Witness Name: Katherine Victoria Burt

Statement No: WITN6392001

Exhibits: WITN6392002 - WITN6392267

INFECTED BLOOD INQUIRY

WITN6392105

SUMMER 2001 ISSUE 2

THE BULLETIN

RECOMBINANT TREATMENT SHORTAGE

US shutdown means worldwide problems

Whilst the Society continues to campaign actively for provision of recombinant for adults and children alike throughout the UK, we are currently in the grip of a major recombinant factor VIII shortage.

As this Bulletin went to press, the Society was still waiting for a firm commitment from Government to extend recombinant provision to all as swiftly as supplies will allow. Our parliamentary supporters at Westminster have continued to question health ministers - to which the same reply has been given, to the effect that government is still considering the issues. We will have to return to this after the election.

No Kogenate or Helixate

In the meantime, the next six months or so will be very difficult as the haemophilia community struggles with the recombinant shortage caused by the shutdown of the Bayer plant in California. This means that there are no supplies of Bayer's recombinant FVIII product Kogenate coming into the UK.

Because Bayer also manufactures Aventis Behring's product, Helixate is not available either. To add to the problems, since Bayer supplies many countries internationally, this is not only a national shortage, but a global one. *(Continued on page 12)*

GRO-D

The Society's CEO, chairman and trustees joined members of the Manor House and Birchgrove groups and others in a lobby of Parliament on 3 April.

Parliamentary campaigns boost

The Haemophilia Society has hired one of the world's largest public affairs consultancies, Weber Shandwick, to help us in our campaigning work. One immediate benefit is that we now receive a comprehensive weekly political and parliamentary monitoring report. This gives a record of every mention (in debates and written answers) that is in any way relevant to issues affecting people with haemophilia, in both the UK and Scottish parliaments.

Debates and lobbies

And there has been much recent activity to report before and after the election. Our president, Lord Morris of Manchester, prompted a debate about Hepatitis C infection by contaminated NHS blood products in the House of Lords on 23 April. Meanwhile, Labour MP Fraser Kemp, (Houghton and Washington East) tabled an Early Day Motion in support of an urgent inquiry into the issue of contaminated blood and the non-testing of concentrates; and further that treatment should be of the highest quality, with fair and just compensation for victims. Haemophilia Society members were active in raising the campaign aims with parliamentary candidates during the election. The Carpet of Lilies campaign, launched in May, was the first phase of the new strategy created by Weber Shandwick.

(See the Chief Executive's column, page 2 and Campaign Update, pages 6-7)

CONTENTS

MAGAZINE OF THE HAEMOPHILIA SOCIETY

NR

Thanks go to the following pharmaceutical companies who are providing valuable support in 2001: Aventis Behring, Baxter, Bayer, Novo Nordisk, Roche, Schering-Plough, Wyeth/Genetics Institute

Copies of the Haemophilia Society's commercial funding guidelines are available on request

Safety and supply:

twin pillars of haemophilia care

The last issue of the Bulletin was dominated by the shadow of variant CJD with the news that a plasma donor had been found to have the disease. This brought to the fore again concerns about treatment product safety. Now, less than two months later, the community has been hit with a serious shortage of recombinant, as reported on our front page. It is timely - and very relevant - that the World Federation of Hemophilia is organising a second global forum this September on the issues of safety and supply. These are the twin pillars on which effective haemophilia care is built - and yet as recent events have shown, neither is fully secure.

To address concerns about safety, the Society is still campaigning for recombinant for adults and children alike in the UK. We know the supplies are not available at the moment to make this a reality. But we want a firm commitment from Government now to the principle of providing recombinant for all - and a pledge to phase recombinant in as rapidly as supplies allow.

This will remain one of the Society's main campaigning aims until that policy is implemented. As Bulletin readers will know from the last issue, we are also re-launching our campaign on behalf of those who were infected with HIV and hepatitis viruses through contaminated blood products. We have hired one of the world's largest public affairs consultancies, Weber Shandwick, to help us fight the campaign for a public inquiry and a hardship fund for those with hepatitis C.

Members and volunteers will have a key role in this campaigning - as they have always. The Carpet of Lilies campaign action pack sent out recently is full of ideas for activities you can undertake.

In the run up to the General Election we targeted all parliamentary candidates with our campaign demands - and we must ensure that the pressure continues relentlessly on the new Government. The haemophilia community may be small but - if everyone does their bit to support the campaign - we can have a loud voice and 'punch above our weight'.

