Community-based treatment providers can help ease pressure on specialists in battle against hep C

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A new study, presented today, demonstrates treatment for Hepatitis C can be provided safely and effectively within a community-based and non-specialist setting. This illustrates the potential for alternative providers to ease pressure on currently overburdened specialists. The study, sponsored by the National Institutes of Health, was presented at The International Liver Congress 2016 in Barcelona, Spain.

Between 130 and 150 million people globally have chronic Hepatitis C virus (HCV) infection.[1] It is estimated that 15 million people in the World Health Organization's EU Region are living with Hepatitis C, representing 2% of adults.[2]

"With such a large patient cohort, ensuring that patients can access safe, effective and appropriate treatment is essential," said Dr Sarah Kattakuzhy of the Institute of Human Virology at the University of Maryland, Baltimore, USA and lead author of the study. "Currently, the limited availability of experienced specialists restricts rapid expansion of Hepatitis C treatment, compromising the goal of global eradication. As such, care models which bypass this therapeutic bottleneck must be explored."

The multi-centre, open label, Phase 4 clinical trial assessed chronic HCV-infected patients at community health centres in the United States. Patients received non-randomised treatment from a specialist provider,

primary care physician or nurse practitioner. According to study protocols, providers underwent uniform three hour training on the Infectious Disease Society of America (IDSA) - American Association for the Study of Liver Disease (AASLD) guidelines for HCV.

To ensure continuity, patients received the same standardised treatments with direct-acting antivirals (ledipasvir and sofosbuvir), with outcomes assessed via unquantifiable HCV RNA viral load 12 weeks after the completion of treatment (SVR12) and by a composite score of attendance.* Patients participating in the study were inclusive of challenging subpopulations; predominantly they were black (96%) and genotype 1a (72%), 24% were co-infected with HIV and HCV, 18% were treatment experienced and 20% had cirrhosis, or scarring of the liver.

The study found that of the 304 patients, 285 achieved SVR12 (93.8% per protocol; 88.2% intention-to-treat including patients who discontinued medication early), with no significant difference identified between providers for achieving this outcome. SVR12 was achieved by 92.1% of patients receiving care from specialists, 96.7% of patients receiving care from primary care physicians and 94.9% of patients receiving care from nurse practitioners.

"The data presented here is extremely welcome and shows great potential to escalate treatment options and protocols for Hepatitis C. We have the therapies, we now need to make sure we can effectively roll them out to patients," said Professor Tom Hemming Karlsen, EASL Vice-Secretary. "We know we have too few experienced specialists treating HCV and this is severely hampering our ability to eradicate this disease once and for all. This research has the potential to be a genuine game changer in the way we look at HCV treatment across the board, and could provide the opportunity to increase access to care and treatment to many regions of the world."

More information: *Statistical analysis included chi-squared or Fisher's exact test and logistic regression using SAS, version 9.3.

References:

1 World Health Organization. Hepatitis C Fact Sheet N°164. Available from: www.who.int/mediacentre/factsheets/fs164/en/. Last accessed: March 2016.

2 World Health Organization. Global Alert and Response - Hepatitis C. Available from: www.who.int/csr/disease/hepati … o2003/en/index3.html. Last accessed: March 2016.

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