Mary Trefgarne - SOL
Carl Evans - POLICY
David Daley - COMMS

From: R.M. Gutowski
Date: 31 July 2003

CC. Vicki King
Jill Taylor
Zubeda Seedat

RECOMBINANT CLOTTING FACTOR

1. Following the last Recombinant Clotting Factor Working Group meeting it is clear that there is still concern over the decision to phase in recombinant by age group. I appreciate that the decision has been taken but I just wanted to make sure we had all the angles covered especially as PS(PH) is keen to have some sort of press coverage when the money is distributed.

2. Following a meeting of the Group in May the justification for phasing by age group, starting with the youngest which is the approach in Scotland and Wales, was posted on the Department of Health web site, attached, and publicised by the various haemophilia groups. As far as I am aware no formal objections were received although it is clear that discontent with the decisions rumbles on.

3. At the last meeting of the Group Dr Schonfield from Croydon PCT tabled an anonymised letter, attached, from a haemophiliac questioning the policy stating the it was contrary to the Department's National Service Framework for Older People one of which is to root out age discrimination. The letter also argues that the policy is in breach of Article 14 of the European Convention on Human Rights. Given Minister's wish to make some sort of announcement we need to be clear that we will not be subject to any challenge. I will be in touch with COMMS separately to discuss handling.

4. I would be grateful therefore if POLICY could confirm that the age phasing decision is not causing them any problems and if SOL could advise on the Human Rights issue.

R.M. GUTOWSKI
PH6.6
633b SkH
Ext GRO-C

ANNEX A

From an email sent to Susan Schonfield 04.06.03

Dear Susan

At yesterday's meeting of the Expert Advisory Group [note: a sub group of the Pan Thames Haemophilia Consortium], you mentioned that a decision had been taken to roll out recombinant clotting factor over a three year period, on an 'ascending age' basis, with the availability of funds being the limiting factor, rather than supply. While this is not a matter for the EAG, I would like to raise some issues on this with you, because the proposed approach seems to go against published NHS principles and the likely course of the law. Although I have not discussed this with him, I can well understand X's anger at what has been proposed as it operates against the interest of those with co-infection and I suspect, deliberately so.

Firstly, the Department of Health has issued a National Service Framework for Older People, which may be accessed at
http://www.doh.gov.uk/nsf/olderpeopleexecstand1.htm.
While primarily focused on securing equal rights in health and social care for the elderly, the Framework has much broader application, its stated aim being to 'root.... out age discrimination'. The first standard is: 'NHS Services will be provided, regardless of age, on the basis of clinical need alone'. Further on, it states: 'Decisions about treatment and care should be made on the basis of health needs and ability to benefit, rather than on a patient's age'. The term 'ability to benefit' is nowhere qualified by the expected duration of that benefit.

The Preface to another document, the 'NHS Plan', specifically states: ' The NHS of the 21st century must be responsive to the needs of different groups and individuals within society, and challenge discrimination on the grounds of age, gender, ethnicity, religion, disability and sexuality'
(http://www.nhs.uk/nationalplan/preface.htm).
Against the background of these two documents, it is difficult to understand why 'age' could be considered to be an acceptable criterion on which the distribution of recombinant should be based.

Secondly, the proposal seems to be outside the spirit of the Human Rights Act 1998. It could leave the body responsible open to claims for damages from patients who feel that they have been unfairly treated because their age has been the sole factor in determining their eligibility for treatment with recombinant at a time when supply can match the demand. This is, of course, a matter on which the NHS's legal advisors should provide guidance and unfortunately, I do not have the time to research case law.

Article 14 of the European Convention on Human Rights (on which the Act is based) provides:
The enjoyment of the rights and freedoms set forth in this Convention shall be secured without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status.

While not specifically mentioned in Article 14, discrimination on the grounds of age is referred to in various EU protocols as contrary to the intent of Article 14. So, phasing the introduction of medication of a particular kind in such a way that a younger patient would receive preferential treatment over an older patient purely on the grounds of their respective ages would seem to be contrary to the Article. Discrimination on that factor alone would seem sufficient ground for an older patient denied such treatment to sue and claim damages from the body responsible for the decision (which body was responsible?), irrespective of whether alternative forms of treatment are available to him.

