MS(PH)

From: Rowena Jecock

Cleared: Liz Woodeson

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Copy: As attached

FURTHER ADVICE REQUESTED ON TWO RECOMMENDATIONS FROM LORD ARCHER'S REPORT ON PATIENTS WHO CONTRACTED HIV &/OR HEPATITIS C THROUGH NHS TREATMENT WITH BLOOD/BLOOD PRODUCTS DURING THE 1970S AND 80S.

1. You requested further advice in relation to two of the recommendations made by Lord Archer. These are:
   - the recommendation to uplift the level of ex gratia payments currently made to those affected and their dependents, together with a change to some eligibility criteria, and a revision of the mechanism by which payments are made;
   - the recommendation that the future of the Haemophilia Society, a third sector organisation, should be supported by provision of on-going funding from Government.

Financial relief schemes

2. Your preferred approach is:

a) to replace the discretionary element relating to on-going payments made by the Macfarlane and Eileen Trusts (MFT, ET) with recurrent fixed payments. These Trusts support those who acquired HIV as a result of NHS treatment with blood/blood products, and their dependents. Currently, recurrent payments are at the discretion of the Trustees, and are made on the basis of their assessment of each applicant's need.
You would also like to see the level of recurrent funding for the MFT and ET increased.

In addition, there does appear to be some discrepancy in the level of initial lump sum payments between the MFT and ET. We have included a proposal to harmonise these payments, and have included what we believe to be a 'worst case' estimate of the likely cost of doing this. Given the sensitivity attached to ministers' consideration of the ex gratia payment schemes, we have not yet consulted the Trusts about this, but will do so when we have a firm steer from you and SofS.

b) to bring the eligibility criteria for the Skipton Fund (SF), which makes payments in relation to hepatitis C infection via blood/blood products, in line with those for MFT and ET. Currently, widow/ers and dependents of those who died before the SF was announced on 29 August 2003 are not eligible for any payment. (Any proposal to amend the SF would need to be agreed by all UK health ministers, as the devolved administrations contribute to the funding. In addition, in Scotland the eligibility criteria are set in primary legislation. This proposal in particular may also be relevant to a public inquiry which has just begun into hepatitis C/HIV infection from NHS treatment in Scotland. This inquiry, chaired by Lord Penrose, was set up by Scottish ministers. We have offered all reasonable assistance to Lord Penrose, who is expected to examine the response to any recommendations from Lord Archer.)

3. The options that you requested we examine for amendment to the financial relief schemes are presented in detail at Annex A. Our best estimate of the cost implications is summarised in the table below.

Summary of estimated one-off and recurrent cost implications of proposed changes to ex-gratia payment schemes

Payments to those affected by HIV and their dependents (MFT &ET)	
Estimated additional cost of harmonising the initial lump sum payments between MFT and ET	In the order of **£19m (one-off)**
Estimated additional cost of providing increased fixed sum payments on annual non-discretionary basis for life to all beneficiaries	**£2.1m (recurrent)**, assuming average payment/beneficiary of £10,000/year. (The current average is £6,400/year)
Payments to those affected by Hepatitis C and their dependents (SF)	
Estimated additional cost of making lump sum payment to widow/ers or dependents of those who died before the current eligibility cut-off date	In the order of **£54m (one-off)**
Total estimated cost implications of making these changes	**£73m (one-off)** **£2.1m (recurrent, but will decrease as beneficiaries die)**

4. Finance advise that reaching agreement both within DH and with Treasury and the devolved administrations over any financial implications will be challenging. As announced at the Pre-Budget Report, Treasury will allocate £5bn in additional efficiency savings across Departments in the Budget, in order to reduce public expenditure. They will be particularly concerned at any increase in spending in 2010/11 and beyond, both because of the wider fiscal position and because these can represent long-term commitments crossing multiple spending reviews. Both DH and the devolved administrations will face the challenge of reducing spending elsewhere

to meet any additional costs as, even if they agree to these proposals, Treasury will not provide any additional funding.

5. You asked whether additional funding for the financial relief schemes could be paid in instalments to ease the burden on central budgets. However, finance colleagues advise against this for the above reasons.

