

H3 is the new newsletter from the Haemophilia Society for people affected by haemophilia, hepatitis C and/or HIV. It is produced in paper form four times a year and distributed to members and subscribers (non-voting members) of the Society. It is available by email eight times a year to anyone with an email address who is interested in these issues. To subscribe, email info@haemophilia.org.uk from the email address to which H3 should be sent.

The email version of H3 and past editions of C Mail, the forerunner to H3, are posted on the Society's website:

www.haemophilia.org.uk/publications/pubs.html

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1. DH *ex gratia* financial assistance scheme update

The Skipton Fund will be established in April 2004 to administer the payments to people infected with chronic hepatitis C through blood and blood products. At time of going to press, a website and email address are soon to be established:

www.skiptonfund.org

The following details have come to light since the last edition of H3.

- The DH (Department of Health) Blood Policy team say that those who have had chronic HCV infection but whose viral load is undetectable will qualify for the payments. The easiest way to prove this appears to be through a past positive PCR test for the virus. This DNA-type test only became routinely available in the late 1990s. It is different from the antibody test, which only detects past exposure to the virus. The antibody test result is positive in most people with haemophilia and von Willebrand's who were treated with clotting factor concentrates before 1985, and so includes those with "chronic" (ie long-term) infection (whether currently PCR positive or negative) as well as those whose infection resolved in the "acute phase" of the illness (ie cleared "spontaneously" within a few weeks or months). This last group of people (who never

developed chronic infection) do not qualify for the Skipton Fund payments.

- The fund is accessible to ex patriots as well as those resident in the UK.
- A complex calculation of blood test results will be used to establish whether cirrhosis is present, making a liver biopsy unnecessary for this purpose.
- The application form is likely to be very simple, comprising a part completed by the claimant giving personal details including address, bank account and National Insurance number, and a section for his or her hospital haematologist or hepatologist to add a brief medical history.

Further information has been made available in a question-and-answer briefing which was originally intended for the Scottish Executive's press office. In summary, it additionally informs people that:

- Claimants will be "asked to sign an undertaking not to institute proceedings against the NHS or Ministers in relation to their having been infected with hepatitis C from blood, blood products or tissue received from the NHS before September 1991".
- Any form of monetary award that has been made in respect of the person being infected with hepatitis C will be deducted from the *ex gratia* award. This applies "as a result of receiving blood, blood products or tissue from the NHS prior to September 1991 – including awards in the civil courts or out of court settlements in the UK or abroad and also awards from the UK government and from other governments".
- Claims can be processed once the Macfarlane Trust has established the new independent Skipton Fund. Because of Social Security legislation, the earliest date by which payments can be made is April 2004. However, callers to the DH Public Enquiries Centre have recently been told of a six-week delay in processing enquiries.

2. Ongoing parliamentary campaign

At a recent meeting of the All Party Parliamentary Group on Haemophilia, MPs reported on their negotiations around the *ex gratia* scheme in meetings they had held with John Reid and Melanie Johnson, Ministers at the DH. Michael Connarty, chair of the group, and others agreed that significant progress had been made in terms of winning the inclusion of those who had cleared the virus via treatment and those living with HIV/HCV coinfection. However, they expressed regret at the exclusion of bereaved dependents.

MPs noted that the scheme is being funded from this year's health budget and there is a finite amount available now. Campaigning for the inclusion of the bereaved and an increase in the level of the payments should continue and focus on winning new resources after the Budget.

Mr Connarty is writing to DH raising queries about various implementation issues the Society has.

3. US Litigation Update

In an interview with Lynne Wilson of Anderson Eden solicitors, she said: “There seems to be lots of confusion with the proposed UK *ex gratia* payments and the American Class Action.

“Some people have said they will wait and see what happens with the UK Government payments and then decide whether or not to go ahead with the US Litigation. This is *not advisable* as this matter will not remain open indefinitely and by the time the UK Government payments are finalised it may be too late to join the Class Action.