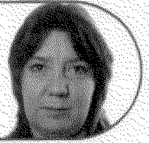
GRO-C

Karin Pappenheim
Chief Executive

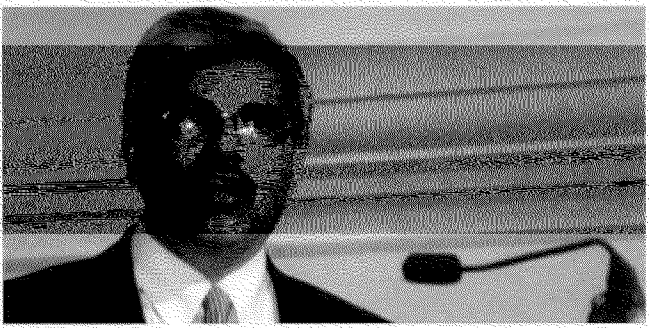
NOT RELEVANT

RED RIBBON

compiled by Babs Evans,
HIV/HCV Worker



HIV AND HEPATITIS C CO-INFECTION SEMINAR



Dr Has Dasani from Cardiff speaking at the seminar, which was attended by over 120 people. This successful event was the first of its kind. More in the next issue...

Hat Trick Group

Haemophilia, HIV and HCV... not the sort of hat trick anyone would ask for. The Hat Trick Group has been offering facilitated peer support for people living with, and affected by, these issues in London and the South-East for the last year. I am a man affected by all of the above and run the group on a voluntary and independent basis, I am funded by Crusaid and supported by The Haemophilia Society, THT Lighthouse and Macfarlane Trust.

Apart from regular meetings held in West London, Hat Trick disseminates current information to over 140 people through the MFT confidential database. Meetings are topic based - recently issues covered include liaison with MFT, and a presentation by Dr Paul Giangrande (Centre Director, Oxford Haemophilia Centre) on blood product safety. These events also give people an opportunity to get together in a safe place to have a chat, share experiences and maybe even have fun!

It is very important that anyone affected by the issues feels welcome. The group actively encourages partners, widows, girlfriends, boyfriends and all those affected to join in. If you have any questions or comments about the group please contact GRO-D or Babs on GRO-C
Email haemophiliagroup@hotmail.com

Weekend for young people living with haemophilia and HIV - and guests

Following the success of last year's 16 to 30 weekend in Blackpool, we are pleased to let you know that the Elton John AIDS Foundation, the Society and Macfarlane Trust are funding a similar weekend this year. It will be held in Manchester from 14-16 September. The working party has acted on feedback received last year, and the programme will include workshops about employment, making the most out of organisations, workshops for partners, HIV, HCV and haemophilia treatment issues and complementary therapies for all delegates (including guests).

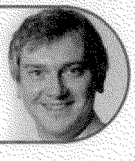
For a booking form or further information, please call Babs or GRO-D at the Society, or email GRO-C

NR

We are grateful for the support of the John Ellerman Foundation, Pilgrim Trust and Elton John Foundation for funding our HIV/HCV work.

HEPATITIS

compiled by John Morris
Hepatitis Worker



SURVEY RESULTS

NATIONAL SURVEY OF PROVISION OF CARE FOR PATIENTS WITH HIV AND HEPATITIS BY HAEMOPHILIA CENTRES.

The Society was concerned that there were reported variations in care provision for people with HIV and hepatitis C. Dr Linda Garvican, Public Health Specialist, was therefore asked to carry out this survey for the Haemophilia Society. Among the main findings were:

- Availability of some support services is good but HCV or HIV clinical nurse specialists are in short supply
- 30% of Comprehensive Care Centres find access to counselling difficult, and doctors and nurses often provide the only counselling available
- All the CCCs had traced and tested patients at-risk of HCV, but only half the smaller centres had done so
- 60% of CCCs had no funding for interferon alpha/ribavirin combination therapy. This situation should improve following publication of the National Institute of Clinical Excellence (NICE) guidance. However, about 20% of CCCs reported lack of money for testing and counselling, which are also essential components of care
- Clinical guidelines for HIV/HCV co-infection are urgently needed

(Unfortunately, not all centres returned completed questionnaires, including Newcastle and St Thomas', the largest Comprehensive Care Centre.)