Support for the Haemophilia Society

6. You expressed the view that the Haemophilia Society is unique, and should receive ongoing 'core' funding. Your preferred approach is to establish a formal arrangement between the Society and the Department, which gives the society preferential status and establishes annual meetings between the Department and the Society. We have discussed this with colleagues responsible for third sector funding and their view is set out below.

7. Changes to the way DH funds and invests in third sector organisations have resulted in a strong commitment to ensuring all grants include the relevant contribution to management and overhead costs (full cost recovery) and a move away from 'core' grants to more strategically relevant investments. These have included funding to develop the capability and strategic relevance of organisations. This approach has been welcomed by third sector organisations as investing in this way also brings closer working relationships between those organisations receiving funding and officials in the Department, whilst at the same time preserving their independence.

8. There are many single-focus and specialist third sector organisations that work with rare and minority conditions and groups. It could be a dangerous precedent to set to identify any single organisation as truly unique when many others could argue similar cases. The Department needs to ensure that there are open, transparent and equitable processes accessible to all organisations across the sector.

9. Officials' view is that the Haemophilia Society would do better to position itself to represent the spectrum of needs of all its members. If it focuses primarily on those members tragically affected by infection as a result of treatment, which may happen if it is given 'core' funding, it will have diminishing relevance to the 20,000 or more people who are not so affected. Consequently, provision of 'core' funding may actually undermine the Society's ability to ensure its relevance to the majority of those with bleeding disorders, and removes a key incentive for the Society to maintain flexibility and best position itself to respond to the changing health and social care environment.

10. As the Society is small and very specialist, this will require increasing partnership working with other third sector organisations that have skills and experience in advising on access to other services that may become increasingly important to patients with bleeding disorders. As

the membership affected by infectious diseases becomes smaller, it is also likely that their specialist needs may be best served by partnership working between the Haemophilia Society and organisations that specialise in HIV/hepatitis support.

11. With advice from the Third Sector Partnership Team, Health Protection Division has identified £100k within its 2009/10 programme budget to provide a development grant to the Haemophilia Society to enable it to develop its capability to support the spectrum of bleeding disorders, and to develop strategic partnerships with other third sector organisations where there are mutual benefits. Similar grants have been provided to other third sector organisations with considerable success. Examples include; investing in the development of a consortium of women's organisations to develop closer partnership arrangements and collaborative working on addressing sustainability issues across the women's third sector; and supporting The Afiya Trust, a small specialist BME organisation, to develop and refine its business model and partnership arrangements to ensure it is able to respond to the changing environment.

12. The Haemophilia Society needs to develop its business model to reflect wider changes in health and social care commissioning and system management, including the developing personalisation agenda. Officials will ensure that the Haemophilia Society is connected with DH led third sector development opportunities including work emerging around specialist commissioning groups and through the work of the Strategic Partner Programme.

13. Officials recommend that providing funding for the Haemophilia Society to develop and build its capability and capacity in this way remains the most appropriate way forward. **You may wish to discuss this with MS(CS), who is responsible for third sector policy.**

Update on work in progress on other recommendations made by Lord Archer

14. Briefly, these are:

- Establishment of a statutory committee to advise Government of the management of haemophilia in the UK
- Free prescription drugs and free access to other NHS and support services.
- Enabling haemophilia patients to have access to insurance.
- Establishing a 'look back' exercise to identify any remaining patients who may have been infected, and may not be aware of this.

Establishment of a UK-wide statutory committee to advise Government of the management of haemophilia

15. In my submission of 19 March, I advised that establishment of a committee to advise Government of management of haemophilia and many other aspects of patients' needs, as recommended by Lord Archer, could have wide-ranging implications for management of other long-term conditions. It could also cut across the work of NICE in England, and the Scottish Intercollegiate Guidelines Network, and upset established mechanisms in England and Scotland for securing the provision of clotting factors, which already closely involve patients (my separate submission of 31 March requests your approval to proceed to tender for work to renegotiate national contracts for the procurement of those products by the NHS in England).

