Ex gratia payment scheme for people infected with Hepatitis C as a result of treatment with NHS blood and blood products

Second meeting to discuss the medical trigger point for the proposed higher payment

27 January 2004

Meeting Note

Present - Professor Maggie Bassendine
Professor Geoff Dusheiko
Dr Paul Giangrande
Professor John Pasi
Professor Howard Thomas

Dr Vicki King (Chair, DH)
Dr Mike Simmons (SMO, National Assembly for Wales)
Dr Hugh Nicholas (SMO, DH)
Mr Richard Gutowski (Policy Official, DH
Mr David Reay (Policy Official, DH)

Apologies - Prof Peter Hayes
Dr David Mutimer
Mr Gerry Dorrian (Policy Official, NICS)

Dr Aileen Keel (DCMO, Scottish Executive)
Mr Bob Stock (Policy Official, Scottish Executive)

Introductions

1. Dr Paul Giangrande (Consultant Haematologist, Oxford and adviser to the Haemophilia Society) was welcomed to the group.

Notes of the first meeting

2. The note of the previous meeting (Oct 03) was agreed. Three typographical amendments were suggested, agreed and noted.

Preliminary discussions

3. The Chair provided a brief summary of the outcome of the previous meeting, at which it was decided that the simple tests discussed on that occasion would be sufficient to provide a basis for a panel of non-invasive tests to determine cirrhosis. The exact panel would need to be defined and threshold values set. The tests chosen should preferably form part of a patient's routine management, be evidence based and widely accepted.

Panel of tests

4. It was suggested that a modified version of the package of tests proposed by Lok et al [citation] might be suitable. This package, which is widely available in diagnostic labs and incurs no commercial charge, would be suitable if appropriate thresholds were determined. This was agreed, but the Lock package of tests was not thought to be sufficient on its own.

5. The experts suggested it would be preferable to offer more than one set of preliminary tests. For example, the Poynard, Bonocini [check spelling]or ALT/AST ratio tests could be used as an alternative to, or to complement the Lok package. This would help to counter accusations of reliance on one system and challenges about the sensitivity of particular tests/panels of tests (eg. Gianini [citation] has challenged the Lok paper).

6. The experts proposed that the Lok test be used in conjunction with the ALT/AST ratio test in the first instance, with the Poynard test being used if these sets of tests disagreed. If the APRI index was ≥2 and the ALT/AST ratio was ≤1, cirrhosis would be indicated. If the index was ≤1 and the ratio was ≥1, a Poynard 'Fibrotest' should be undertaken. In the event of challenge by an applicant, DH envisages that an appeals panel would review the case.

7. It was pointed out that the Poynard 'Fibrotest' could only be carried out in specialist labs. The test also incurs a commercial charge. Labs upgrading to undertake the 'Fibrotest' would require re-accreditation (from the CPA) and need to be quality assured to ensure consistency. ***Action: Prof Dusheiko volunteered to approach Intralab and Poynard to assess the feasibility of introducing 'Fibrotests' in the UK.***

8. The affect of age on interpreting test results was not thought to be an issue as results for the suggested tests would be independent of age. However, alcohol consumption would need to be factored in as this affects the AST/ALT ratio.

Possible validation of chosen panel of tests

9. It was suggested that the proposed tests could be validated using records available from the National Hepatitis C Register, administered by the CDSC - HPA. There was some uncertainty as to whether the register held the necessary data, for example AST levels. ***Action: DH officials would approach the HPA to determine if the Register was a suitable dataset for validation.***

Decision making process

10. ***DH agreed to draft an application form to record clinical information, the basis of which would be taken from the form tabled by DH at the meeting.*** Ideally, information would be presented for lay rather than expert assessment, to facilitate handling by administrators. If the outcome of the biochemical/XXX tests proved inconclusive, the form would be passed to a medical panel for advice and adjudication.

11. It remains unclear as to who decides if a Poynard 'Fibrotest' should be undertaken. *Due to the additional costs involved, this would have to be a policy decision.*

12. To strengthen the test process and provide a comparison, a 3-6 month wait between tests, or referral to tests undertaken in the last 12 months of a persons medical history, was recommended.

13. Consecutive tests would be expensive and may not be in a patient's best interest. In addition, the Lok and Poynard tests may not be effectively used in this way and would therefore be open to challenge. The experts requested a professional statistical view on the quality of the statistics to demonstrate predictive values stated in the four papers (Lok, Poynard, Bonacini and Gianini). *Action: The Chair suggested that DH Economic and Operational Research/Statistics branch colleagues may be able to comment on the quality of statistics.*

14. Where possible, biopsy would be the test of choice. However, concerns were raised that if non-invasive tests and the appeals process were inconclusive or dismissed, claimants unsuitable for biopsy may feel compelled to undergo biopsy in pursuit of their claim. *DH agreed that this would require careful wording in the application literature to ensure that claimants were fully aware of the risks.*

Whose responsibility?

15. In the first instance, it was suggested that the patient/patient's clinician should initiate a claim. If not by biopsy, this would require submitting the application form presenting the clinical information from the test(s) to the Skipton Fund. If the results were clear-cut (when compared against the criteria set by the Fund eg. APRI <1, ALT/AST ratio ≥1) the claim would be validated and authorised by the fund. If not, a medical panel would consider the results or perhaps commission a Poynard 'Fibrotest'. If still inconclusive, it is envisaged the medical panel would review the case.

16. Financial responsibility for the tests would fall on the NHS. As such, and due to the natural history of cirrhosis, claims requiring the non-invasive tests would be limited to one per year. *The issue of which labs to use and how to ensure that samples are policed would be considered by DH once more information on the existing facilities was available.*

AOB

17. It was recommended that DH take action to justify the testing process to the public, not just those undergoing tests. *DH agreed to seek a suitable vehicle for this.*

18. For the benefit of policy officials, *Dr Paul Giangrande offered to provide DH with an up to date breakdown of the number of haemophiliacs suffering from different stages of liver disease, including cirrhosis.*

19. Following the tabling of the press statement that announced the details of the Skipton Fund, Dr Giangrande and Prof Bassendine both expressed disappointment that the scheme had not been extended to dependants of those who had died.