The Royal College of Pathologists
Pathology: the science behind the cure

Comments on the Appraisal Consultation Document (ACD) produced for the NICE single technology appraisal of *Sofosbuvir for treating chronic hepatitis C [ID654]*

NICE has thoroughly considered the merit of sofosbuvir based on available evidence. We agree that further information that distinguish the treatment outcome of cirrhotic and non-cirrhotic is essential

There are, however, a few issues that we would like to raise:

1. The use of historic controls is unlikely to introduce bias. Historic treatment outcome data is very robust and well known. It should be recognised that sofosbuvir represents a significant therapeutic advance over conventional treatment despite not having head-to-head comparison.

2. Some patient categories are likely to benefit from the use of sofosbuvir significantly more than others. For example, those not eligible or cannot tolerate interferon, and patients with whom there is logistic difficulties implementing a complicated treatment regimen (e.g those in prison service). NICE recommendation should also consider the benefit for these minority patient groups.

3. The assumption that “up to 100% of people with genotype 3 HCV receive sofosbuvir plus ribavirin for 24 weeks” and that “an increased proportion of interferon-eligible people may be unwilling to have interferon treatment and therefore receive sofosbuvir plus ribavirin for 24 weeks” is questionable. It is likely that a substantial number of these would only require treatment for 12 weeks, hence reducing the cost significantly.

4. It is recognised that treatment experienced individuals are more difficult to treat and may require a longer duration of a sofosbuvir based regimen during re-treatment. In order to avoid this, it is essential that an effective first treatment is employed. Many patients are now opting to wait rather than risk failing the current NICE recommended regimen. This in turn results in increasing number of patients progressing in their illness during the time of waiting.

The development of direct acting agents for hepatitis C is moving forward in a very fast pace. There is a risk that the recommendation lacks behind the science and therefore delaying transferring the benefit to patients. We urge NICE to act on the evidence swiftly and allow clinicians in England to include sofosbuvir in the treatment regimen for hepatitis C as soon as possible.

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