Lord Hunt

From: Gwen Skinner HSD 2

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cc:
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HAEMOPHILIA AND HEPATITIS C INFECTION - TREATMENT/CARE

As you suggested we have looked at the scope for doing more for people with haemophilia infected with hepatitis C, focussing on counselling provision. This includes information from haemophilia/hepatitis C counsellors and the UK Haemophilia Centre Doctors Organisation (UKHCDO) whom we met to discuss. Two main options emerge for improving counselling provision and these are set out below. In addition this note includes an assessment of other possible initiatives you might consider supporting.

2. You also requested an outline costing of a hardship fund and this is at **Annex A.** A timetable of year 2000 blood events, which may attract campaigning activity or opportunities for constructive messages about haemophilia/hepatitis C is **at annex B. Annex C** is a supporting paper on issues in haemophilia with annexes listing relevant publications, Comprehensive Care Centres and the Haemophilia Alliance's service specification. It contains a number of other possible actions unrelated to counselling you might wish to consider. These are summarised under 'action' at the end of this note.

Counselling

3. The Haemophilia Society claim that sufficient counselling is not available for haemophiliacs with hepatitis C. Counselling needs vary - supportive counselling at times of stress, working with families in crisis, genetic counselling for people intending to start families, benefits and housing advice including home adaptations to support daily living. The UKHCDO members and social workers suggest that while counselling services for people with haemophilia are under threat largely due to the financial pressures on local health economies, they are in the main holding up at present. In some places the threat is because the counsellors are employed by Social Services Departments and retained by NHS Trusts on a grace and favour basis. In others where the counsellors are funded from HIV funds the reducing workload is the threat..

4. All 18 Comprehensive Care Centres (CCCs) in England offer the full range of counselling services. However Haemophilia Centres (about 80) do not always do so, nor indeed could the smaller Centres be expected to provide this very specialised care.

Action on retaining/extending hepatitis C counselling provision - Spring 2000

5. The UKHCDO has offered to issue advice to members on the importance of retaining and promoting counselling services in the CCCs and the larger Haemophilia centres. We will monitor the effectiveness of this initiative.

6. The Organisation will also ask its members in the 18 CCCs to ensure that counselling services are made available to patients who attend the smaller haemophilia centres, where there is more basic provision.

7. We are also following up the UKHCDO approach actively and supporting it through the ROs. We are also encouraging links with local Mental Healthcare Trusts, academic psychology departments, and GP counselling facilities to maximise current provision in systems of clinical care.

8. You have in year approved a S.64 bid for £20k for haemophilia/hepatitis C counselling. This will provide additional support for the Haemophilia Society's current hepatitis C helpline giving people with haemophilia and their families/carers access to expert telephone advice and counselling. This independent and confidential resource will also be available to support staff in the smaller Haemophilia Centres.

Medium term improvements in haemophilia/hepatitis C counselling provision

9. The professional groups with an interest in haemophilia suggest that the most effective way of improving counselling provision(and other aspects of haemophilia services) for the longer term is to incorporate minimum standards in a national service specification. The recently formed Haemophilia Alliance (bringing these groups together including the Haemophilia Society) has started work on a proposed national specification. This is based on work done in LRO and we plan to support the consensus specification through Regional Office Commissioning later this year. An outline of the specification is attached to **Annex C.**

10. The NHS Executive's Head of Specialised Commissioning has already written to the Regional Offices about the Alliance's specification seeking the involvement of people with regional commissioning responsibility. When we have a clearer idea of what the specification entails, how it fits into the national priorities, and how useful it is likely to be you might consider commending the work.

Possible Long term Impact of the specification

11. Haemophilia centres are currently designated by the UKHCDO based on criteria agreed in 1993. A new demanding service specification -see **Annex** 3 of the background paper -coupled with more effective commissioning, is likely to reduce the number of CCCs from 18 to 10 in England. There are in fact too many CCCs, clustered in the Metropolitan areas, providing variable service with little benchmarking. The specification, driven locally and supported centrally, should encourage better standardised patient care and more rational geographic provision. In addition it is likely to support a more effective system of clinical care in Haemophilia.

Action

12. We recommend

- supporting an extension of the Society's telephone counselling service
- encouraging the UKHCDO to protect current counselling services and
- commending the Haemophilia Alliance's service specification to cover key counselling needs.

13. You might also wish to consider

- Providing recombinant treatments for all people with haemophilia para 12
- Publicising the Society's materials on hepatitis C on the NHS web para 19
- Exempting them from prescription charges para 20
    - Publicising the outcomes of the co-infection seminar para 21

Annex A

Estimate of hardship fund costs for haemophiliacs infected with hepatitis C

Cost estimates

Full scheme: A scheme comparable with the HIV special payment scheme for haemophiliacs infected with hepatitis C, would cost an estimated £220 million. If the scheme were extended to non-haemophiliacs infected through transfusion, as for the HIV, the estimated would be £400 million. These estimates reflect payments of £55k for every infected person with iatrogenic hepatitis C over a 20/30 year period. The estimates remain valid and if anything underestimate the level of resource required –set up and running costs of the scheme were not included.

