarily after heavy drinking, and usually raised in people who are overweight. The test would have many false positive and false negative results in relation to Hepatitis C. This is therefore not an accurate way of detecting infection with hepatitis viruses. Since the discovery of the Hepatitis C virus, it has been possible to compare surrogate testing directly with the specific test for the virus. A number of studies have shown that there is little or no correlation, suggesting that ALT testing would have been largely ineffective as a screening tool for Hepatitis C.

It was suggested that research was carried out on ALT testing instead of introducing routine screening, and that this knowingly put people at risk of transmission of non-A, non-B Hepatitis. This is a serious allegation, and I cannot accept that people were knowingly put at risk.

It is correct that epidemiological research was undertaken on the blood donor population in England and Scotland to establish the feasibility of performing routine ALT testing and interpreting the results in a meaningful way. The research was to try to understand more about the possible reasons for an individual having an elevated test result. As noted above, the principal causes of an elevated ALT result in the blood donors who participated in Scotland were obesity and alcohol intake. These findings did not suggest that excluding donors with an elevated ALT result would reduce infection risks to recipients, and the authors of the research concluded in their published reports that their results did not provide support for the introduction of donor screening. This was later supported by the absence of any correlation between non-specific tests and the specific test for Hepatitis C. The research had ethical approval from the appropriate Ethics Committee, and no concerns were raised about it.

Reference was also made during the Committee discussion on 18 April to a letter from the then Medical and Scientific Director of SNBTS about the introduction of testing for the Hepatitis C virus for all blood donations. This was fully introduced from September 1991 as a result of a UK-wide policy decision, based on relevant clinical evidence and scientific advice. However, some testing was introduced earlier in parts of Scotland where this was possible – for example, in Glasgow from early July 1991. Testing was therefore introduced to Scotland in line with other parts of the UK as soon as a reliable test was available and could be practicably implemented. Scotland was not behind the rest of the UK in implementing this test, and there was therefore no disadvantage to patients in Scotland. As far as the terms of the letter quoted are concerned, clearly this was intended when it was written as an item of private correspondence and it would be inappropriate to draw conclusions from the language used.
The question was raised in the Committee of whether blood donations are always tested for the Hepatitis C virus. I can give absolute assurance that this is always undertaken. The Scottish National Blood Transfusion Service are not aware of any case since testing was introduced in 1991 where the Hepatitis C virus has been transmitted through a blood transfusion.

There is reference in the papers submitted to the Committee to untested plasma being retained for use beyond 1991. This material did not represent a Hepatitis C risk as all plasma products underwent virus inactivation steps during processing, and coagulation factors were Hepatitis C safe from 1987.

Public Inquiry

I cannot accept that there is any need for a full public inquiry into the infection of patients with Hepatitis C through treatment with NHS blood and blood products. I have set out fully the background to the UK look-back exercise, and the decisions that were taken about the groups to be covered. These decisions were taken by UK Ministers prior to devolution, based on professional advice, and reflected considerations of proportionality and practicability. There can be no case for reopening these issues now. The look-back exercise was a complex undertaking which was a carried out in a targeted and robust way.

The look-back exercise was fully communicated at the time to the public and to doctors. There was advice available through a helpline to those who were concerned about the risks from transfusion, and advice to doctors on counselling for people at risk and how to arrange for testing. I would like to emphasise that testing and counselling are still available for anyone who considers they are at risk as a result of a transfusion before 1991. Anyone who has concerns can raise those with their GP and request testing.

A full judicial inquiry would be a major and time-consuming exercise which would depend on the recollections of witnesses about events which took place twenty or more years ago. This would make it difficult to construct a clear and detailed picture of what took place.

An inquiry would not add significantly to our understanding of how the blood supply became infected with Hepatitis C, or the steps needed to deal with problems of this kind now or in the future. The transmission of Hepatitis C through the blood supply took place in the period before testing was introduced in 1991, and at a time when there was limited scientific and medical knowledge about the condition and the outlook for patients. There is already substantial published evidence on how the understanding of Hepatitis C and its implications for blood donation, blood products and blood transfusion developed over time. A public inquiry would not add to this.

Practice in terms of communication between health professionals and patients, and assessing and communicating the risks of medical treatment, has changed significantly since the 1980s when these infections occurred and important lessons have been learned. It is unlikely that an inquiry would identify new issues or areas for improvement in practice for the future which have not already been discussed or implemented.

Conclusion

I have considered very carefully the points which were put before the Committee, and discussed by it on 18 April. I do not believe a public inquiry would either uncover any new evidence or information that is relevant to the causes of the infection of NHS patients through blood and blood products, or lead to significant lessons for the future. It would be a diversion of effort from delivering and improving health services today. I cannot see that there is any possible justification for the efforts and costs that would be involved, or that this would bring any benefit to the patients involved.

On the basis of this position I would ask the Committee to reconsider the decision regarding the call for a public enquiry.

Yours

GRO-C

ANDY KERR