Response to 2nd ACD on Sofosbuvir by The Hepatitis C Trust

The Hepatitis C Trust would like to express its disappointment that NICE is minded not to recommend Sofosbuvir for any patients with genotype 4, 5 or 6. These patients will therefore have no access to any drugs other than peg-interferon and ribavirin, despite the fact that the sub-group analysis of NEUTRINO should a 96% SVR12. There are a significant number of patients who would look at 96% SVR with less interferon and consider that a good trade-off who would not do just peg-interferon and ribavirin with maybe a 60-70% chance of SVR (and whose comparator is therefore no treatment, greatly lowering the ICER).

One of the issues is of course the small numbers of genotype 4, 5 or 6 in the relevant trials, so that for example a single non-SVR cirrhotic can have a significant impact on ICERs, and the small numbers also make the ICERs more uncertain. The reason for the small numbers in the trials is that these are comparatively rare genotypes in the developed world, where trials typically are held. This applies equally to the UK where only some 5% of people living with hepatitis C have genotypes 4, 5 or 6. We feel that in some sense the small numbers result in discrimination and we do not think it should count against them. Indeed, we would argue that, if the genotypes were combined in proportion to their prevalence and genotypes 1, 4, 5 and 6 considered as a combined group, Sofosbuvir would be cost effective for the group as a whole. We therefore request that NICE reassess these genotypes.

We also feel that the ICERs across the board are almost certainly too high. As we continue to note, the cost of transmission prevention as a result of successful treatment cannot logically continue to be excluded from calculations for infectious diseases such as hepatitis C. Furthermore, much of the evidence used for disease state transition is old and, in our view out of date. Early estimates of the likelihood of progression to cirrhosis may be too conservative, as we see larger cohorts with infection of more than 30 years. Equally we do not believe that quality of life estimates have properly taken into account either the debilitating consequences of interferon treatment that for some people persist *after* treatment has ended for some years or the positive impact of treatment on people with co-morbidities such as haemophilia or cryoglobulinemia.