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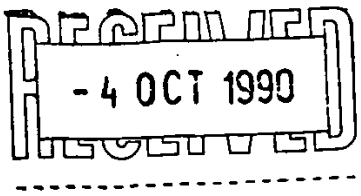

REPORT FOR NATIONAL MEDICAL DIRECTOR

DONOR COUNSELLING: HCV

PREPARED BY THE SNBTS WORKING PARTY

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INTRODUCTION

Dr J Gillon was requested by the NMD to constitute this small working party to discuss the donor counselling requirements of SNBTS in the light of imminent introduction of HCV testing. The remit was:

1. To produce operational guidelines for BTS doctors (or other doctors engaged by the BTS), in the context of counselling anti-HCV confirmed positive donors.

2. To liaise as appropriate with Dr Harold Gunson.

3. To produce a first draft guideline for consideration by the Directors on 14th August.

The Group met on Tuesday 3rd July in the Edinburgh RTC. The following points were discussed and agreement reached as a necessary preliminary to the drafting of guidelines:

1. It was agreed that, at the time of introduction of testing, we would all attempt to work within the agreed flow chart for management of test results and donor records. It was noted that the problems in managing plasmapheresis donors were not addressed in the flow chart, and, in the light of the problems encountered in managing HIV false positive plasma donors, the Group expressed concern at this. A related issue is the question of whether donors with apparently false positive results after confirmatory testing might be reinstated to the panel. The view of the Group was that reinstatement should not be considered until much more is known about the performance of the confirmatory tests and the liklihood of being able to predict confidently which donors were infected and which were not. We therefore felt that for the first year or so these donors should simply be managed using the "medical hold" or whatever local appropriate system is in operation at present.

2. We assume that a highly sensitive and specific confirmatory test will be available, since our guidelines relate to the counselling of donors with a positive confirmatory test. The assumption is therefore made that all donors counselled will be regarded as potentially infectious. We note that the AABB proposes notification of donors who are repeatably reactive on the EIA, regardless of the availability of a "supplemental" test. They propose to take frozen serum samples from such donors, and to test these samples when a "supplemental" test becomes available. This implies that they will use these "supplemental" tests to decide on donor re-entry, although at present there are no firm plans to use the tests in this way. They further propose to use the additional more specific tests to generate some "medically appropriate message" in their first written communication with the donors.

3. The Group felt that it is important for careful consideration to be given to the question of providing information to all blood donors. This may be important for the validity of the consent which donors give, and this in itself is an issue which may need to be

addressed in respect of the other tests. The Group felt that an individual leaflet with information on hepatitis C was not necessarily the most satisfactory way of informing donors. A suggestion was made that a composite leaflet dealing with matters of donor health, the benefits of screening, and the implications of the various individual tests which we carried out might be the most advantageous way of doing this. Dr Gillon agreed to consult the RDO's on this through Mrs Thornton.

4. It is important to redefine the SNBTS policy on our responsibility to the donor regarding the way in which we convey information about positive tests. The Group noted a letter from Dr Whitrow to Dr Gillon in which he outlined some of the practical difficulties encountered in donor counselling in the North Region. The Group therefore agreed that the extent of counselling and investigation undertaken must be at the discretion of any RTD, depending on local circumstances. It is our view that our duty is to inform the donor personally, ie at an interview with a member of SNBTS medical staff or another doctor recruited for that purpose. The decision on the need for further investigation or referral to either the donor's GP or a local specialist should be taken by the Consultant responsible in the Regional Transfusion Service in conjunction with the doctor carrying out the primary counselling. We recommend that a second counselling visit will usually be useful, and that the decision on the need for investigation or referral should be based on additional information including, where possible, a physical examination and the results of liver function tests. In addition to the information documents enclosed with this report, RTC's should ensure that counselling doctors receive written guidance for positive donors which includes some background information and advice on protecting others. Each RTC should identify one or more suitable hospital physicians who would be willing to evaluate cases with possibly significant liver disease and to offer appropriate therapy as available. The group noted the American advice that Interferon therapy should be offered only in the presence of severe liver damage. As clinical trial data come to hand, the situation will change and the group made no specific recommendation on therapy. Donors with no evidence of significant liver disease could be referred to their General Practitioners with the advice that regular ALT checks should be done, perhaps every six months, with referral for expert advice where doubt remains.

5. Though the Group felt that the decision about the need for referral should ideally be taken by a BTS Consultant, the need for delegation of much of the counselling work was accepted in view of the large numbers of seropositive donors likely to be identified. It should be noted, however, that even where the counselling is delegated, considerable extra work and responsibility will be created for the Consultants involved.

6. The Group discussed the question of lookback. Donors may well ask about the outcome of their previous donations, and a clear policy on lookback is essential. We note the logistical difficulties, which have been taken as justification by the AABB for not recommending a lookback, but our view was that this position is untenable in view of the desirability of informing recipients so that they can protect others, and also receive treatment with Interferon if the benefits of this form of therapy are confirmed.

