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REPORT FOR NATIONAL MEDICAL DIRECTOR

DONOR COUNSELLING: HCV

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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. The prevalence of confirmed anti-HCV in UK donors is likely to be around 1 in 1000. This is similar to HBsAg carrier rates. 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 appears to be inefficient, most studies showing less than 10% seropositivity in long-term sexual contacts. Studies have suggested that spread within a household can occur, at much the same sort of rate as in heterosexual contacts. The routes of spread are not yet known. Vertical transmission from mother to baby occurs, but studies differ very widely in outcome. One such study indicated that 50% of babies born to seropositive mothers seroconvert, and that half of these develop a chronic elevation of ALT. Other studies, however, have not confirmed this high transmission rate.

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

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 (approximately 0.1% of all donations according to the most recent information).

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 asscciated 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.

Epidemiological data

It is recommended that the route of infection should be identified and recorded at the first interview, as such data are likely to prove extremely valuable (eg drug abuse, previous transfusion etc).

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.

At this point it will generally be appropriate to allow the donor to ask questions, but it is recommended that the following information must be conveyed to the donor at the initial consultation, and preferably reinforced at a subsequent interview:

1. That chronic liver damage can occur, and that their liver function therefore should be assessed. If abnormalities are detected, long-term follow-up will be necessary.

2. That even where abnormal liver function is detected, the prognosis is good in the majority of cases, and treatment is available for those in whom more severe liver disease occurs.

3. That there is little known about the routes of spread of the virus in the population, and that sexual transmission does not readily occur. Detailed instructions about protecting others should be given, preferably in written form.

The following list of questions and answers is meant to illustrate sorts of questions the donors will present, and will give the basis for satisfactory answers. The questions are in no particular order.

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. If the PCR test for viral genome is available, a positive will mean that the donor must be regarded as infectious (but a negative does not necessarily rule out infectivity).

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 possible 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. It is felt by some hepatologists 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.

Progressive chronic hepatitis C has been treated successfully with Interferon, and though this treatment is at present experimental it holds out considerable promise for the future.

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, but should only be offered if the donor asks directly.

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.

It is recommended that any health care workers coming in contact with the donor should be informed of their status. This should include dentists as well as the General Practitioner and any hospital doctors, for instance in Accident and Emergency.

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.

Q: Will it affect my insurance policies?

This result does not affect existing insurance policies, but in taking out any new policies the donor will be obliged to answer all questions truthfully. To do otherwise, or to appear to conceal relevent information, might make any policy invalid.

JG

RECOMMENDED PROCEDURE FOR THE MANAGEMENT OF ANTI-HCV POSITIVE DONORS

The following is an idealised standard procedure for managing anti-HCV positive donors. It should be seen as a guideline to providing a reasonable standard of care, but it is acknowledged that for practical reasons the procedure may be adapted to local circumstances without jeopardising the standard of care.

1. Donors with repeatably positive screening test but negative confirmation

   It is recommended that these donors should be kept on the panel, but placed on "medical hold" or some equivalent status which prevents transfusion of future donations. No policy has yet been formulated to allow re-entry of donors whose screening test subsequently becomes negative, pending the results of studies of test performance. Donors should not be informed of unconfirmed positive screening tests.

2. Donors with positive screening tests and positive confirmation, as defined by the SNBTS Microbiological Laboratory

   2.1 As soon as positive confirmation results are received, the donor must be placed on "permanently off-service" status.

   2.2 The standard letter is sent, informing the donor that the test is positive and requesting attendance for further samples (note: letter must be timed to reach donor during the first half of the week).

   2.3 An appointment for initial counselling and assessment is offered at the earliest opportunity (note: allow at least 1 hour).

   2.4 The initial counselling and assessment is carried out by a Medical Officer experienced in donor counselling and/or familiar with the SNBTS information package.

   2.5 The donor is informed that he or she must not give blood or carry an organ donor card. Permission to inform the donor's GP is requested.

   2.6 The donor is given the written advice (provided by each Centre individually) on the implications of a positive test.

   2.7 The donor should be given a contact telephone number for further advice.

   2.8 The donor may be offered a second counselling interview within 1 week, if it is considered necessary.

2.9 Samples are taken for repeat HCV antibody tests (screening and confirmation), hepatitis B markers, liver function tests (preferably including ALT) and any other tests considered to be indicated by the Medical Officer.

3. Donors confirmed anti-HCV positive on the second sample

3.1 On receipt of the repeat results, provided they confirm the donor's seropositivity, the donor is informed, and advised on the need for further investigation or follow-up.

3.2 The Donor Consultant decides on the need for specialist referral or follow-up, based on the epidemiological features and results of liver function tests.

3.3 The donor's General Practitioner is informed by letter, with the donor's permission.

3.4 In the case of regular donors, the fate of previous donations is determined and "lookback" initiated in accordance with SNBTS policy.

4. Donors with negative tests on the second sample

4.1 Proceed according to SNBTS flow chart to investigate the apparent discrepancy.

4.2 Review donor status in light of investigation, and proceed accordingly.

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