Cynulliad Cenedlaethol Cymru
The National Assembly for Wales

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Dr A Keel
Deputy Chief Medical Officer
Scottish Executive Health Department
St Andrew's House
Regent Road
Edinburgh
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Eich cyf / Your Ref
Ein cyf / Our Ref

GRO-C

01 November 1999

Dear Dr Keel

HEPATITIS C

You may have seen the minute from Mike McGovern (attached for convenience) summarising the hepatitis C allegations made in the News of the World.

Preliminary investigations here in Wales led us to believe that no blood products produced in Scotland were requested by the Welsh Blood Transfusion Service, but my colleagues here in the National Assembly for Wales have been informed by DoH that some non-virally inactivated blood products found its way to Wales and, presumably, was used.

Would you or the Protein Fractionation Centre be able to trace through invoices/records etc whether or not some of the blood products from the allegedly less than safe plasma might have found their way to Wales.

With kind regards,

Yours sincerely

GRO-C

~~DR~~ **BILL SMITH**
Senior Medical Officer

CC Dr Salter
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Angel, Janet (HP)

From: Smith, Bill (HP)
Sent: 26 October 1999 17:04
To: Angel, Janet (HP)
Subject: FW: Hepatitis C and Reports in Scottish News papers

Janet, There included with Gareth's e-mail a cryptic message from DoH. Gareth may already have a copy in which case could you please ask him for a copy so that I may read learn and inwardly digest before replying. Many thanks.

Bill

From: Griffiths, Gareth (HSM)
Sent: 26 October 1999 08:45
To: Salter, David (HP); Smith, Bill (HP)
Subject: FW: Hepatitis C and Reports in Scottish News papers

David/Bill

To see. I am never quite sure where your roles are in relation to blood and Hep C and so I am copying this to both of you.

Para 7 of Mike McGovern's note is worrying. When I first raised the issue with the WBS of potentially infected blood products from Scotland coming to Wales during this period, their understanding was that none had come. Mike's information disagrees with this. I am not sure how we should be handling this; asking WBS to re-check their facts with Scotland or asking Haemophilia Directors covering Wales whether any Welsh patients were affected or doing both and perhaps more. Your thoughts would be welcome.

Gareth Griffiths
HSM3B
NHS Directorate
Ext GRO-C

From: Mike.McGovern@GRO-C [SMTP:Mike.McGovern@GRO-C]
Sent: 25 October 1999 08:11
To: Ann.Handicott@GRO-C
Cc: Rachel.Dickson@GRO-C; Hester.McLain@GRO-C; Sheila.A.Adam@GRO-C; Charles.Lister@GRO-C; mike.palmer@GRO-C; john.mcgrath@GRO-C; Gareth.Griffiths@GRO-C
Subject: Hepatitis C and Reports in Scotttish News papers

NoW Article oct.doc

PQ and reply by hand

(See attached file: NoW Article oct.doc)

CMO From: Mike McGovern

Date: 25 November 1999

Cc List

Fears over Killer Bug Mix Up –NoW Scotland: 17 October

You asked for advice about the claims made in this article which appeared in the Scottish edition of News of the World 17 October. The claims were that hundreds of patients across the UK would need to be tested following possible infection with hepatitis C that lord Hunt had ordered an inquiry into the release of '190 doses of blood' possibly infected with hepatitis and that the enquiry would try to discover why the safeguards set up to prevent hepatitis C transmission through blood had failed.

Origin of the story

2. The article picks and chooses from PQ 3435 put by Lord Morris and answered by Lord Hunt 18 October. Han Ref:Vol 605, Col WA 89-90 - attached. This explained that 190 vials of coagulant factor processed in Scotland at temperatures insufficient to eliminate hepatitis C were used in England, Wales and Northern Ireland. The answer went on to say that we were asking all UK Haemophilia Directors to ensure that all who might have been infected by hepatitis C should be counselled tested and where appropriate, treated. The answer rejected an inquiry into hepatitis C.

A Scottish problem

3. The report is a conveniently inaccurate report and attempts to extend a specific Scottish problem with the heat inactivation of plasma in the production of blood products to the UK in general. Susan Deacon, Scottish Health Minister, is currently investigating why the viral inactivation processes used Protein Fractionation Centre in Edinburgh (run by the Scottish National Blood Transfusion Service) between 1984 and 1987 did not fully inactivate hepatitis C. We are in close touch with her officials on the handling of the issue.

Heat inactivation of plasma

4. Heat inactivation of plasma was introduced in the early 1980s primarily to eliminate HIV, not hepatitis C. At that time hepatitis C was not fully characterised and a diagnostic/screening test did not become available till 1989 up when it was only known as hepatitis non A non B. Scotland introduced heat inactivation in September 1984 and England in February 1985. It was known that heat inactivation would also get rid of hepatitis non A non B but the were questions about the intensity required. Of course the greater the intensity the less active coagulation factor could be extracted.