PROVISION OF COUNSELLING

There are difficulties with access to counselling in 30% of CCCs. Even when centres do not appear to have a problem, the service may not be provided by a professional counsellor. In smaller centres, it appeared that this was generally from the haematologist. In CCCs most counselling and support came from the centre team of doctors and specialist nurses, with occasional access to the hepatic clinic team (we have no information whether these clinicians had any specialist training in counselling). The Haemophilia Society has anecdotal evidence through its helpline that patients have difficulty accessing adequate counselling. In March 2000 the Department of Health asked the UK Haemophilia Centre Directors Organisation (UKHCDO) to make counselling available to all haemophilia patients with HCV and this should include access through CCCs for patients at smaller centres.

John Morris is running a three-year project to look into the counselling needs of everyone affected by HCV and haemophilia and would be interested to hear your views or experience. If you would like a copy of the survey report, or to receive our newsletters about HIV and HCV, please contact John Morris or Babs Evans at the Society.

NATIONAL SURVEY OF HEALTH AUTHORITIES AND BOARDS

This survey, carried out by Dr Linda Garvican, achieved a 60% response rate from health authorities. Of these, few knew how many people in their areas were infected with Hepatitis C. The survey showed:

- 96% of HAs consider HCV an important public health problem - although only 25% had included it in their Health Improvement Programme
- Over 85% of Health Authorities/Boards support national initiatives such as a UK-wide prevention strategy, clinical guidelines and public education programmes - but only 59% support a National Service Framework
- 27% support a national screening programme for HCV
- 66% had protocols in operation
- 50% had reviewed treatment options formally in committee

Three Health Authorities did not provide any treatment for those with HCV, and information, counselling and support were either unavailable or restricted to certain groups in up to 20 more. Although over 90% of authorities were funding interferon and/or combination therapy, complete diagnostic testing was unavailable in one-third (against established guidelines) and 23 authorities had some restrictions on how patients could be treated.

The amount of funding available varied widely. Of the two-thirds of HAs who earmark funding for HCV care, some will only pay for one or two patients per annum, others over 100, with a mean of about 25 - but the typical funding per patient is insufficient to provide the course of combination therapy. A follow-up survey later this summer will measure the change.

WEBSITES:

- www.britishlivertrust.org.uk
- www.nice.org.uk
- http://members.aol.com/linersmain

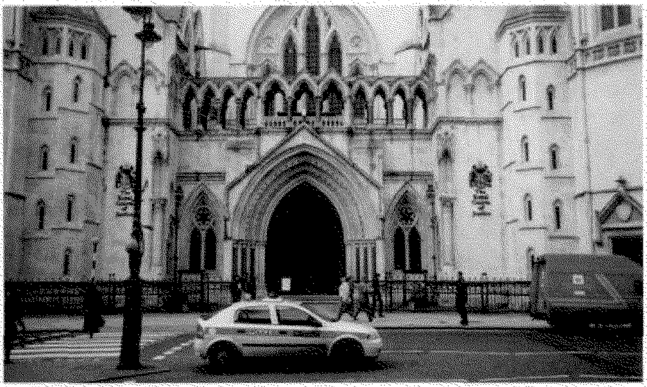
WORKING FOR A C-CHANGE

C-Change is an umbrella organisation of three charities heavily involved in HCV treatment, care and awareness issues - The British Liver Trust, Mainliners and the Haemophilia Society, together with pharmaceutical companies Roche and Schering-Plough who provide funding. Its areas of concern are:

- **'It's more than drug therapy'**
  C-Change also concentrates on HCV infrastructure, social welfare and individuals' access to services
- **'Policing post-NICE'**
  The National Institute for Clinical Excellence's guidance on combination therapy for HCV still needs to be translated into universal funding at a local level
- **HCV on the agenda**
  A conduit for information and promotion of HCV into the government's, health services' and the media's agenda.

LANDMARK COURT RULING

National Blood Authority ordered to pay compensation for damage caused to claimants' lives.



On 26 March, 114 people were successful in their claim against the National Blood Authority (NBA) for compensation for having contracted hepatitis C through their NHS treatment. Their action was taken out using the Consumer Protection Act 1987, which applies to all products supplied from 1 March 1988. The claimants were infected with HCV through contaminated blood transfusions, blood products (not necessarily clotting factors) and organ/tissue transplants between 1 March 1988 and 1 September 1991 when the UK finally introduced screening of all blood for hepatitis C.

> *'The public expects (and is entitled to expect) clean blood'*
>
> **Mr Justice Burton**

Mr Justice Burton said that people generally were entitled to expect clean blood and that the NHS should have introduced routine screening of all blood transfusions by 1 March 1990. Damages ranged from £10,000 for two young men who were infected by blood transfusions who later cleared the virus (either with or without treatment) to over £210,000 for a woman in her fifties who contracted HCV in the course of routine surgery and later developed cirrhosis of the liver and required a transplant.

