NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH TECHNOLOGY APPRAISAL PROGRAMME

Equality impact assessment – Guidance development

STA Sofosbuvir for treating chronic hepatitis C

The impact on equality has been assessed during this appraisal according to the principles of the NICE equality scheme.

Consultation

1.	Have the potential equality issues identified during the scoping process been addressed by the Committee, and, if so, how?
It was raised during scoping that hepatitis C adversely affects certain populations, who could be considered at risk of being disadvantaged in terms of accessing the healthcare system and therefore at risk of inequity of access to innovative new treatments (such as certain immigrant populations, prison populations and people who inject drugs). Attendees at the scoping workshop agreed that this issue related to implementation and could not be addressed through technology appraisal recommendations.	

2.	Have any other potential equality issues been raised in the submissions, expert statements or academic report, and, if so, how has the Committee addressed these?
Consultees have raised the following potential equality issues in their submissions: "HCV infection disproportionately affects ethnic minorities in the UK, particularly those of South Asian family origin but the virus is also at increased prevalence in people from the Middle East, Africa and Eastern European family origin. It is also of higher prevalence in the socioeconomically deprived and there is emerging data of frequent sexual transmission in men who sex with men." *This is not considered to be an equalities issue, as any guidance will apply to*	

all people in the UK equally.

"Given the high prevalence of hepatitis C in people who inject drugs or have a personal history of drug use, HCV services must ensure that they are easily accessible and that they use outreach programmes to enable these distinct populations to access potentially curative therapy. There has been a reluctance to treat people who inject drugs. Although this appraisal will not of itself lead to exclusion of this group, a failure to specifically include them in some form in the text may lead to their continued exclusion."

This is not technically an equalities issue and people who inject drugs are assumed to be included in any guidance published for the treatment.

Section 4.1 of the ACD states that "the Committee acknowledged the concerns of the patient experts that there is a stigma attached to having chronic hepatitis C, because of its link to injectable drug use. In addition, there is a reluctance to treat chronic hepatitis C in people who use injectable drugs, partly because of mistaken beliefs that they do not adhere to treatment and often become re-infected. The Committee heard from the patient experts that people who use injectable drugs whose chronic hepatitis C is successfully treated often go on to address their drug use, leading to broader societal benefits that are not captured in the manufacturer's evidence submission. The Committee recognised the effect of chronic hepatitis C on the lives of people with the virus, and concluded that treatments that give a sustained virological response (which is considered equivalent to a cure), and that consequently help reduce the rate of HCV transmission and the stigma associated with having chronic hepatitis C, are of significant importance."

In section 4.20 of the ACD, the Committee discussed comments from the patient experts indicating that in practice the availability of treatment for people with chronic hepatitis C who use injectable drugs was limited, which could represent a potential equality consideration. The Committee heard from the clinical specialists that treatment for these people is considered on an individual basis because of concerns about safety and treatment adherence, but that clinicians would like to offer sofosbuvir to people using injectable drugs, taking into account any precautions in the summary of product characteristics. The Committee acknowledged that access to treatment for this patient group was an issue related to implementation and could not be addressed through technology appraisal recommendations. However, the Committee concluded that although people who use injectable drugs were not represented in the pivotal clinical trials for sofosbuvir, based on the current evidence available, there was no reason to deny them access to treatment; therefore any recommendations on the use of sofosbuvir would

be irrespective of injectable drug use.

3.	Have any other potential equality issues been identified by the Committee, and, if so, how has the Committee addressed these?
No additional issues have been identified by the Committee.	

4.	Do the preliminary recommendations make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?
Not applicable.	

5.	Is there potential for the preliminary recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?
Not applicable.	

6.	Are there any recommendations or explanations that the Committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 4 or 5, or otherwise fulfil NICE's obligations to promote equality?
Not applicable.	

7.	Have the Committee's considerations of equality issues been described in the appraisal consultation document, and, if so, where?
In section 4.1, 4.20 and the summary table.	

Approved by Associate Director (name): Helen Knight

Date: 06/06/2014

Consultation 2

8.	Have the potential equality issues identified during the consultation process been addressed by the Committee, and, if so, how?
It was raised during consultation that people with HIV are considered disabled in law under the provisions of the Equality Act 2010. The Committee was aware that the interim results of both studies suggested that sustained virological responses in people with HCV and HIV-co-infection were similar to those seen in people with HCV mono-infection. The Committee understood that the summary of product characteristics states that people with HCV and HIV-co-infection should have the same sofosbuvir treatment schedule as people with HCV mono-infection, and concluded that this was appropriate.	

