The BSG Liver section would like to respond to the Appraisal committee's published view that it is "minded not to recommend sofosbuvir for the treatment of chronic hepatitis C". The STA appraises health benefits and costs of new drugs and makes recommendations based on evidence (clinical efficacy, quality of life, mortality) and considers cost and impact on NHS (direct and indirect). Our view is that NICE can fulfill both aspects of its directive and still recommend Sofosbuvir.

Sofosbuvir is one of a number of new drugs which have emerged to treat hepatitis C. Drug development in this field has progressed as a response to the shortcomings of current therapies. These shortcomings can be identified directly, but there are also indirect consequences which can only be 'estimated'. Measurable 'shortcomings' include the lack of efficacy and the significant side-effects. Current treatment regimes are dependent on Interferon which has a significant side-effect profile. Side-effects range from physical to mental health and hence many patients do not access treatment because of these known adverse consequences. The indirect consequence of this is that patients do not access testing as they perceive there is no 'acceptable' treatment. Hence the assumption that only 5-10% of patients are truly 'intolerant' of interferon , ignores the significant number who do not access treatment or testing because of the perceived side-effects. Access to all therapeutic options would promote confidence in patients, encourage testing and improve treatment take-up, whereas opposing Sofosbuvir will do the opposite.

The development of a drug such as Sofosbuvir, which has dramatically improved efficacy with minimal side-effects must be viewed as a significant step forward in the management of chronic hepatitis C. The fact that this drug has demonstrable efficacy in both cirrhotic and pre-cirrhotic stages and can be safely used in those circumstances, will alter the management strategy away from observation and expectation of liver failure to cure and subsequent recovery. The impact of this step change cannot be overstated.

Cleary the cost of this new therapy cannot be ignored, and it's potential impact on the NHS is almost certainly behind the expressed concern of NICE. If however the efficacy of the medication is clear-cut in terms of clinical efficacy, quality of life and mortality, NICE must be helped to understand how the clinicians will *responsibly* utilise this important new resource. NICE should therefore not oppose the introduction of Sofosbuvir, but be persuaded that it's use will be limited by a stratified approach to treating HCV. All hepC patients should be considered for treatment in a multidisciplinary environment and straightforward cases be offered treatment with standard PEG-Interferon based regimens, whereas those with the greatest need (who cannot safely receive PEG-Interferon based therapy) should be treated with new therapies. The MDT's will need to demonstrate adherence to such a strategy, and drug costs re-imbursed on evidence that such a strategy is being adhered to.

There is undoubtedly a moral and ethical imperative to recommend a drug which can cure a disease. There is also a moral imperative to manage budgets responsibly and clinicians bear that responsibility as do NICE. Sofosbuvir is an

effective drug and there is considerable pressure from patients and clinicians for access to this valuable therapeutic option. NICE should recommend Sofosbuvir but insist its use is linked to MDT's to ensure that it can be affordable.