“Heather Foster, Lead Attorney Lief Cabraser Heimann & Bernstein (LCHB) has outlined that registering for the UK Government award does not bar claimants from participating in the US litigation; the two matters are entirely separate: ‘The answer is that any award from UK Government is likely to be “offset” or deducted from any US award, either through a negotiated grid type of settlement or possibly even a trial verdict. Other than that, there is no bar for these claimants to participate in the litigation.’”

Lynne concludes: “In all of the circumstances, this opportunity is an excellent one. The potential benefits are considerable. This group action is likely to be the last opportunity for most UK sufferers to secure redress for the actions of the past and receive an appropriate level of compensation. Once this action is finished there will not be another opportunity to seek compensation from the US drug companies concerned.”

The Society is grateful to Lynne for providing an opportunity to interview her. Readers of H3 should note that the Society does not accept responsibility for these legal opinions and can neither recommend or discourage taking part in this litigation, for which the outcome is uncertain. Individuals are advised to consider for themselves the advantages and disadvantages of joining it.

Society: Is there a deadline for lodging claims?

Lynne: Heather Foster tells us: “As of yet, there is still no deadline for seeking to join the Class Action. The answer of course is that you should lodge your claim the sooner the better, as we constantly have to report to the Court and to defendants an accurate tally of the numbers of clients we represent. But there is no deadline yet. If the defendants seek to impose one, we will of course advise you immediately.

“Lots of sufferers have registered an initial interest in the Class Action but have failed to follow this up by completing the necessary forms. If you fall into this category it is vital that you return all paperwork to Anderson Eden as soon as possible.”

Society: How is the litigation progressing?

Lynne: Heather Foster says that the litigation is progressing well. Updates were sent to clients about a month ago. A procedural/directions hearing is to take place soon before Judge Grady in Chicago. There will probably be a lot more news to report following that hearing.

Society: Is it true that the families of those who died before June 2001 (a year before the class action was filed) cannot make a claim?

Lynne: Yes, a ‘cut-off date’ does apply for deceased claimants unless certain criteria apply. This is because of the California Statute of Limitation (SOL) law. This cut-off date is 31st May 2001 and means that LCHB will be unable to represent the families of those who have died before this date.

However, the exceptional criteria to this are as follows: Either: (i) The deceased person had a partner, or a spouse who is HIV and/or HCV positive; or: (ii) the person had surviving children who reached the age of 18 on or after May 31 2002.

If either or both of these apply, LCHB are able to maintain representation on behalf of the partner and/or children of the deceased.

Society: What will interested parties have to do once they have registered an interest in claiming with you?

Lynne: Once an interest has been registered, the claimant must return the signed Attorney Representation Agreement and completed Questionnaire to Anderson Eden. They must also send the relevant medical records. These documents will then be forwarded to LCHB for their review.

Society: If people are having difficulty accessing their medical records, what assistance can you offer?

Lynne: The emphasis in this case is on the person obtaining their own records. However, if a person has tried every possible way to obtain the required records, we can assist if necessary. This may involve:

- Writing to hospital on their behalf
- Advising to contact previous solicitor i.e. (for those who received a payment from the Macfarlane Trust) contacting the solicitor who originally handled their claim for a copy of their file notes although there may be a charge for this
- Contacting LCHB, or any other interested party, to see what further steps can be taken

Lynne encourages those who have any queries either in relation to points dealt with in these questions or generally to contact either herself or Denis Whalley at Anderson Eden Solicitors:

Lynne lynne.wilson@andersoneden.com (01772 272 081)
Denis denis.whalley@andersoneden.com

No form of recompense has been granted to people in the US with haemophilia and hepatitis C monoinfection. The following letter from the country’s patient organisation explains their current position and helps clarify the background to blood-borne viral infection in the US.

Dear Member of the Bleeding Disorders Community,

The following is a letter from NHF President Jordan Lurie, MD regarding NHF efforts on behalf of people in the bleeding disorders community affected by Hepatitis C

(HCV). In addition, you can also read a paper online explaining NHF's position and efforts regarding these issues.