16. I have explored the option to extend the remit of the CMO's National Blood Transfusion Committee to enable a sub-group to be established which could perform some limited aspects of the functions Lord Archer proposes for a statutory committee. This option would only be available only to England and North Wales, as the area within the committee's remit (covered by NHS Blood and Transplant), and Welsh officials could be uncomfortable with this. Also, this option is not likely to be acceptable to the UK Haemophilia Centre Doctors' Organisation (UKHCDO), who are concerned that it cuts across the established mechanism for production of guidelines on bleeding disorders, which it operates in conjunction with the British Committee for Standards in Haematology.

17. There already exists a UK-wide partnership, the Haemophilia Alliance, between patients with inherited bleeding disorders (via the Haemophilia Society) and clinicians involved in their care. The Alliance is jointly chaired by the Haemophilia Society and the UKHCDO. The Alliance was formed in 1999 and its first major task was the preparation of a National Service Specification (NSS) for Haemophilia and related conditions which was published in 2001 and updated in 2006. The UKHCDO view is that members of the Alliance would warmly welcome Government participation, including the majority of patients, although we have not yet consulted the Haemophilia Society. In our view, this would be a suitable route to enable all four UK administrations to formally engage with this group of patients, and the specialist medical, nursing and allied professions involved in the delivery of haemophilia care. It would also allow all to build on an established mechanism, and consequently make best use of available resources. We advise that you consult the Devolved Administrations on this proposal.

18. At Grand Committee on 17 March Lord Morris of Manchester withdrew his amendment to the Health Bill to establish a statutory UK-wide committee, as recommended by Lord Archer (votes are not permitted in Grand Committee). Lord Morris has retabled an identical

amendment for Report stage, at which votes can take place, which is expected to begin in late April.

19. Advice from the Whips is that, without significant reassurances, Government risks losing the vote. This would require the use of a Government amendment in the Commons to remove the new clause, protracting the debate on the committee for several months and potentially leading to difficult negotiations in Lords' consideration of Commons' amendment

20. We believe our argument in rejecting Lord Archer's recommendation is strong, and our proposal to work within existing structures will avoid unnecessary disruption. We will aim to have the Government response to Lord Archer's response prepared in time to pre-empt the debate on the amendment. Should this not be possible, we will likely recommend that you meet with Lord Archer and Lord Morris to clearly explain the reasons behind our decision not to set up the committee, to avoid this being taken to a vote.

Free prescription drugs

21. Professor Ian Gilmore, President of the Royal College of Physicians is undertaking a review of prescription charges that will consider how to implement the commitment to exempt patients with long term conditions from prescription charges. This will include advice on how the exemption should be phased in. The review is expected to report to you and SofS during the Summer. Professor Gilmore has not been asked to consider patients with haemophilia, HIV and hepatitis C separately from other long term conditions, but it is likely that extending exemption from prescription charges will result in these groups becoming exempt. Depending upon the timescale for introducing exemptions, there may be pressure to fast-track exemption for patients who have contracted HIV/hepatitis C through NHS treatment with blood/blood products.

Access to insurance

22. We have received some preliminary information from the Association of British Insurers, and plan further discussions with them to better understand the scale of premiums which infected haemophilia patients may be required to pay to obtain insurance. It may be that increasing the level of payments available through the financial relief schemes, especially for HIV, may address the main concerns about ability to pay insurance premiums.

Establishing a 'look back' exercise to identify any remaining patients who may have been infected, and may not be aware of this.

23. The UKHCDO believes it is possible that there may be some occasional recipients of clotting factor concentrate during the relevant

period (from about 1970 to 1985, after which heat treatment of clotting factor products eliminated the risk of infection via this route), who may have been infected, and are unaware of their condition. This is most likely in relation to hepatitis C, which, even if it progresses to severe disease, can be asymptomatic for decades. The UKHCDO does not, after the time that has elapsed, envisage identifying any undiagnosed cases of HIV.

24. UKHCDO estimate that a 'lookback' study to identify patients infected with hepatitis C would take between 6 to 12 months. We have asked them for an estimate of the cost, with a view to providing funding from the Health Protection Division programme budget in 2009/10, likely to be in the region of £50,000.