During the meeting yesterday, X argued that patients with co-infection should be given priority over others for treatment with recombinant clotting factor. In my opinion, there are very compelling moral grounds for supporting that line: many such patients have reached the understandable conclusion that they have effectively been written off by the very body that caused them to be infected in the first place! But these grounds would probably need to be coupled with good clinical reasons if they are to stand the test of being non-discriminatory.

Furthermore, I can see the accountant's argument that it might be difficult to justify the additional cost of treating these patients with recombinant if they already have infections and that the money is better spent on those who have not been exposed to infection, but that is an argument based on 'costs' not on 'natural justice' or equity. It is also contrary to the intentions set out in the NHS Plan to which I refer above, because it would amount to discrimination on the grounds of disability. There must remain a risk that some further infection might be transmitted through blood products and it must surely be unethical to continue to expose one group (those who are older) in order to protect another (those who are younger). It is a fact that patients with co-infection will generally be older than those lucky enough to have escaped it.

I must emphasise that these are my personal views and not those of the Haemophilia Society, which I suspect might prefer to remain silent on the issue as many of its members would be beneficiaries under the phasing arrangement which has been proposed. I should also make clear (if it hasn't already become evident) that this is not an area in which I can claim to have any policy expertise.

If there is to be a phasing in, then either an assessment of clinical need - perhaps based on the severity of the haemophilia/frequency of treatment - or even the lottery suggested by another member of the EAG, are probably the only non-discriminatory ways of determining the order of eligibility for treatment. However, I for one would be happy to see those who are co-infected being accorded some preferential treatment for once!

GRO-A
Representative of The Haemophilia Society
Pan Thames Haemophilia Consortium's Expert Advisory Group

PS - GRO-A added:
If it helps, the link between age discrimination, healthcare and Article 14 of the Convention on Human Rights is discussed in the paper accessible from this link: http://www.coe.int/T/E/Social_Cohesion/Health/Conferences_of_Health_Ministers/06%20(1)%20Overbeek%20report.asp#P55_1329 <http://www.coe.int/T/E/Social_Cohesion/Health/Conferences_of_Health_Ministers/06 (1) Overbeek report.asp#P55_1329> . I think it is an interesting read.

As (I hope) I mentioned in my earlier email, these are matters on which legal opinion should be sought. An expert in EU law is probably best placed to advise.

04.06.03

ANNEX B

PATIENT PRIORITY ORDER –RECOMBINANT CLOTTING FACTORS

STATEMENT BY THE RECOMBINANT CLOTTING FACTORS WORKING GROUP

The Department of Health has made available £13m in 2003/04, £21.7m in 2004/05 and £53.4m in 2005/06 to phase in the provision of recombinant clotting factors for the estimated 1500 haemophilia patients aged 22 and above not currently receiving recombinant. The Recombinant Clotting Factors Working Group has been set up by the Department to advise on the phasing process. Members include haemophilia doctors, public health doctors, patients and nurses and local NHS managers as well as Department of Health officials.

The level of funding available in the first two years means that not all patients can be moved to recombinant initially and that a phasing process is required. The group therefore considered ways this might be done and looked at two options:

- phasing by age group, starting with the youngest. This was the approach followed in Scotland and Wales where patients are now all treated with recombinant.

- giving first priority to groups that might be seen to present a 'special case', ie those infected with HIV or with hepatitis C or those exposed to plasma products traced to a variant CJD donor.

The Group's first objective was to agree on a set of principles that could be used to assess these options as a basis for prioritising. It was agreed that prioritising must be as equitable as possible, with an objective and transparent justification and should be practical to implement with minimum delay.

The group discussed the case put forward by the Birchgrove Group for prioritising HIV/HCV co-infected people to receive recombinant first. On the basis of initial estimates, it was agreed that the level of funding available in year one would probably not be sufficient to place all people infected with HIV/HCV on recombinant until the second year of the phasing process. Moreover, the group had strong reservations about using HIV status as the basis for eligibility for recombinant when there was no accepted clinical case for this.

The group felt that it would be difficult to justify prioritising this group of patients above those infected with hepatitis C alone or those exposed to plasma products traced to a vCJD donor, all of whom could also make a case.

Overall, therefore, the group concluded that phasing in by age banding offered the most equitable approach as all groups of patients, not only those with HIV/HCV co-infection, would start to benefit immediately.

May 2003