BACKGROUND INFORMATION FOR SNBTS MEDICAL OFFICERS COUNSELLING ANTI-HCV POSITIVE DONORS

The enzyme immunoassay test for antibodies to hepatitis C virus is the first specific test for one of the viruses associated with non A, non B post-transfusion hepatitis. There are thought to be at least two such viruses, but hepatitis C is almost certainly the most common form, thought to be responsible for around 70% of post-transfusion hepatitis. The SNBTS considers it has a responsibility to donors to inform them of test results which suggest that the donor may be infectious, and may be at some risk of illness as a result of the infection. The following is a summary of the essential information for those involved in counselling such donors:

1. The incidence of post-transfusion non A, non B hepatitis currently in the UK is unknown. Work in progress in London suggests an overall figure of around 1% of transfusion recipients, although higher figures have been found in prospective studies in the USA and other parts of Europe. Most of these will be asymptomatic, but some will go on to long-term liver damage. Around 10-15% of those infected by this route may eventually develop significant liver disease. The incidence of NANBPTH has fallen in the USA as a result of the exclusion of donors at risk of HIV, and perhaps also the implementation of surrogate testing.

2. The prevalence of carriage of non A, non B hepatitis in the general donor population is not known. Estimates range from 0.1 - 2% (ie much higher than for hepatitis B or HIV). Both chronic carriage and acute cases occur, but their relative importance is not known. Acute cases may be infective without developing a detectable antibody and some studies indicate that the antibody may disappear with time. The routes of spread are poorly understood. Sexual transmission does occur, but is less efficient than with hepatitis B (see below).

3. Many attempts to identify the responsible virus or viruses using conventional serological methods have failed. The virus or viruses have never been cultured.

4. By using the latest in DNA transcription techniques on the ultracentrifuged plasma from infected chimpanzees, Chiron corporation have synthesized a protein of less than 400 aminoacids, which is part of a non-structural protein in the virus which has become known as hepatitis C. Rigorous studies of PTH patients have confirmed the specificity of this test, indicating that the protein is indeed a true viral antigen. Based on this the whole virus has now been sequenced.

5. This small antigen has been used as the basis for the enzyme immunoassay test. Many populations have now been screened using this test, and more details of the epidemiology of hepatitis C have emerged. The prevalence of antibody positivity is high in haemophiliacs treated with non heated-treated products, some groups of multi-transfused patients, and intravenous drug abusers. There is a relatively low prevalence in homosexuals, and heterosexual

transmission, though recorded, does not appear to be efficient. Studies have suggested that spread within a household does not occur. There are no data on vertical transmission from mother to baby.

6. Preliminary studies on Scottish blood donors show that approximately 0.5% are repeatably positive. This correlates with our presumed low incidence of PTH, and is lower than other countries, eg USA, where the prevalence is around 1%. The anticipated number of positive donors for each region is therefore:

	n/year	n/month	n/week	n/day
WBTS	750	64	16	3
SEBTS	400	33	8	1.5
EBTS	150	12	3	<1
NEBTS	200	16	4	<1
NBTS	100	8	2	<1
SNBTS	1,600	133	33	>5

ie WBTS will have the equivalent of 2 'new patient' clinics each week, SEBTS one and the other regions at least one "clinic" per month. The majority of these "repeatably positive" donors are likely to have a negative confirmatory test. Thus they will not be recalled for counselling, though their blood will not be transfused (see below).

7. At present we lack a totally acceptable confirmatory test, though we expect that by the time testing is started on Scottish donors a suitable test will be available. It will be SNBTS policy only to inform those donors who have a positive confirmatory test. Donors with a positive EIA but negative confirmatory test will be kept on "hold", and allowed to continue donating without their donations being transfused, until further information is available allowing a decision about their suitability as donors. It is assumed that those donors with positive confirmatory tests will usually be infective.

8. It is important for individual donors to receive further medical assessment, since they may well be at risk of chronic liver disease. There is some evidence suggesting that various types of chronic liver disease, associated for instance with alcohol, may be associated too with a high prevalence of anti-HCV, and counselling should take this into consideration. Appropriate referral for investigation of those with abnormalities of liver function will be essential, particularly since there is some hope that treatment with Interferon may be effective.

9. Those donors with normal liver function tests probably have a good prognosis, though they too should probably be advised to show moderation in alcohol intake, and to take precautions to avoid infecting others.

10. Little is known as yet about the magnitude of risk for sexual and other contacts of HCV positive donors, but those confirmed positive should probably receive advice similar to that given to carriers of hepatitis B.

INFORMING THE DONOR

The Letter

The initial contact will usually be by a standard letter, which should be reassuring in tone and specifically mentioning that the reactive test result has nothing to do with AIDS. The donor will be invited to come back for further testing in order to clarify the significance of the findings. An early appointment should be offered.

