

New hepatitis C drugs will place strain on health care system

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The cost of treating people infected with the hepatitis C virus (HCV) with newly approved therapies will likely place a tremendous economic burden on the country's health care system. The prediction comes from a cost-effectiveness analysis led by researchers at The University of Texas MD Anderson Cancer Center. The findings, reported in the March 17 issue of the Annals of Internal Medicine, predict that the cost of providing patients their daily regimens could total \$136 billion over five years - 10 percent of the country's annual prescription drug spending.

Jagpreet Chhatwal, Ph.D., study lead and assistant professor of Health Services Research at MD Anderson, reported a combination of two drugs - sofosbuvir and ledipasvir - recently approved by the U.S. Food and Drug Administration to treat hepatitis C is cost-effective as opposed to the old standard of care. The budget needed to treat all diagnosed patients, however, is unsustainable.

More than two million people are infected with HCV, a virus found in the liver. It is transmitted through blood-to-blood contact.

In recent years, management of the disease has come to a crossroads. In 2012, the Centers for Disease Control and Prevention and the U.S. Preventive Services Task Force both recommended a one-time hepatitis C screening for baby boomers - people born between the years 1946 and 1964. Two years later, the Food and Drug Administration approved the medications sofosbuvir and ledipasvir for disease management. Yet, while the drugs lead to improved outcomes, the cost of the newly approved oral regimen comes considering such costs. Therefore, patients almost at a staggering price to payers - as much as \$1,125 per day.

"We have millions of people who need treatment for hepatitis C and payers obviously don't have the budget to cover this tremendous expense," says Chhatwal. As a result, physicians have to prioritize

the new drugs to the sickest of patients, and several payers have added restrictions that only those with the most advanced disease receive treatment."

For the study, Chhatwal and his team used a simulation model to fully evaluate the costeffectiveness and budget impacts of sofosbuvir and ledipasvir treatment. Their model conducted a cost analysis involving patients with four major HCV genotypes.

The researchers found the new therapies would reduce the clinical burden of the disease. They determined that the newer, more expensive medications would be most beneficial for select groups of patients: those with advanced disease, have the HCV genotype 1, or are younger.

The results show that using new therapies is costeffective in the majority of patients. However, the budget required to treat all eligible patients would be \$136 billion over the next five years. Compared with the old drugs, new therapies would cost an additional \$65 billion, whereas the cost offsets would be only \$16 billion. [See note to media above.]

Our analysis clearly does not support an assertion that the new treatments will save health care money using the drug discounts given in 2014," said Chhatwal. "However, competition from AbbVie has recently brought down drug costs, which may change the outlook."

"While most developed countries factor in treatment cost before approving a drug, U.S. law prohibits always end up paying more for the drugs that were developed in the U.S.," Chhatwal explains. "Considering the law also prohibits Medicare from negotiating drug pricing, the new treatment cost could strain the budget of Centers for Medicare and Medicaid Services."



"Economics need to play an important part of improving the <u>health care system</u>," said Chhatwal. Hepatitis C presents an unusual case where we have cost effective therapeutic options that our <u>health care</u> system cannot afford," Chhatwal continued. "While lower drug prices will help, that's not sufficient. Both the government and private insurers will need additional resources to effectively manage this epidemic."

Senior author Michael Dunn, M.D., professor and associate chief of Gastroenterology, Hepatology and Nutrition at the University of Pittsburgh said, "We have an obligation to fully inform patients about the actual human value and real costs of these treatments. That knowledge is crucial for good decisions when such large resources are at stake."

Provided by University of Texas M. D. Anderson Cancer Center

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