Websites:
www.courtservice.gov.uk www.deas-mallen.co.uk

Repercussions of the ruling

None of the claimants in this action were people with haemophilia, most of whom would have been infected with HCV well before March 1988 when the Consumer Protection Act came into force. The repercussions of this judgement for the haemophilia community are being considered carefully throughout the United Kingdom, by both the legal profession, the Government and devolved administrations. However, there is no immediate financial benefit to people with haemophilia as a result of the ruling - although some may see it as a moral victory.

The court judgement against the NBA is the first time that any public body has been held to account for the disaster of contaminated blood.

COMPENSATION FOR CLINICAL NEGLIGENCE

A second group of people is being assisted by the solicitors who led the case against the NBA, Deas Mallen. They are making different types of claims, arising out of infection with either hepatitis B or C. The group includes some people with bleeding disorders. The court will make its assessment of injuries and financial damages in June.

These are clinical negligence cases and liability has been admitted. If you have mild (ie not moderate or severe) haemophilia/von Willebrand's and were first infected (not diagnosed) in 1982 or later, then a legal opinion is that you might have a case for compensation, particularly where it was possible to manage your bleeding in some other way. If you would like to follow this up then make contact with the Society's hepatitis worker, John Morris, for more information.

Soundbites

"The unmistakable logic of the ruling is that [the haemophilia community] too must now be urgently compensated."
Lord Morris of Manchester

"...we have no plans for the introduction of a no-fault compensation scheme. Such a scheme would have far-reaching policy and financial implications which would need to be explored very carefully."
Lord Burlison (Lab, Government Whip). Hepatitis C Debate – House of Lords, 23 April

"Although the recent ruling in England has no direct bearing on what happens in Scotland, it places a moral obligation on us to consider no-fault compensation."
Shona Robison – SNP, NE Scotland. Scottish Parliament Hepatitis C Debate – 26 April

"This is not a party political issue...MSPs on all sides of the chamber have expressed support in a range of ways for the affected haemophiliacs. It is about fairness and justice. A group of people in Scotland – albeit a very small group – have been denied justice. We can start to put that right today..."
Nicola Sturgeon, SNP, Scottish Parliament debate 26 April

Government estimates the cost of giving recombinant to all haemophilia patients in England currently on plasma derived products as £47 million (written answer)
Lord Hunt, 27 February 2001

"The Government's refusal to instigate a public inquiry surely fails the morality test. Surely the sequence of events which led up to what has been widely referred to as one of the greatest tragedies in the history of the NHS needs to be examined with the utmost scrutiny"
Lord Clement-Jones, House of Lords 23 April 2001

New three-stage campaign strategy

WEBER SHANDWICK
PUBLIC AFFAIRS

Weber Shandwick have devised a three-stage campaign, to be proactively implemented over the next nine months, starting with the Carpet of Lilies initiative involving Society members all over the country. The campaign combines parliamentary activity with press and media work.

The Carpet of Lilies campaign features white lilies as an emblem of people with haemophilia who have died - or are still suffering - as a result of HIV or hepatitis passed on through contaminated blood products. Haemophilia Society members have been asked to target, in their own constituency, politicians of all parties, to seek a pledge to support the campaign aims and to present a symbolic lily. As pledges come in, the Society will use them to build a 'carpet of lilies' representing political support for all parties across the UK.

Campaign contacts

Jo Nove, Ben Abbotts - Weber Shandwick Public Affairs
Karin Pappenheim, GRO-D, John Morris - Haemophilia Society. *(see page 2 for contact details)*

Our campaign aims

The Haemophilia Society has intensified its campaign activity with the help of Weber Shandwick Public Affairs.
Our campaign aims to achieve:

- Recombinant for all, children and adults alike, throughout the UK to avoid the risks of future blood-borne infections
- A public inquiry into the tragedy of contaminated blood products that infected people with haemophilia with HIV and hepatitis viruses.
- Financial recompense through a hardship fund for people with haemophilia infected with hepatitis C in addition to the financial assistance scheme established by Government in 1987 for those infected with HIV (the Macfarlane Trust).

