Cost-effectiveness and long-term outcomes of Sovaldi (sofosbuvir) for the treatment of chronic hepatitis C infected (HCV) patients from a Swedish societal perspective

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Introduction

- Hepatitis C is the result of a ribonucleic acid (RNA) virus (hepatitis C virus; HCV), which mutates at a greater rate to that of DNA viruses. Six major HCV genotypes (GT) (i.e. GT 1, 2, 3, 4, 5, and 6) and a large number of subtypes have been described in the literature.
- In Sweden, it is estimated that approximately 40,700 individuals are chronically infected with HCV in 2013. The number of HCV cases in Sweden is forecasted to increase by 15% by 2030 and the number of liver related deaths by 5%. GT1 represents approximately 50% of HCV cases, GT3 some 30% just last 20% of, and GTs 4/5/6 around 1% of cases.
- The treatment of hepatitis C infection aims at eradicating the virus and consequently preventing cirrhosis and its complications, reducing extra-hepatic manifestations, and preventing infection of other people.
- Sofosbuvir (SOF) is a nucleotide analogue that inhibits NS5B directed HCV RNA replication in vitro and has demonstrated high rates of sustained virological response (SVR) when given with ribavirin (RBV) to subjects with chronic GT1, GT2, GT3 or GT4/5/6 HCV infections.

Objective

- To model the cost-effectiveness of SOF in Swedish treatment-naïve (TN) GT1/4/5/6 and GT2 and 3 patients who are TN, treatment-experienced (TE), interferon eligible (IE) or unsuitable for interferon (UI).

Methods

- A cohort of 10,000 patients (age 40 to 45 years), with 20% initiating treatment at the compensated cirrhotic stage, was followed for a lifetime using a Markov model. The model structure is shown in Figure 1. There were two points of patient entry for treatment into the model (non-cirrhotic and compensated cirrhosis) (the non-cirrhotic stage includes patients with mild and moderate fibrosis).
- Patients move to the SVR health state after completion of treatment if they have undetectable HCV RNA, 12 or 24 weeks (wks) after the end of treatment. They are considered to be virologically cured. Patients without a SVR face an annual probability of progression to more advanced stages of the disease.
- A societal perspective was adopted by considering productivity losses associated with treatment and advanced liver disease, such as death, decompensated cirrhosis, hepatocellular carcinoma and liver transplant.
- Table 1 presents the treatment strategies and SVR rates in the model.
- Transition probabilities, health state utilities and clinical data for the comparator treatment strategies were obtained from the literature.
- Outcomes were discounted at 3.0% as recommended by Sweden’s Dental and Pharmaceutical Benefits Agency (TLV). The impact of uncertainty around the input data and key assumptions was assessed by considering productivity losses estimated the productivity loss to society from sick-leave due to chronic GT1, GT2, GT3 or GT4/5/6 HCV infections. Due to data scarcity, the costs associated with treatment-related adverse events were not included.
- Drug costs were obtained from the TLV. Monitoring costs were obtained from Swedish price lists and databases. Health state costs were obtained from the literature.
- Due to data scarcity, the costs associated with treatment-related adverse events only included drug costs.
- Indirect costs associated with productivity loss to society from sick-leave due to chronic hepatitis C treatment during GT1, GT2, GT3 or GT4/5/6 HCV treatment.
- The impact of uncertainty around the input data and key assumptions was investigated by means of deterministic sensitivity analysis (DSA), probabilistic sensitivity analysis (PSA) and scenario analysis.

Results

- Treatment with SOF is expected to prevent more cases of ALD and increase life expectancy and quality of life compared to all comparator arms (Figure 2).
- SOF treatment was particularly favourable for patients with no current treatment option where up to 7,000 ALD cases were estimated to be avoided.
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Conclusion

- From a societal perspective, SOF-based regimens offer a cost-saving alternative to the current standard of care for HCV. In order to optimally allocate scarce societal resources, arguably all costs related to HCV treatment need to be included in the cost-effectiveness analysis.
- The combination of higher cure rates with improved tolerability, decreased treatment duration and regimen complexity, and the ability to treat patients who currently lack treatment options, means that SOF has the potential to help reduce the long-term disease and economic burden of HCV in Sweden.

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