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Date: 12th Dec 2005
Subject: NICE 'Interferon alfa and ribavirin for the treatment of mild chronic hepatitis C'

Dear Dr Longson,
The following letter outlines Mainliners response to the National Institute for Health and Clinical Excellence in relation to the 'Interferon alfa and ribavirin for the treatment of mild chronic hepatitis C – part review of existing guidance no. 75, Assessment Report'.

Firstly, we regard this as an excellent review with a well thought out mythological approach to this complex area for which there is less evidence unfortunately compared to the management of moderate to advanced chronic HCV.

The criteria for inclusion of papers is understandably limited to RCTs, the definition for mild HCV and the required threshold of mild HCV in study populations are all reasonable and have taken existing data and its limitations into account as best as possible.

In examining this paper, several points of notes were raised which the authors may wish to consider :

1. We did not feel the review adequately considered the impact of the study population on cost and clinical effectiveness in its conclusions or final discussion although there is some reference in 2.2. Current and future populations presenting with mild HCV will increasingly comprise of individuals infected through drug use (as the major risk group in the UK) rather than infection through infected blood or blood products. It is not apparent that this has been fully considered in the review given the additional care and treatment complexities often associated with this risk group. For example, DNA rates, additional support requirements from specialist nursing/social care staff and new or exacerbated side effects related to previous or current addition such as depression and injecting association on treatment.

   Perhaps the 'impact of study population' could be a recommendation for future 'cost and clinical effectiveness research' since evidence is surely lacking in this regard. The authors may wish to consider discussing former users separately from current drug users in this regard.

2. We would suggest the statement that 'drug costs will be incurred all in the first year rather than at a later date' should be balanced by an indication that a sudden surge in referrals for mild disease would be unlikely beyond patients already being monitored. Those at risk remain largely unaware of their infection with mild HCV and a suitable referral system could potentially be implemented to improve the timing of referrals (especially for those infected through substance misuse in terms of stability, support and preparedness for

treatment).

3. Incremental cost effectiveness ratios are quoted as being sensitive to a number of factors in 8.2 but there is nor reference to the frequency of monitoring, notably biopsies as one such factor. We understand that a three year biopsy period is assumed in the author's own model but as this varies in clinical practise we question whether this should be listed as another factor affecting cost effectiveness ratio sensitivity.

   Secondly, we would suggest that the authors include a recommendation to NICE to appraise monitoring cycles and biopsies for HCV patients to determine a national standard in this regard, especially for mild HCV patients and those with genotypes 2 or 3.

In relation to the above suggestions, it is possible the authors have considered these but it and it is simply not apparent to the reader that this is the case. We are delighted to see a review of this nature and will await the final document with much interest. In the meantime, I hope the above feedback is of help to all concerned.

Future NICE Appraisals and Guidelines – Contact at Mainliners

On a separate matter, Mainliners is currently part of The Scottish Intercollegiate Guideline Network (SIGN) Team for Hepatitis C. Mainliners would similar appreciate being involved in any future appraisals on hepatitis B, C or HIV that NICE are undertaking. Mainliners is an organisation that operates across the UK and has a UK Hepatitis C Resource Centre dedicated to both the public and professionals, sexual health and HIV projects that are well established.

I would ask that all future correspondence from NICE be forwarded directly to myself at Mainliners using the contact details below to avoid delay in our responding. I am now Mainliners main contact for NICE having recently taken up the position of Mainliners Director of Blood Borne Viruses. I am based in Glasgow but operate and travel across the UK with direct responsibility for our work on blood borne viruses in England and Wales as well as Scotland.

SIGN Guideline Request

As part of the SIGN HCV Guideline Team, we are currently involved in producing a guideline on hepatitis C due out in 2006. As such, it is important that SIGN are aware of this key Assessment Report in order to be abreast of current literature. I would therefore like permission to forward a copy of this appraisal document to the Chair of the SIGN HCV Guideline Team and to Lorna Thomson SIGN's coordinator for this team.

I look forward to hearing from you

With Kind Regards

Dr Nicola Rowan
Director or Blood Borne Viruses
Manager, UK Hepatitis C Resource Centre
Mainliners