Comments on the ACD Received from the Public through the NICE Website

Name	[redacted]
Organisation	
Role	NHS Professional
Job Title	
Location	England
Conflict	No
Comments on the ACD:	
I think that the document as a whole is a massive leap toward the beginning of the eradication of hepatitis C which has been a long time coming - it is positive about the new advances in this field and acknowledges that we need to be able to treat as many people as possible effectively and with the least amount of time, including potential time from work, with a greatly improved side effect profile. I would like to make a couple of other points however: I treat patients with genotype 4/5/6 on a frequent basis, due to local demographic (including those who are co-infected with HIV and these genotypes) and, bearing in mind that the clinical trials show much improved efficacy with these types of HCV, it is disappointing that I will have to continue to use 48 weeks of Peg/Ribavirin with these genotypes. I would also like to be able to ready patients to start treatment as soonas possible on the new regimes, so is there any way the lead times for starting patients on treatment could be cut? Many thanks	
Date	2014 08 18

Name	[redacted]
Organisation	
Role	NHS Professional
Job Title	Consultant Hepatologist, University Hospital Southampton
Location	England
Conflict	No
Comments on the ACD:	
I am surprised at the committees decision to exclude patients with genotype 3 who are treatment Naive and non cirrhotic. It is difficult to see how having to have failed treatment with PEG Riba (about 45% of patients) before being allowed Sofosbuvir can be cost effective or clinically sound. Given the absence of alternative agents with good activity against genotype 3 (most of the new DAAs are for genotype 1) this greats a really poorly served and quite large patient group at a time when most patients with HCV should be anticipating a swift cure.	
Date	2014 08 21

Name	[redacted]
Organisation	
Role	NHS Professional
Job Title	viral hepatitis nurse
Location	England
Conflict	N/A
Comments on the ACD:	

1.4 Sofosbuvir, in combination with peginterferon alfa and ribavirin, is not recommended for treating genotype 4, 5 and 6 chronic hepatitis C in adults.

This recommendation will further widen the health inequality gap between the white population and the ethnic minorities who are mainly infected with genotype 4 in the UK. Combination therapy (pegylated interferon and ribavirin) has never been effective in eradicating the HCV virus in these communities from trial data and clinical observations . There is an opportunity to cure those ethnic minorities infected with HCV (genotype 4) and reduce the burden of disease and improve quality of life and ICER seems to determine who should be given treatment and have a chance of a cure and who should be sentence to death. Are their lives not worth saving? Where is your duty of care or your utilitarian stance? I am aware you have a duty to abide by guidance in spite of the serious consequences of your actions, however, be the change and not let the Government cost effective guidance destroy lives of some of the most vulnerable groups in our society.

Why not recommended the following

Sofosbuvir, in combination with peginterferon alfa and ribavirin, is recommended for treating genotype 4, 5 and 6 chronic hepatitis C in adults, only if they had treatment for hepatitis C before

Sofosbuvir, in combination with peginterferon and ribavirin, is recommended as an option for treating genotype 4, 5, 6 chronic hepatitis C in treatment naive adults with cirrhosis.

Date	2014 09 04

Name	[redacted]
Organisation	BASELINE Magazine
Role	[redacted] community magazine about HIV and hepatitis
Job Title	Editor
Location	England
Conflict	Yes Gilead along with all other HIV pharma companies provide support to print and distribute the magazine. Our relationship respects the ABPI code.
Comments on the ACD:	
I would just like to underline how appropriate I feel it is that NICE has reflected on the evidence of the effectiveness of sofosbuvir in people coinfected with HIV. I feel this second draft guidance is much more equitable, reflects the science as well as recommendations in the European Association for the Study of the Liver Treatment Guidelines that co-infected people should not be treated any differently to mono-infected people. Thank you for this making this huge step towards access to improved hepatitis therapy for people with HIV.	
Date	2014 09 04

Name	[redacted]
Organisation	British Viral Hepatitis Group & British Association for the Study of the Liver
Role	National Organisations - BVHG and BASL
Job Title	Consultant in Infectious Diseases & Chair BVHG
Location	
Conflict	Yes Some of the members of BVHG and BASL involved in preparing this response have been involved in the SOF study programme and with Gilead in other roles (advisory boards etc). However the comments submitted are from the organisations listed above and not from specific individuals.
Comments on the ACD:	

We thank NICE for its considered assessment of the cost effectiveness of sofosbuvir, and for noting and acting on the consultations received after the promulgation of the first appraisal. The revised NICE appraisal offers the opportunity to achieve high rates of cure after treatment for patients with genotype 1, 2 and 3. However we believe that patients with genotype 4 also merit treatment with sofosbuvir. The in-vitro data indicates that sofosbuvir is active against genotype 4. Although the clinical trial data is limited, the available data confirms that sofosbuvir, PEG IFN and RBV is highly efficacious against genotype 4.

