Researchers evaluate cost-effectiveness of genetic screening to guide initial HIV treatment

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A major study from a team of researchers from Weill Cornell Medical College and Massachusetts General Hospital has found that a recent change to HIV-treatment guidelines recommending genetic screening is cost-effective under certain conditions. The new recommendation suggests conducting a genetic screening test prior to prescribing the drug abacavir, one of the preferred first-line drugs for the treatment for HIV-infected adults.

"The guideline change represents one of the first situations in which a genetic test has been recommended for use in clinical practice to guide drug selection that will affect treatment decisions for thousands of patients each year," says lead author Dr. Bruce R. Schackman, associate professor of public health and chief of the Division of Health Policy in the Department of Public Health at Weill Cornell Medical College. "While the guidelines now recommend that physicians order this new test before prescribing abacavir, policy makers and insurers want to know whether the additional cost of the test is appropriate compared with not testing and using a different drug."

The study appears in the latest online issue of the journal *AIDS*.

The study findings provide guidance for policy makers in response to changes earlier this year in the U.S. Department of Health and Human Services' (DHHS) clinical guidelines for HIV treatment. A recent FDA-

approved change in the abacavir drug label warns that it can cause a hypersensitivity reaction, especially in patients who carry a particular genetic variation (the HLA-B*5701 allele) that can be identified by the genetic test. Severe hypersensitivity reactions are very rare, but affect multiple organs and can be serious enough to cause hospitalization or death.

Dr. Schackman, Dr. Paul E. Sax, clinical director of the HIV Program and Division of Infectious Diseases at Brigham and Women's Hospital, and Dr. Kenneth A. Freedberg, director of Epidemiology and Outcomes Research at the Partners AIDS Research Center/Massachusetts General Hospital (PARC/MGH), collaborated on the study with Callie Scott and Drs. Rochelle P. Walensky and Elena Losina of PARC/MGH. Drs. Walensky and Losina are also affiliated with Brigham and Women's Hospital, and Drs. Freedberg and Losina are also affiliated with Boston University School of Public Health.

The authors determined that genetic testing for HLA-B*5701 is cost-effective, but only if abacavir-based treatment is as effective among those testing negative for the genetic variation as not testing and initiating treatment with tenofovir, another preferred first-line drug. In both cases, the drugs were assumed to be part of a "cocktail" that includes the drug efavirenz, which is commonly used in treating new HIV patients, and one other drug. Both abacavir and tenofovir are considered effective when used in this way, but no clinical trial results have been published that directly compare using these drugs in patients newly initiating HIV treatment. Separate "head-to-head" clinical trials that include this comparison are currently being conducted by the federally funded AIDS Clinical Trials Group and by GlaxoSmithKline, the manufacturer of abacavir.

Critically, genetic testing was found to be cost-effective based on published drug prices in the United States, where abacavir-based

treatment costs less than tenofovir-based treatment, and based on Medicare reimbursement rates for the genetic test. Actual costs for drugs and tests vary by insurer and laboratory, and at lower tenofovir prices or higher test costs the genetic testing strategy was no longer cost-effective.

The authors used a computer simulation model to project the treatment outcomes and HIV medical care costs for patients initiating treatment with and without genetic testing. They used data from previous studies to project the likelihood of developing serious or mild side effects on each drug and substituting an alternative drug, and considered the implications of drug selections for subsequent HIV treatment decisions. Cost-effectiveness ratios were reported as cost per quality-adjusted life year.

"We found that genetic testing has a cost-effectiveness ratio of $36,700 per quality-adjusted life year," says Dr. Freedberg. "In the U.S., this cost-effectiveness ratio is below commonly accepted thresholds for medical interventions that are delivering 'value for money.' In other words, based on available evidence, physicians using the test are making good decisions both for their individual patients and for society."

"With a negative result on the genetic screening test, both patient and physician can feel more confident about prescribing abacavir," says Dr. Sax. "This allows them to preserve alternative drugs as future options and can help save the health care system money by using a lower-priced drug."

Source: New York- Presbyterian Hospital

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