Summary

25. We welcome your views on the above, in particular:

- the proposals for increased funding for MFT and ET (paras 2-5)

- that you to write to the DAs, seeking their views on the proposal to amend the eligibility criteria for the Skipton Fund. The letter could also seek their views on the other recommendations, and on co-ordination of a UK-wide response;

- the proposal to enable the Haemophilia Society to receive a £100k development grant in 2009/10 (paras 15-20) ;

- the proposal to ask the UKHCDO to conduct a UK-wide lookback exercise (paras 23-24).

Rowena Jecock
Head of Blood Policy
531 Wellington House
GTN: GRO-C

Copy:
Penelope Irving
Sarah Kirby
Morven Smith
Mat Fogarty
Katie Ratcliffe
Mike Davies
Joanne Jones
Clare Montagu
Mario Dunn
Freya Lock
Beatrix Sneller
David Harper
Sian Jarvis
Richard Douglas
Richard Murray
Gareth Jones
Elizabeth Woodeson
Ailsa Wight
Jonathan Stopes-Roe
Brian Bradley
Michael Rogers
Ian Matthews
Patrick Hennessy
Murray Devine
Catherine Pearson
Richard Kelly
Carolyn Heaney
Olivia Butterworth
Dilip Chauhan
Mary Simpson
John Sherriff
Steve Pugh
Peter Bennett
Richard Lawes
Ian Hudson MHRA
Nigel Goulding MHRA
Judith Moore
Graham Kent (DH legal service)
Paula Cohen (DH legal service)
Sylvia Shearer (Scotland)
Caroline Lewis (Wales)
Karen Simpson (Northern Ireland)

ANNEX A

Options for revising the Macfarlane and Eileen Trusts and the Skipton Fund

1.Harmonising the ET and the MFT

In order to harmonise the ET and the MFT it would be reasonable first to merge the two trusts into a single new trust. This would need to be agreed with the Charities Commission. When the Eileen Trust was created in 1993, the intention was to mirror the payments to Macfarlane Trust beneficiaries. There appears, however, to be a discrepancy between the sums paid to beneficiaries of the two Trusts, which we are unable to resolve without consulting the administrators or the Trustees. The following estimates are based on a worst case and may be reduced when we consult more widely.

A merger of the two Trusts may require bringing the MFT registrants up to the level of one-off payments provided for in the Eileen Trust Deed. Currently, new MFT registrants receive a £20,000 lump sum on acceptance of their claim. Eileen Trust registrants receive a lump sum payment of £41,500 for an infant, £43,500 for a single adult, £52,000 for a married adult with no children, and £80,500 for an infected person with dependent children (although there have been no new ET registrants for several years). Using worst case assumptions based on figures provided by the MFT in 2005 of 384 original registrants (of whom 113 are single or separated), 41 infected partners and 184 dependent children, this could cost up to **£19m** in non-recurrent back-dated payments (discounting the lump sums already paid). [Calculation provided at the end of this Annex]

Estimated one-off cost of equalising the payments under the MFT and ET: in the order of £19m

2.Removing discretionary payments and increasing the recurrent funding for the MFT & ET

Currently, all the recurrent payments made by the two Trusts are discretionary, although the Trustees have chosen to make a number of seasonal or annual payments which are paid automatically. These are of the nature of regular monthly income supplements and winter payments intended to pay for heating costs. In their business case for increased funding, put to DH in 2005, the Trustees estimated that over 80% of their disbursements went on regular monthly or annual payments which were made to “virtually all registrants and those bereaved households who qualify”. On this evidence, it should not be a complicated matter to devise a scheme whereby these payments become non-discretionary – but the Trustees. and possibly representatives of the beneficiaries, would have to be involved in developing the details.

The combined recurrent funding to the MFT and the ET is approximately £3.8m (including administration costs). This provides payments, on 2008 figures, to some 562 MFT beneficiaries and 22 ET beneficiaries - a total of 584*. Broadly, the average annual *per capita* payments equate to £6,400pa. If Ministers agreed to raise the *per capita* payments to, say, £10,000pa and remove the Trustees' discretion, this would cost around £5.9m pa – a recurrent increase of £2.1m pa. This figure would decline as the numbers of beneficiaries diminishes - on current trends about 20 beneficiaries die each year, and they are not being replaced by new claimants.