Hardship fund: A hardship fund for people with haemophilia and hepatitis C based on the amount disbursed by the Macfarlane Trust (MFT) so far in single grants and winter payments for haemophiliacs with HIV would cost an estimated £15 million over 10 years. This does not include the range of other benefits available under the MFT scheme like support with insurance, mortgage payments and home improvements.

Wider picture

£15 million is likely to be unacceptable. There would be no initial lump sum payments paid simply because people became infected - under the HIV scheme this was £43k for a single adult and over £80k for those who were married. Nor would a hardship fund provide a regular monthly payment like that under the HIV scheme. This in turn would lead to many more demands on any hardship fund. The qualification criteria for hardship payments would therefore need to be very tightly defined in relation to the impact of primary infection, the development of illness and the need for support over and above that provided through the Benefits Agency. There would be a continuing demand for parity with the HIV scheme.

Annex B

Forthcoming blood initiatives

Lord Morris debate on Hepatitis C blood products 30 March

We are providing you with a speech and briefing material for this. There is little more to say but Lord Morris is likely to be more eloquent than Michael Mates and will repeat the forceful contributions he has made over the past years. Lord Morris is president of the Society.

World Health Day 7 April

"Safe Blood" is the theme of World Health Day on 7 April. Initiatives in this country include the launch of the third annual report of "SHOT", (Serious Hazards of Transfusion) on that day. SHOT is a national audit of adverse blood transfusion events (eg viral, bacterial transmission , wrong blood transfused, or serious immunological reactions).

Action: You are opening the new/refurbished West End donor centre in the morning.

Issue and launch of hepatitis C booklets - 17 June

The hepatitis C booklets for young people and parents, which were funded through a S.64 grant are being issued to the public and will be launched formally on 17 June. You will be invited to this.

Co-infection seminar

S.64 funding is being provided in 1999/2000 to support the Haemophilia Society's HIV/hepatitis C co-infection seminar. It will take place in the 2000/2001 financial year, focussing on informing the professions. Again the Society plan tio invite you to the opening.

Decision on Combination therapy by NICE - July and September

The combination therapy for hepatitis C, alpha interferon with ribavirin, has been referred urgently to NICE. NICE's website advises the date for receipt of external submissions is 15 May, receipt of assessment report 15 June, initial appraisal 27 July, final appraisal 27 September.

Out of court settlement for people who developed hepatitis C through blood transfusion

The National Blood Transfusion Services only introduced universal (infact screening was happening anyway in about 50% of the service) hepatitis C screening of blood donors in September 1991 for a number of reasons, 6-9 months after there a valid screening test became available. 113 people are seeking damages against the National Blood Authority because they were infected with hepatitis C over a period including this gap in screening. Discussion continues and this will come to court in October if no settlement is reached.

Lilies at Downing Street - November

This is an annual event and in 1999 it was on 23 November. There were 113 lilies to mark deaths of haemophiliacs from hepatitis C.

Annex C

BACKGROUND PAPER - HAEMOPHILIA AND VIRAL INFECTION

Numbers

1. Approximately 6-7,000 people have haemophilia in the UK.

2. 500 are infected with HIV (800 have already died). Most of those with HIV are co-infected hepatitis C. (5% to 6% of all haemophiliacs are co-infected).

3. About 4000 haemophiliacs (55% to 60%) have hepatitis C.

4. Approximately 2000 - 3000 of haemophiliacs (30% to 35%) have neither HIV nor hepatitis C.

5. An estimated 200,000 to 300,000 people in the population as a whole are infected with hepatitis C. The majority of the people infected are unaware of their hepatitis C status. In the general population infection is related to IV drug misuse. The infection is only poorly transmitted through sex or intimate contact.

Patient group

6. People with haemophilia are mostly male, with the women being carriers. Some female carriers also present mild symptoms of the disease and require treatment especially for surgery and at childbirth. Some rarer forms of haemophilia affect both sexes equally.

7. The number of people with haemophilia is likely to be increasing slightly. With the development of blood products to treat the disorder in the 1960s/70s, people with haemophilia increasingly had families. While genetic counselling and termination is a possibility, this is often difficult in a family with a history of haemophilia especially where there are good treatments and the family want male children.

8. In about one third of cases there is no family history of haemophilia, and the condition has arisen as a result of spontaneous genetic mutation.