9.	Have any other potential equality issues been raised in the submissions, expert statements or academic report, and, if so, how has the Committee addressed these?
No.	

10.	Have any other potential equality issues been identified by the Committee, and, if so, how has the Committee addressed these?
No.	

11.	Do the preliminary recommendations make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?
No.	

12.	Is there potential for the preliminary recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?
No.	

13.	Are there any recommendations or explanations that the Committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 4 or 5, or otherwise fulfil NICE's obligations to promote equality?
No.	

14.	Have the Committee's considerations of equality issues been described in the appraisal consultation document, and, if so, where?
Yes, in section 4.11 of the FAD.	

Approved by Associate Director (name): Helen Knight

Date: 08/08/2014…….

Final appraisal determination

(when an ACD issued)

1.	Have any additional potential equality issues been raised during the consultation, and, if so, how has the Committee addressed these?

The Committee considered comments received during consultation that recommending sofosbuvir plus peginterferon alfa and ribavirin only for a proportion of people with genotype 1, 2 or 3 HCV, but not for anyone with genotype 4, 5 or 6 HCV could potentially be interpreted as indirect discrimination.

It heard this was because a larger proportion of minority ethnic groups, people with HIV-co-infection and haemophilia are represented in the genotype 4, 5 and 6 HCV populations.

In light of the Institute's legal obligation to promote equality, the Committee considered the additional evidence provided by the company that included family origin by HCV genotype, and the prevalence of HIV and HCV co-infection and HCV infection in people with haemophilia.

The Committee noted that the family origin evidence was self-reported (and could therefore not be verified), and used broad categories and considered this evidence to be uncertain. The Committee, however, noted additional anecdotal evidence provided by consultees that minority ethnic groups and people with HIV co-infection are more highly represented in the genotype 4, 5 and 6 HCV population.

The Committee considered the commercial in confidence evidence presented by the company regarding the genotype distribution of HCV in people with HCV and HIV co-infection and agreed that a disproportionate number of people had genotype 4 HCV and HIV co-infection compared with the overall population of people with HCV in England.

The Committee noted that the evidence presented by the company suggested that 96% of people with haemophilia and HCV had genotype 1, 2 or 3 HCV, and 4% had genotype 4 and 5 as no patients were identified with genotype 6 HCV and haemophilia. The Committee noted that the distribution of HCV genotypes in people with haemophilia presented by the company was actually similar to the overall population of people with HCV in England The Committee concluded that there was not a disproportionate percentage

of people with haemophilia who had genotype 4 HCV in England.

The Committee noted that the ICERs for sofosbuvir for people with genotype 4, 5 or 6 HCV for the combined cohort (people with and without cirrhosis) were very high. However, it agreed that, in the light of evidence on the higher representation of minority ethnic groups and HIV co-infection in these genotypes, further consideration should be given to whether anything could be done to remove or reduce the disproportionate impact for the protected groups.

The Committee considered that the people with the highest unmet need within this population are those with cirrhosis. The Committee considered whether the ICER for genotypes 4, 5 and 6 responded in a similar manner as for other genotypes, that is, whether it would be significantly lower for treatment in people with cirrhosis than in people without cirrhosis. Taking into consideration the potential equality issues raised about genotypes 4, 5 and 6 HCV, the high unmet need and the lack of treatment options for people with cirrhosis, the Committee considered it was reasonable to conclude that sofosbuvir plus peginterferon alfa and ribavirin for treating people with genotype 4, 5 or 6 treatment–naive HCV who have cirrhosis was a cost-effective use of NHS resources.

No clinical evidence or cost-effectiveness analysis was presented to the Committee specifically for people with haemophilia and HCV. The clinical trials excluded patients with haemophilia, so no evidence-based decision or modelling would be possible for this patient group.

2.	If the recommendations have changed after consultation, are there any recommendations that make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?

The recommendations changed as described above for genotypes 4, 5 and 6 in light of the potential indirect discrimination. No further barriers were identified.

3.	If the recommendations have changed after consultation, is there potential for the recommendations to have an adverse impact on people with disabilities because of something that is a consequence of

	the disability?
No	

4.	If the recommendations have changed after consultation, are there any recommendations or explanations that the Committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 2 and 3, or otherwise fulfil NICE's obligations to promote equality?
No	

5.	Have the Committee's considerations of equality issues been described in the final appraisal determination, and, if so, where?
Yes in section 4.36-4.38 and 4.42 and the summary table.	

Approved by Centre or Programme Director (name): Meindert Boysen

Date: 23/02/2015