Estimated recurrent cost of providing increased, non-discretionary payments to the MFT and ET - £2.1m p/a

***Note**
This lower figure is more recent than the 2005 figures used in Section 1 above, due to natural decline. We do not have the breakdown of the 2008 data to calculate the 'equalising' payments.

3. Bringing the eligibility criteria for the SF in line with those for the MFT & ET

We do not have data on the numbers of people who died before 29 August 2003 from hepatitis C infections as a result of NHS treatment with blood or blood products before September 1991. According to the Archer report, a total of some 4670 cases of treatment-acquired hepatitis C infection have occurred. If, say, a quarter of them (i.e.1200) died before August 2003. each of whom left a dependent, payments to their widow/ers or dependents could cost up to:

1200 x £20000 = £24m (stage one payment) plus, where indicated,
1200 x £25000 = £30m (stage two payments) = £54m.

We do not envisage that this payment would be extended to the estate of a deceased, only to a person who was a partner or dependent at the time of death, and who (now) makes a claim on the Fund. We do not have a list of such potential claimants and it would be virtually impossible to identify them proactively, beyond placing suitable advertisements inviting them to come forward.

Any changes to the Skipton Fund would have to be agreed with the Devolved Administrations, especially with Scotland.

Estimated one-off cost of a payment to widow/ers or dependents: in the order of £54m

Calculation of one-off equalising payments to bring MFT and ET into line (refers to Section 1 above)

Based on 2005 Macfarlane Trust figures in their business case for increased funding 'Funding Long term Survival'.

Registrant community
379 Male
5 Female
Total 384

Plus 41 Infected partners
184 Dependent children (average age 11.5 (in 2005))

Of the total registrants 113 were single or separated,
hence (384 – 113) = 271 married or with partners.

Assuming 1 child per couple:
(271 -184) = 87 childless couples

184 @ £60,500	= £11,132,000
87@£32,000	= £2,784,000
113 @ £23,500	=£4,915,500
Total	**£18,831,500**

ANNEX B

Background on bleeding disorders and their treatment

Inherited bleeding disorders are relatively rare. There are currently around 24,000 people diagnosed with inherited bleeding disorders in the UK. Most of these individuals have mild to moderate bleeding disorders with around 3,000 having the most severe forms of disease. Currently, there are estimated to be around 2,500 patients still living who contracted hepatitis C, and around 450 who contracted HIV through clotting factor concentrates. These surviving patients who acquired HIV and Hepatitis C as a result of their treatment during the 1970s and 80s, are now in their 40s and older, and have special healthcare needs as a result both of their infections, and the problems associated with their underlying haemophilia which results in joint damage, requiring orthopaedic surgery, arthritis care, and associated services. The majority of younger patients, even those with severe haemophilia, have far fewer health problems as a result of the introduction of prophylactic clotting factor treatment in 1996. Clotting factors are now available as bio-engineered and plasma-derived medicinal products and both are subject to the strict criteria of medicines regulation. The risk of transmission of known infectious agents has been reduced significantly.

ANNEX C

Current insurance industry practice for provision of insurance to haemophilia patients

The following information has been provided by the Association of British Insurers (ABI). ABI members constitute over 90 per cent of the insurance market in the UK.

There are two main considerations which insurers must take into account:

- the first is the presence of the underlying condition, i.e. haemophilia;
- the second is the impact of any other condition, such as hepatitis C and/or HIV infection.

Insurance for haemophilia sufferers

Insurers do not treat patients with haemophilia differently from any other patients with a pre-existing condition. In all such cases, the insurance premiums are determined by assessment of the morbidity and/or the mortality risk each individual brings to the insurance pool.

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How might insurance availability/cost change if a haemophilia sufferer also has an infectious disease?

The higher the mortality and/or morbidity risk that each individual brings to the insurance pool then the higher the premium they will be asked to pay. This ensures equality in the risk pool with each individual being charged a premium relative to the risk they bring. If a haemophilia sufferer also has an infectious disease then, at application stage, the underwriter will assess whether this additional condition increases the individual's morbidity and/or mortality risk.