The Interview - First Counselling Session

Requirements: donor record, including list of previous donations, screening and confirmatory test results with interpretation further test results on original serum if available - ALT, anti-HBc, anti-HBs.

Blood samples:

It is recommended that further specimens be taken in order to confirm the results on the donation, and to check liver function tests.

Breaking the news

The initial news-breaking should be direct and simple, with the minimum of preliminary. The essential information is that one of the tests done on every donation has shown a positive reaction. Explain that this is a new test for a mild form of hepatitis, or jaundice, called hepatitis C. This can be passed on by blood transfusion, but we have not been able to test until now.

Q: What does a positive test mean?

Since only donors with positive confirmatory tests will be counselled, it is reasonable to explain that we do extended testing with very specific tests, so that we are already fairly sure that the donor truly has antibodies to the virus known as hepatitis C.

This virus is very common in the population - about 1 in every 200 donors has a positive test. This may mean that they have been in contact with the virus at some time in the past. Emphasize that the tests detect antibodies, not the virus itself, and that the virus is not necessarily still present.

Q: Does it mean I've got hepatitis?

At the moment we have very little in the way of data from blood donors with anti-HCV, but from studies of patients who develop post-transfusion hepatitis C, we know that the vast majority have no symptoms whatever, the infection just showing up as a rise in transaminases (sometimes referred to as "transaminitis"). In about half of those infected the liver function abnormality lasts 6 months or more. In a third of these a liver biopsy will reveal some evidence of inflammatory activity, and in approximately 10-15% this may ultimately result in chronic active hepatitis or

cirrhosis. It is worth exphasizing that the natural history of the infection in transfused patients may be quite different. Thus it is likely that the long-term consequences are much less serious for carriers in the general population than for patients infected by blood transfusion.

If the ALT has already been done, the result will be very useful in finding the reply to this question. When it is not available, it is important to emphasize that a few simple tests will help to determine the significance of the test result for the donor.

Q: Will I die of this?

If the donor asks for a prognosis, it will be necessary to be slightly guarded without causing alarm. If the ALT is raised explain that there are many possible reasons for this, and that it will be possible to sort it out after one or two further blood tests have been done, but that sometimes a period of monitoring will be needed to be absolutely sure of the significance. We can say with confidence that very few cases of serious liver disease due to hepatitis C occur in the community, so for most people this is an incidental finding unlikely to cause serious disease or symptoms of any kind.

Q: How did I get it?

Though hepatitis C is very common in the community, we have little idea as yet of the routes of spread. We don't know if it can be spread by food or water, nor is much known about mother-to-baby spread, but sexual transmission can occur (albeit not as efficiently as other viruses, eg hepatitis B). There seems to be a high incidence in intravenous drug misusers, suggesting that parenteral spread is the most efficient. Thus tattoos, ear-piercing, acupuncture, dental treatment, electrolysis and so on could be relevant.

Q: Am I likely to infect other people?

It is not yet known with certainty what proportion of antibody-positive donors will be true carriers, able to transmit to other people. Initial studies suggested that the majority of donors would not be infectious, but this was before a confirmatory test was developed. We should regard all donors with confirmed positive tests as potentially infectious.

Situations in which others are at risk are those in which blood or body fluids may be exchanged, eg blood transfusion, needle sharing, and probably sexual contact, though it may not be logical to take any additional precautions with a longstanding partner. A condom should be advised with new sexual partners, while the necessary precautions for longstanding partners should be talked through.

There is no evidence of risk associated with ordinary daily contacts within the same household, and some evidence that there is no risk of transmission. Ordinary rules of hygiene should be observed, and donors should be advised not to share toothbrushes or razors. Donors must be advised to tell doctors and dentists that they are carriers of hepatitis C.

Q: Can I ever give blood again?

At the moment there is no prospect of readmitting seropositive donors, even if on follow-up they go seronegative. Further refinements in testing may lead to this being reconsidered.

Q: What about my previous donations?

The recipients of previous donations will be traced and their Consultants or GP's informed. We hope to obtain results of any tests carried out. However, it may cause distress to the donor to discuss this matter in any detail. A general comment suggesting that we are going to check to see that the recipients are alright, that they get any treatment they may require, should be sufficient.

Q: Could I be sued if anyone was infected?

We guarantee the confidentiality of the donor. We strongly advise that the donor's GP be informed, but we shall not divulge the information to any other party without the donor's consent.

Q: Could I have got it from giving blood?

No.

Q: Should I tell anyone apart from my spouse? My employers, for instance?

At present there are no official guidelines, and therefore no requirement exists to inform any other person. In the case of health care workers, consultation with the appropriate occupational health service is recommended.

Q: Do I need to change my diet or take any other health precautions?

Regardless of the results of ALT etc, donors should be advised that a period of medical supervision and repetition of the blood tests is advisable, either through their GP or at a suitable hospital clinic. The only specific advice justifiable is that those with liver dysfunction should avoid alcohol, and even those with normal liver function should take no more than modest amounts.

JG
20th September 1990