5. Therefore PFC used a process in which the plasma used to make blood products was heated to 68 degrees whereas in the BPL process the plasma was heated to 80 degrees. Both processes inactivated HIV. In retrospect it was discovered that heat treatment also inactivated non A non B hepatitis but that full inactivation of this virus could only be achieved by heating to a higher temperature than that required to inactivate HIV. When this information became available in 1987, PFC increased the temperature at which they heated the plasma to 80 degrees as BPL was already doing, and further transmission of hepatitis non A non B was checked.

Consequences of using the Scottish heat inactivation process

6. It is unlikely that the failure of full viral inactivation of Scottish blood products led to any significant increase in the numbers infected with hepatitis C. This is because over 98% of all haemophiliacs treated up then would have been hepatitis C positive in any case from previous exposure. It is true that new previously untreated patients would have been at risk. Information from Scotland indicates that less than patients are likely to have been infected. This could not be interpreted as negligence as the critical inactivation temperature for hepatitis C was unknown and the process was introduced primarily for HIV.

Export of Scottish blood products to other UK countries

7. Information form the Scottish Executive indicates that a total of 190 vials of clotting factor blood products went to England and Wales during this time. Scotland occasionally provides clotting factors to E&W when there are supply problems. Scotland processes all plasma derived clotting products used in Northern Ireland. Again the numbers infected are likely to be vanishingly small in view of the hepatitis C status of the majority of English and Welsh haemophiliacs at the time as well as the small quantity of Scottish material used.

Summary

8. The News of the World article is confused and inaccurate. This may be intentional -to exaggerate the scale of the problem, to extent what is essentially a Scottish issue to the other UK countries and to increase pressure for hepatitis C compensation which Ministers are resisting. Susan Deacon will take a view on the Scottish issue in due course.

Line to Take agreed with Scotland

The circumstances surrounding those who may have contracted hepatitis C through treatment with blood products are tragic. Ms Deacon met the Haemophilia Society last month to hear their comments first hand and officials within the Scottish Executive Health Department are making enquiries into the

circumstances surrounding this issue. Ms Deacon will be better placed to consider whether any further action on the part of the Scottish Executive is indicated when these enquiries are completed.

Mike McGovern

Health Services Directorate

Hester McLain
Ann Handicott
Sheila adam
David Hewlett
Charles Lister
Gwen Skinner
Mike Palmer Scotland

SCOTTISH EXECUTIVE

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Karin Pappenheim
Chief Executive
The Haemophilia Society
Chesterfield House
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Date: 27 September 1999

GRO-C

Dear Karin,

At our meeting on 14 September I promised to write to you outlining the way forward agreed between us on the issue of Hepatitis C and the safety of blood products received by haemophiliacs in Scotland.

I hope you will agree that our meeting was a worthwhile and constructive one. I want to reiterate that I come to this issue willing to look afresh at your concerns in the light of the facts which I have asked my Department to gather. As I said at the meeting, that means that until I have had the opportunity to assess the evidence it would not be right for me to begin to speculate on the rights or wrongs of the issue and on whether or not financial compensation might be warranted.

I have made clear that I want to satisfy myself that the Executive properly addresses any matters which may require action. That is why I have asked the Department to look at the events surrounding the introduction of heat treatment for blood products in the mid-1980s, and in particular the concerns you have raised regarding the discrepancy between developments in England and Scotland.

The Department would expect to have examined the necessary evidence on this matter within a month. Having received the Department's advice I would then propose to issue their findings into the public domain. I have also made clear that the Executive would then require a period of time to arrive at a considered position on the matter, taking into account any relevant legal advice.

As part of this process the Scottish National Blood Transfusion Service have invited representatives from the Society to an internal meeting, during which SNBTS can explain the factual chain of events behind the development of heat-treated blood products in Scotland in the 1980s and take any questions on the subject from the Society. I understand that Michael Palmer from the Department has been in touch to discuss arrangements for this meeting.

During our meeting a number of other matters were raised concerning an alleged lack of information given to patients about the risks of contracting HCV/NANBH from blood products, and about an alleged delay in informing haemophiliacs that they were HCV positive after they had been tested as such. Concerns were also raised about the need for authoritative data on the numbers of haemophiliacs infected with HCV and to ensure that all of those affected are receiving appropriate counselling and other support.

As I intimated at the meeting, the Department will also consider these points, although I expect a longer timeframe will be required to complete any enquiries around these issues.

We share the same objective of gathering the evidence which will enable us to come to a conclusion based upon the facts of the matter. To this end you should feel free to submit any information which you think would be relevant to the Department's investigation to Michael Palmer.

Finally, I should confirm that I would be content to hold a further meeting with the Society once our enquiries are complete and the Executive's position is clearer.

GRO-C

SUSAN DEACON