PARLIAMENTARY DEBATES

In the House of Lords on 23 April, Lord Morris asked Her Majesty's Government "what further help they are considering for people who were infected with hepatitis C by contaminated NHS blood products and the dependants of those who have since died as a result of their infection". In the course of the debate, Lord Clement-Jones (LibDem) called for recombinant for all, financial reparation and a public inquiry. Lord Astor of Hever (Cons) requested the standardisation of all aspects of haemophilia services by calling for the provision of recombinant for all and comprehensive care centres to be geographically evenly spread. He asked what plan the government has to set up a nation-wide system to identify and monitor all people with haemophilia; how the government plans to ensure that plasma-derived treatments are screened for vCJD; and finally called for far more funding into HCV research.

A few days later, on 26 April, a debate on hepatitis C took place in the Scottish Parliament. The Haemophilia Society was active in briefing Scottish parliament members for this debate and previously in March, giving evidence to the Scottish Health and Community Care Committee. The Scottish Health Minister, Susan Deacon, appeared before the committee on May 23.

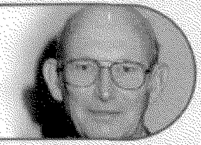
NR

NR

NR

NR

Compiled by Dr David Evans



RECOMBINANT - ABOUT THE SHORTAGE

Why has Bayer stopped supplying?

The US Food and Drug Administration (FDA) imposes very strict monitoring controls over the production of recombinant (and other products). Following an inspection of Bayer's plant in Berkeley, California in December 2000, some issues were raised about the data management and record keeping systems and the documentation relating to the manufacturing process. Product release has been suspended whilst Bayer addresses these quality control processes. The Society has been assured that this problem does not affect the final stage quality of the products.

Could recombinant be supplied by another company?

The other main recombinant factor VIII producers (Wyeth who make Refacto, and Baxter who make Recombinate) are already producing to full capacity and are unable to make up the shortfall. Unfortunately, even before the current difficulties, recombinant supplies were not sufficient to cover all UK patients.

When will supply of recombinant resume?

At present, it is unclear when Bayer 'Kogenate' and Aventis Behring 'Helixate' will be able to fully resume normal supplies to the UK. The situation is changing day by day. Whatever happens, the current difficulties could well be with us for several months and probably for the rest of the year. The shortage does not affect recombinant factor IX products.

What is being done in the UK to ease the situation?

The UK Haemophilia Centre Doctors Organisation (UKHCDO) has produced a set of guidelines to limit the amount of recombinant clotting factor being used and conserve the now very reduced supplies. The impact of the shortage will mean that some people - particularly anyone over the age of 16 years - are asked to switch to plasma derived products.

Priority will be given to children who have always received recombinant (ie never had plasma products). As the shortages continue, some centres may find they have no recombinant FVIII stocks at all, even for young children. The UKHCDO is therefore calling on all haemophilia centres and recombinant suppliers to work together to manage the situation, and if need be, to redistribute recombinant from centres with supplies to others without, in order that these children can stay on recombinant. The Department of Health has written to all health authorities and trusts to urge them to co-operate in managing this crisis, and requiring haemophilia centres to participate in this redistribution scheme. The other recombinant manufacturers, Baxter and Wyeth, are also collaborating in this effort.

The Haemophilia Society has been in close contact with the UKHCDO since the start of these difficulties, and we have sent information out to members as it became available as well as providing information and advice via the national helpline. For the latest see our website or call 0800 018 6068.

STOP PRESS: See update insert with this issue.

NR

TREATMENT update

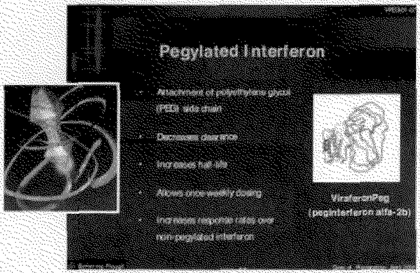
The latest on variant CJD

No-one with haemophilia has contracted variant CJD, and there is still no evidence that it can be transmitted by blood products. Ninety-nine cases have now been reported in the UK. Although some factor VIII and IX concentrates were made in 1996-7 from plasma of a donor who has since died of variant CJD, no evidence has been found of transmission to people who received material from this donor.

A group of researchers in New Zealand have proposed that BSE (the disease in cattle which causes variant CJD in man) was introduced into the UK in antelopes who were brought to safari parks. This seems a reasonable explanation; but isn't it strange how bringing animals from one country into another seems always to cause unexpected problems? The grey squirrels brought from America have nearly driven out the native red squirrels. Mink brought from abroad into fur farms have escaped and are killing other small wildlife. Rabbits that were taken to Australia have ruined crops there. Perhaps we should be worrying more about the animals that come into this country from abroad, and less about the human beings.