The British Association for the Study of the Liver and the British Viral Hepatitis Group would like to highlight that genotype 4 is found in minority populations in the UK, and that the inability to offer sofosbuvir to patients with genotype 4 may risk challenges via equality policies. Patients with genotype 4 who have not responded to PEG IFN and RBV presently have no other options for treatment. The ICERS for sofosbuvir, PEG IFN and RBV suggest that a 12 week regimen is cost effective within a Â£30,000 per QALY ceiling. Relatively few patients are chronically infected genotype 4.

Thus, for these reasons, we would ask NICE to consider including the approval of a

12 week regimen of sofosbuvir, PEG IFN and RBV for naÃ¯ve patients and prior non-responders who are tolerant of IFN.	
Date	2014 09 05

Name	[redacted]
Organisation	
Role	NHS Professional
Job Title	Consultant Hepatologist
Location	England
Conflict	No
Comments on the ACD:	

Many thanks for the opportunity to comment on this second appraisal document.

I was very encouraged to see that NICE has decided to modify the earlier decision to not recommend Sofosbuvir for Genotype 3 HCV and that it now recognises the unmet need in this population. Similarly, I fully agree with the decision not to recommend the use of the drug for patients with Genotype 5 and 6 as I do not think there is sufficient data to recommend this.

However, I am concerned that patients with Genotype 4 will not have access to the drug as currently stands. Patients with Genotype 4 represent 5% of the population of HCV patients in the UK. There are, therefore, substantial numbers of patients who would benefit from Sofosbuvir. These patients mostly come from specific ethnic backgrounds; indeed Egyptian patients are mostly G4.

Whilst I recognise that the manufacturer did not submit data for more than 28 patients in the original submission, data that has been presented since includes significantly more numbers. Rune et al presented data at the European Association for the Study of Liver Disease in London in April 2014 showing SVR rates of 100% and 87% respectively in 14 treatment naive and 15 treatment experience patients treated with 24 weeks of Sofosbuvir and Repairing only. The equivalent figures with 12 weeks of the same regimen were 79% and 59% respectively in 14 treatment naive and 17 treatment experienced patients. This data represents good efficacy in 60 patients with G4 and is comparable and probably superior to the 40-50% historical success rates with PEG-IFN and repairing.

There is also a study from Egypt that will be presented at the AASLD meeting in November 2014 with 100 patients showing significantly better efficacy of Sofosbuvir containing regimens (Professor Imam Waked, personal communication).

Only this week I saw a genotype 4 cirrhotic 65 year old lady who had failed dual therapy and also had failed a simeprevir containing triple therapy regimen for 4 weeks. Without access to Sofosbuvir I have nothing to offer her to prevent the inevitable progression of her liver disease.

With the data above in mind, I would urge the committee to review the recommendation for treatment of G4 patients with Sofosbuvir as this drug would be an important addition to our armamentarium for the treatment of G4 patients; whose options are currently very limited.

Date	2014 09 05

Name	[redacted]
Organisation	British HIV Association (BHIVA) and British Association for Sexual Health and HIV (BASHH)
Role	NHS Professional
Job Title	[redacted] BHIVA Hepatitis Society Subcommittee
Location	England
Conflict	No
Comments on the ACD:	
BHIVA and BASHH would like to thank the NICE Appraisal Committee for considering HIV/HCV co-infected patients in this appraisal and for agreeing that responses in co-infected patients are no different to those seen in mono-infected patients. BHIVA and BASHH agree with the NICE Appraisal Committee that manufacturers and the Evidence Review Group (ERG) need to show a separate cost-effective analysis for co-infected for future single technology appraisals, taking into account the high rates of progression of liver disease and normal life-expectancies of HIV patients successfully treated with antiretroviral therapy. 'Genotype 4 accounts for up to 30% of the UK HIV/HCV co-infected population (UK CHIC study - unpublished data) and represent a significant unmet need in terms of liver disease burden and risk of progression. Both BHIVA and BASHH would urge reconsideration of allowing Sofosbuvir treatment for the IFN-eligible G4 sub-group with advanced fibrosis.	
Date	2014 09 05