Worldwide treatment of hepatitis C could be within sight at the right cost

February 23 2015

A 12-week course of the new drug sofosbuvir in the US is priced at as much as $84,000 per person

Lowering the cost of hepatitis C drugs is possible and key to achieving global access to treatment, according to new research by the University of Liverpool and Imperial College London.

There are an estimated 185 million people infected with the hepatitis C virus worldwide and 160,000 in Britain. Currently there is no vaccine and, if left untreated, infection can lead to cirrhosis and liver cancer,

causing up to 500,000 related deaths globally per year.

Hepatitis C is particularly problematic in low to middle income countries ; for example 12 million people are infected in Egypt.

A new and effective generation of direct-acting antiviral drugs (DAAs) has been developed to treat hepatitis C. However, at present these drugs are highly expensive. A 12-week course of the new drug sofosbuvir in the US is priced at as much as $84,000 per person and £55,440 in the UK. The NHS has recently delayed introduction of sofosbuvir due to its high price.

The treatment of HIV provides a precedent for cutting the costs of drugs on a large scale to make them available across the world. The drugs that have been rolled out worldwide for HIV are similar in chemical structure and mechanisms to the new generation of hepatitis C drugs.

Monitoring costs

Researchers at Liverpool believe that it is feasible that global hepatitis C treatment could be achieved if the manufacturing and monitoring of costs of those drugs were minimised in the same way as with HIV treatments, which involved the lifting of patents to allow drugs to be made by generic manufacturers.

In the study, published in *Hepatology*, the researchers used HIV drugs as a framework for the analysis to explore what would be possible if drugs were produced at a large scale with the removal of patents to enable generic versions of these DAAs to be manufactured. This is feasible since India has recently filed a patent opposition to sofosbuvir and, if successful, this would mean the patent would no longer restrict the manufacture of the drug and generic versions could be made by a range of manufacturers.

By taking a bottom-up approach using information on the drugs' raw materials, molecular structure and doses, the researchers estimated that if production was done at a large enough scale, it may be possible to dramatically reduce the cost of these news drugs. The study estimated that to treat at least five million people with a combination of the two DAAs sofosbuvir and daclatasvir could cost $122 per person.

Bringing down the price

Co-author, Dr Andrew Hill, from the University of Liverpool's Institute of Translational Medicine, said: "As hepatitis C drugs are so similar to those used to treat HIV we assumed they have the potential to be made in the same way; producing the drugs at economies of scale in large factories and within a freely competitive market where patents have been lifted to allow generic production.

"We know from the experience of HIV treatment that charitable funders want to be able to donate a large sum of money and know it will treat a large amount of people. Our results indicate that this is possible by bringing down the price of hepatitis C drugs for a set target for the number treated."

Through a review of clinical trials, the study identified the four most effective combination regimes of DAAs for a 12-week treatment course for Hepatitis C. The study estimated the minimum costs of treatment by this new generation of DAAs, assuming large scale manufacture to treat at least five million patients per year, in a freely competitive market without the limitations of current patents. The analysis involved going back to the basic chemistry of the drugs to ascertain the cost of the raw materials, synthesis and manufacture of the drugs.

Barriers

Dr Graham Cooke, from the Department of Medicine at Imperial College London, said: "We now have treatments to deal with hepatitis C, but there are operational, legal and political barriers preventing us from ensuring access for people on a global and national scale.

"To break down these barriers, we need to learn lessons from the large-scale rollout of HIV treatment and accelerate the process. In this study we have estimated the possible reduction in cost of these new drugs if some of these barriers are removed and they can be produced at a large scale with free competition and improved production efficiency. "

The results showed that the combination of sofosbuvir and daclatasvir to treat five million people could potentially cost $122 per person. These two drugs are already licensed and considered to be the most promising for large-scale programmes.

More information: van de Ven, N., Fortunak, J., Simmons, B., Ford, N., Cooke, G. S., Khoo, S. and Hill, A. (2015), "Minimum target prices for production of direct-acting antivirals and associated diagnostics to combat hepatitis C virus." *Hepatology*. doi: 10.1002/hep.27641

Provided by University of Liverpool