9. Though the numbers with haemophilia and hepatitis C are relatively small, the underlying disease is said to make the hepatitis C more difficult to manage -liver biopsies cause bleeding even in non haemophiliacs and severe disease causes further bleeding disorder problerms.

Care and Treatment

10. Blood product development for the treatment of people with haemophilia began in the late 1950s with the establishment of 5 reference centres for the treatment of hereditary bleeding disorders. Based in hospitals in Oxford, Cardiff, Manchester, Sheffield and Newcastle, these were the forerunners of today's Haemophilia and Comprehensive Care Centres .

11. Blood products such as Factor 8 & 9 became available from the late 1960s in the form of cryoprecipitate –obtaines form plasma from blood donors. Up to then haemophiliacs had reduced life expectancy, and by their teens they suffered severely

from arthritis and joint deformity. In many cases the children attended special schools (ie Lord Mayor Treloar).

Hepatitis

12. The quantity and quality of blood products increased significantly during the late 1970s, but known to transmit viral infections in particular hepatitis. Hepatitis B and later hepatitis C or "nonA, nonB hepatitis" existed since the beginning of blood transfusion medicine and were associated with the new blood products. Because blood plasma goes into large pools (20,000 to 60,000 units) for the manufacture of blood products, and because of the prevalence of hepatitis C, all haemophiliacs using blood products were infected with hepatitis C before heat treatment was introduced in the mid 1980s. Hepatitis C was not fully characterised until 1989 and there was no reliable screening test for it until 1990/91.

13. Although research had shown that heat treatment inactivated the "non A non B" hepatitis in blood products, the technology was not sophisticated enough to allow adequate inactivation of viruses while at the same time producing sufficient quantities of blood products. In the 1980s heat treatments were developed to inactivate HIV which was also transmitted by blood and blood products. HIV was however much more sensitive to heat than hepatitis C and while early heat treatment regimens got rid of it hepatitis C could still be transmitted through blood products. From the mid 1980s a range of heat treatments were developed that eliminated both HIV and hepatitis C.

Genetically engineered blood products

14. Up to 1990 clotting factors were made from human plasma. Then, recombinant (synthetic) products began to be available. Recombinant products are commercially produced through genetic engineering outside the human body. They are not however entirely free from human products as they contain small amounts of human albumin as a stabiliser. From the point of view of infection they are safer than the human plasma derived blood products but are associated with a number of other adverse events including the development of antibodies and hypersensitivity reactions.

Variant CJD

15. In the light of patients' worries about the theoretical risk of the transmission of vCJD through human blood products, Ministers required HAs to provide recombinant Factor 8 for all young people with haemophilia under 16 and new patients from April 1998. The same applied to recombinant Factor 9 when it was licensed in the following year. The logic was that these patients would have had limited exposure to the vCJD agent (through plasma derived blood products) compared with older people and that their exposure to the theoretical risk of infection through blood products might be reduced if they only received recombinant factor 8.

12. Policy in Scotland and Wales is to provide Recombinant Factor 8 and 9 to all, but availability limits provision to about the same scale as in England.

Possible option: to request that all HAs in England fund recombinant Factor 8 and 9 for all people with haemophilia. This will have no direct relevance to those who are already infected with hepatitis C, but it is likely to please the haemophilia community as a whole.

> **Estimated cost:** approximately £40 million per annum in additional cost of the synthetic products, plus the effect on BPL of losing its home market for coagulation factors
>
> **Elephant traps:** there may not be sufficient quantities available not all haemophiliacs may want recombinant products

Treatment of haemophiliacs with hepatitis C

13. The indications are that the newly licensed combination therapy (alpha interferon with ribavirin) is considerably more effective than interferon monotherapy (40% against 20% or less). We have referred the combination therapy to NICE for urgent consideration. In the meantime enquiries are being made through ROs on cases where haemophiliacs with hepatitis C have been prescribed the therapy but it is not being funded. Our position is that a) the imminent NICE decision does not constitute a moratorium and b) there are no "blanket bans" in the NHS.

14. The Haemophilia Society consider that there is not enough counselling for people with haemophilia infected with hepatitis C. Counselling may be particularly needed at certain times by haemophilia patients, for example to inform decisions about genetic testing, before and after hepatitis C testing, and when new therapies become available.

Counselling

15. Counselling services for hepatitis C are very variable in the NHS. They are provided by HIV counsellors, haemophilia nurses, by hepatitis C nurse specialists and by hospital social workers with general counselling skills and a reasonable level of knowledge about hepatitis C.

16. The Haemophilia Society's hepatitis C worker regards the haemophilia counselling at the Newcastle CCC as an excellent service. They are employed by the local authority; because funding is stretched their contracts are reviewed each year. Their view is that the most constructive way to develop counselling for haemophilia/hepatitis C is through the service specification being drawn up by the Haemophilia Alliance.