The National Hemophilia Foundation (NHF) appreciates recent inquiries to our national office regarding the status of Federal compensation for persons affected by the hepatitis C virus (HCV). NHF has long recognized the impact and burden placed on individuals and families by this disease. We also respect the efforts of affected community members to pursue compensation legislation. NHF is committed to working with the bleeding disorders community to seek support for an independent review of the Federal government's responsibility in the spread of HCV through blood and blood products. However, similar to the community's successful campaign to achieve passage of the Ricky Ray Hemophilia Relief Fund Act, significant groundwork must be completed prior to the consideration of Federal HCV compensation legislation.

To build this foundation, earlier this year NHF broadened its outreach within the larger HCV community. Nearly four million Americans have HCV, with 10 percent of these individuals contracting HCV through blood transfusions. Like other HCV advocacy organizations, NHF's efforts over the last 15 years have focused on blood and blood product safety as well as improved diagnosis and treatment of HCV, including non-invasive mechanisms for liver biopsy, access to clinical trials, and increased Federal funding for HCV disease research. At this year's Washington Day program, NHF will join with other HCV organizations in seeking support for passage of the Hepatitis C Epidemic Control and Prevention Act (S. 1143/H.R. 3539). This legislation mandates additional resources and a more coordinated Federal approach for improving HCV prevention, treatment, and disease management.

The Centers for Disease Control and Prevention (CDC) estimates that 6,200 individuals in the bleeding disorders community have been exposed to HCV. On their behalf, NHF seeks the best strategies for addressing HCV, including compensation. As the Federal government's role related to HCV has not been documented in an authoritative manner and litigated court cases have not provided a strong advocacy base, an independent review is a first and necessary step towards any future Federal HCV compensation effort. We look forward to working with you and to keeping you informed of our steps in seeking this review.

Sincerely,

Jordan Lurie, M.D.
President, National Hemophilia Federation

www.hemophilia.org.

4. Interferon therapy in children with hepatitis C and haemophilia

Little data is available on the response of children infected with hepatitis C treated with combination therapy, especially those with bleeding disorders.

Peutz *et al* report in *Haemophilia* (87, 10, 2004) the results of a single paediatric haemophilia treatment centre's treatment, using standard interferon and ribavirin therapy, of adolescents with haemophilia and hepatitis C mono-infection.

Eleven patients agreed to participate in the study. Three patients had an unmeasurable viral load after six months of combination therapy. All three completed 12 months of medication and continued to remain free of hepatitis C for 12 months after discontinuation of therapy. Side-effects of combination therapy were significant but tolerable. The sustained response rate in this very small study is similar to the historical response rate seen in adults but less than the other reported response rates seen in children treated with combination therapy. However, the results are of more historical interest, as there is now unlikely to be anyone with haemophilia or von Willebrand's under 18 in the UK who is living with hepatitis C.

5. NICE Appraisal of pegylated interferon

Technology Appraisal Guidance 75 for interferon alfa (pegylated and non-pegylated) and ribavirin for the treatment for chronic hepatitis C was issued by the National Institute for Clinical Excellence in January 2004. It is due for review in November 2006, a process that will begin by consultation a year before that date.

There is no significant change to the draft guidance reported in the September 2003 edition of *C Issues*. It should be noted that treatment is not recommended for those with mild chronic hepatitis C, although this will be reviewed in August 2004 once the results of two clinical trials investigating treatment in this type of patient are available.

www.nice.org.uk/cat.asp?c=101627

6. Hepatitis C Mentoring Conference, 10 June, London

Davinia Springer, Development worker for the UK Assembly on Hepatitis C, writes: The Hepatitis C Mentoring Conference is an annual event, which is organized by people affected with hepatitis C for people affected with hepatitis C. The mentoring conference provides delegates with the opportunity to discuss:

- The key issues for HCV+ individuals
- How to meet the needs of HCV+ individuals
- Empowering the HCV+ community

The conference, titled "Preparing to C changes", is organised by The UK Assembly on Hepatitis C, a national forum representing the needs and views of hepatitis C positive (HCV+) individuals. The conference is patient-focused and through information provision and exchange, we aim to encourage HCV+ individuals to make their own choices about their support, testing and treatment options.