So far, variant CJD has only been found in the 40% of humans who have one particular genotype. This could mean that only 40% of the population are susceptible to the disease - or in other words, that 60% are unable to catch it. Another explanation is that the other 60% have a longer incubation period and will only become ill in the years ahead. Time will tell.

Pegylated Interferon and Ribavirin



Pegylated Interferon

- Attachment of polyethylene glycol (PEG) side chain
- Decreases clearance
- Increases half-life
- Allows once-weekly dosing
- Increases response rates over non-pegylated interferon

ViraferonPeg (peginterferon alfa-2b)

12kDa Peginterferon alfa-2b
Inset: Roche's drug "Pegasys" 40kDa Peginterferon alfa-2a

Schering-Plough launched their new treatment for hepatitis C at the end of March 2001. The combination of pegylated interferon (ViraferonPeg) and ribavirin (Rebetol) is now available to practitioners in the UK. It has significant advantages over standard interferon and ribavirin which is the current treatment of choice.

The company boasts a sustained virological response rate (SVR) of 54% in patients undergoing this treatment, which compares to 47% for non-pegylated combination treatment and 12% for interferon-alone treatment. A projected figure of 61% is given when the dose is adjusted according to body weight. The figure of 54% is defined as patients continuing to be negative for the presence of the virus six months after the end of the treatment. The headline figure is reduced to 42% for patients with genotype 1 (unfortunately the type most commonly found in people with haemophilia).

Benefits of pegylation

The modification of interferon by pegylation (the attachment of an inert substance to the interferon molecule) results in the human body being slower to attack the drug before it is allowed to do its work on the virus. It also acts as a slow-release mechanism to even out the amount of active drug in the blood over the period of treatment. As a result, it only needs to be injected under the skin once a week rather than three times a week, which is currently the practice with non-pegylated interferon.

Because of the way quality of life measurements are reported, no advantages in terms of reducing side-effects or increasing drug safety are claimed. However, there is anecdotal evidence that the side-effects attributable to interferon are more manageable in the once-weekly pegylated interferon treatment since they are less prolonged than in the three-times-a-week non-pegylated treatment. Patients have often chosen to inject themselves just before the start of the weekend, accepting that they might suffer the 'flu-like' side-effects of the pegylated interferon over the first few weekends when they are at their greatest, but leaving themselves relatively free to work a normal Monday to Friday week.

Roche is the other company working on pegylated interferon and hopes to register its Pegasys and Ribavirin early next year. Recent large-scale trials showed a SVR of 56% (11% higher than the old combination) and 46% for genotype 1. Roche also reports significantly reduced flu-like side effects and rates of depression.

John Morris
Hepatitis worker

If you would like to discuss the implications of these results, and the new drug, for you or your family, please ring John Morris at the Society.

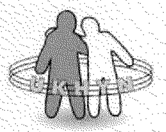
Some good news on recombinant. Baxter inform us that their new production suites at Thousand Oaks, California are now licensed and they have been able to increase their production of Recombinate. They supplied 30% more Recombinate to UK haemophilia centres during the first quarter of this year compared to the same period last year, and anticipate that they will be able to continue to supply at this increased level during the coming months. They have also increased the imports of their plasma-derived factor VIII, Hemofil M, so this will be available to help make up the shortages.

NR

NR

NEWS Update

UK Haemophilia Youth Network



Hi, my name is GRO-A I am 24 and I have severe haemophilia A. I have been the Haemophilia Society's youth representative for the past year. A trip to Montreal for the Haemophilia 2000 Congress inspired me to create the UK Haemophilia Youth Network. Meeting other people from around the world – involved in youth groups for the haemophilia community in their own countries – helped me understand that something was needed in this country.

The network is designed to allow people with haemophilia, who fall into the 'youth' bracket of 18-30 to be put in touch so that we can provide each other with support and exchange ideas and information.

As a group, we also have a voice that, perhaps, may be stronger than that of individuals. And as such, we may be more influential in matters that concern us directly – be that treatment, care or general support.

We are currently involved in a youth event for co-infected people in Manchester this September (*see page 4*) and hope to make it even better than Blackpool last year.

Talia Barry and I will be hosting a focus group at the Society's AGM to look at the future of the network. We are also looking to recruit a panel of volunteers to represent us and help with our management.

If you would like information or to be put in touch with the Youth Network, please e-mail or contact me via the Haemophilia Society – telephone GRO-C or Macfarlane Trust on GRO-C GRO-A GRO-C

GRO-A

NR