17. The part time Social Worker at the Nottingham Haemophilia Centre has provided a breakdown of counselling tasks in relation to haemophilia and hepatitis C over one year:
    benefits advice – 17;
    housing problems – 5;
    adaptations and aids – 9;
    bleeper/telephone – 8; family fund applications – 10;
    general advice and counselling – 13;
    school problems – 5; liaison work – 2; and
    local support group work, haemophilia out patient clinics and research work

18. Recommendations on pre and post hepatitis C test counselling have been drawn up by "C Change", an umbrella group comprising representatives of the British Liver Trust, hepatitis C patients, consultants and hepatitis specialist nurses.

19. The hepatitis C booklets which the Department funded (£83k) are beginning to be distributed by the Haemophilia Society. We understand that the take up of the booklets is likely to be high, because they are being requested by non haemophiliacs with hepatitis C, but the Society have advised that distribution through haemophilia centres can be erratic. There will be a formal launch and it is likely that Lord Hunt will be invited.

Option: We could also offer to refer to the booklets in publications, eg CMO's Update so that doctors are aware of them or publicise them on the web

<u>Prescription Charges</u>

20. The issue of prescription charges for haemophiliacs infected with hepatitis C has surfaced with the advent of anti-viral therapy for hepatitis C. Although people with haemophilia can use the Low Income Scheme or prepayment certificates as other patients can if they are eligible, they are not otherwise, as a group, exempt from prescription charges. PPB are exploring the possibility of an exemption and the implications for other groups.

Option: Prescription exemptions for people with haemophilia

<u>Co-infection seminar</u>

21. S.64 funds (£21k) have been provided for the HIV/hepatitis C co-infection seminar which be held this year and which will aim to keep professional groups well informed.

Option: We might publicise the seminar and its outcome through our website.

ANNEX 1

NHS Executive Guidance in HSG (93)30 set out the functions of Haemophilia Centres and CCCs respectively. It stated that -

both CCCs and haemophilia centres have to provide the following:

clinical service from experienced staff, day or night, at short notice

laboratory service capable of carrying out all necessary tests for the definitive diagnosis of haemophilia and monitoring therapy

participation in quality assurance and audit

an advisory service to patients and close relatives on matters specific to haemophilia, and an advisory service to GPs

maintenance of records and a register of patients attending the centre

counselling patients and relatives in privacy

organise and provide advice on home therapy programmes.

<u>In addition, CCCs have to provide:</u>

prophylactic treatment programmes

24 hour advisory service to haemophilia centres

specialist consultant service for all surgery including orthopaedic and dental, and specialist consultant service for infections such as HIV and hepatitis, and for genetic, and social care and any other counselling services

a reference laboratory service for haemophilia centres, together with advice

educational facilities for staff to promote optimal care

coordination of meetings and undertaking research programmes, including clinical trials.

ANNEX 2

Comprehensive Care Centres

England

Birmingham QEH
Birmingham Childrens
Cambridge (Addenbrookes)
Kent & Canterbury
Hampshire
Leeds
Leicester
Liverpool (Royal and Alder Hey)
Manchester (RI and Childrens)
Newcastle
Nottingham (QMC)
Oxford (Churchill)
Sheffield (Hallamshire and Childrens)
London (GOS)
London (Royal Free)
London (St Thomas's)
London (Royal London)
London (St George's)

In terms of NHS Executive Regional Office location, there are 2 CCCs in the West Midlands, 1 in ERO, 6 in LRO, 2 in SERO, 2 in NYRO. 3 in Trent. 2 in NWRO and none in SWRO. (The CCs in the other UK countries are in Edinburgh, Glasgow RI, Glasgow Childrens, Cardiff UHW and Belfast.)

ANNEX 3

KEY ELEMENTS OF SOUTH THAMES SERVICE SPECIFICATION

all patients with severe haemophilia to have access to CCCs

all Haemophilia Centres establish a formal relationship with CCCs, according to locality

arrangements for CCC/Haemophilia centre shared care

3 yearly audit of CCCs by the UK Haemophilia Centre Directors Organisation; provision of audit results to HAs (leading if appropriate to appraisal of the configuration of haemophilia services)

clearer emergency arrangements

appropriate facilities – car parking, access for disabled people, dedicated clinical area

all patients to have regular clinical review and tests: minimum - yearly for those with mild haemophilia, or those with HIV, hepatitis B or hepatitis C, three times a year for those with moderate or severe haemophilia

referrals to specialised HIV/HCV units

recommendations on prophylactic therapy

treatments

carrier detection, genetic counselling, antenatal diagnosis

purchase of blood products (eg CCCs purchasing on behalf of Haemophilia Centres)