Each year the conference grows in attendance, this year we will attract over 200 people from all parts of the UK.

Throughout the conference there will be an exhibition of private, statutory and voluntary agencies displaying their products and information services.

It will take place at the Oval cricket ground and the Haemophilia Society will be represented. Entrance is free for HCV+ individuals and £100 for healthcare professionals. For more details see www.hepccentre.com or ring 020 7735 7705.

7. Trials of peginterferon with HIV/HCV coinfectd

The long-awaited results of the international **APRICOT** trial were presented at a recent conference. 868 patients living with HIV/HCV coinfection were treated with either Pegasys and ribavirin (RBN), standard interferon (IFN) and ribavirin, or Pegasys alone. The results are given as sustained virologic responses (SVR, the internationally recognised success rate):

	Overall	Genotype 1	Genotypes 2&3
PEG+RBN	40%	29%	62%
PEG alone	20%	14%	36%
IFN+RBN	12%	7%	20%

This is the largest trial of pegylated interferon in HIV/HCV coinfectd patients ever conducted. Better results have been achieved in two trials with HCV monoinfectd patients using this pegylated combination, with Genotype 1 SVR results of 46% and 51% compared with 29% from this trial.

A similar trial (**RIBAVIC**) with a total of 412 coinfectd French patients treated with a combination of ViraferonPeg or standard interferon, and ribavirin, was also reported with poorer success rates (27% overall SVR with 15% SVR for those with Genotype 1

An American trial, **ACTG A5071**, with just 133 coinfectd patients, compared the Pegasys combination with the standard interferon combination. The results were broadly similar to the RIBAVIC trial.

The UK charity, Aidsmap, provides the following analysis of these varied results:

The RIBAVIC study population was considered harder to treat, with a higher proportion of injection drug users, subjects with persistently normal ALT, and patients with more advanced liver damage - perhaps more reflective of some "real world" coinfectd populations. Drop-out rates and rates of severe adverse events were both considerably higher in RIBAVIC than in the other two studies.*

The data from these three studies are inconsistent, and in some senses perplexing. Nevertheless, the impressive results from APRICOT (the highest SVR rate ever seen in the coinfectd population), along with the encouraging early response rate seen in ACTG A5071, provides reason for renewed hope for successful treatment of people with HIV/HCV.

*The overall SVR achieved in those patients who completed the course of PEG/RBN treatment was 36%.

8. DTS dating

An enterprising couple has set up what it believed to be the UK's first dating agency for people living with sexually transmitted diseases such as HIV. (DTS stands for 'Diseases Transmitted Sexually'). It is a commercial venture which aims to help people suffering from relational and social isolation that such conditions can bring. The agency was recently launched with interest from the HIV and national press.

DTS Dating Ltd, PO Box 11816
Birmingham. B35 6YD
Tel/fax 0121 748 1312
Email office@dtsdating.com
Website www.dtsdating.com

9. Birchgrove Woodland Grove opening

On Sunday 23 May at 1pm there will be an official opening event of the Birchgrove Woodland Grove, in Stratton, Swindon. More details and a photograph are in *Haemophilia Quarterly* which accompanies this newsletter.

To get in touch with Birchgrove email birchgrove1@hotmail.com or write to PO BOX 9755 Solihull B92 9WA, particularly if you are interested in attending the unveiling. The Woodland Trust website gives further information about the Stratton Wood which people are free to visit all year round.

www.woodland-trust.org.uk

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John Morris, H3 editor 19 March 2004
john@haemophilia.org.uk
Haemophilia Society UK
Chesterfield House, 385 Euston Road
London, NW1 3AU

Freephone helpline: 0800 018 6068
Direct line (JM): 020 7391 9137
Haemophilia Society Admin: 020 7380 0600
Fax: 020 7387 8220
Website: www.haemophilia.org.uk
Charity no: 288260

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