4/5/012

HEPATITIS C - LOOKBACK
Notes for GM, CSA & Executive Group

1. *Introduction*

The overall position on the introduction of formal hepatitis C lookback programmes remains much as it was in my previous report in July 1994 but this note has been prepared as a brief update as requested.

Pilot studies continue to assess the impact for SNBTS. Appropriate liaison with colleagues in England is being pursued. We understand that DoH are involved and that it is still hoped to reach an agreed position on full UK implementation before the year end.

Based on the outcomes of the above a formal submission will be made to CSA/ME for approval in due course. The detailed timetable will depend upon the decision of the Departments of Health, but the SNBTS would anticipate being able to complete our programme within weeks rather than months following the go ahead. In the meantime the answers to the specific questions raised in the GM's memo of 9th September are set out below (2 - 5).

2. *Number of people likely to be affected*

Based on the pilot studies already undertaken in Edinburgh the number of living recipients of HCV compromised transfusions would probably be approximately equal to the number of donors involved. Dr Jack Gillon (Edinburgh & SE Scotland BTS) believes the worst case scenario for Scotland is that up to 300 patients could be found to have been infected by blood transfusion. However, a more realistic estimate is 150. This should be put into perspective against the fact that there are around 5,000 individuals in Scotland who are anti-HCV positive due to other causes. (Circa 1:1000 population).

3. *How to trace affected individuals/links to GPs/counselling arrangements*

The recommendations of the SNBTS Medical & Scientific Committee for lookback arrangements are as under:-

On finding a "known" (or regular) donor who was now anti-HCV positive, the SNBTS should:-

i. Retest previous archive samples to exclude "missed" sero conversion.

ii. For donations issued to hospital blood banks, other RTCs etc, the SNBTS will provide the following minimum information to the clinician to whom the components were sent.

- the component type/s
- donation number/s
- relevant information/advice concerning the infection risk and recommended action.

iii. For donations issued to named patients by SNBTS blood banks, the SNBTS will identify recipients of all relevant components then provide the medical officer responsible for administering the component/s with relevant information/advice concerning the infection risk and recommended action.

iv. It was agreed that the procedure to be followed would be based on that outlined in a forthcoming publication on the subject in Transfusion Medicine from SE RTC. (Appendix I)

Donors confirmed HCV positive are of course already being recalled and offered counselling (since September 1991). This is normally initiated by SNBTS consultants and pursued with the individual's own GP where appropriate. Look back does not affect this area..

→ BC✓ (Lo Info) S File

4. SNBTS Costs of HCV Lookback

The SNBTS costs involved are not expected to exceed a total of £50,000 for which funds have been set aside from non-recurring sources.

5. Patient counselling and Treatment costs

Decisions on counselling and treatment of affected individuals rests with the clinicians responsible in each case. The SNBTS would have no locus in this area beyond advising these clinicians of the facts (3ii and 3iii above).

We have however made some enquiries and, as previously advised, there may be some immediate treatment cost implications arising from look back. It may be relevant however to note that the overall benefit/cost ratio over the life of the individuals involved could well prove to be highly positive; and total NHS costs might indeed be lower as a result of making these diagnoses earlier rather than only after the virus has really got a grip.

There is some evidence to suggest that treatment with interferon may induce remission in some patients who have already developed liver disease. Although research in this area is at a very early stage interferon may also be used as a prophylactic treatment in anti-HCV positive patients in an attempt to prevent development of liver disease.

We understand that the cost of treatment is likely to be approximately £3,000 per year per patient on average where interferon treatment is deemed appropriate.

6. Medico-legal aspects

Finally, this summary of the HCV situation would probably be incomplete without some reference to possible medico-legal exposure. The main points of interest in this context are probably:-

(a) The numbers involved and the relatively high level of "naturally occurring" anti-HCV positivity in the population at large.

(b) The fact that the donations involved were negative for all the tests then current and were fully acceptable for clinical use according to the standards in force at the time.

(c) The fact that understanding of the virus has greatly improved since 1991 and the Service took (is taking and will take) steps to inform affected patients just as soon as scientific developments made/make it appropriate to do so.

(d) Now that scientific developments clearly ***have*** made it appropriate to tell patients as soon as possible, what may be most likely to be seen as actionable is further delay in actually getting round to doing so.

I hope the above is helpful but please do not hesitate to get in touch if more is needed before we hear the final decision from the Departments of Health.

David B McIntosh
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23rd September 1994