'Blood-free' monitoring as good as blood tests in predicting the course of AIDS

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Researchers at the University of Pennsylvania School of Medicine have shown that monitoring treatment adherence to AIDS therapy is a simple blood-free way to monitor risk of disease progression. The international study was published in the May issue of the journal *PLoS Medicine*.

"The current approach in the developing world, when they cannot afford to measure the virus in the blood, is to monitor the CD4 blood cell count. But, CD4 counts drop after failure has occurred and the virus is already getting the upper hand," said lead author Gregory Bisson, MD, MSCE, Assistant Professor of Medicine and Assistant Professor of Epidemiology.

"By keeping track of how frequently AIDS patients refill their prescriptions for combination anti-retroviral therapy [cART] medications on time, we can predict how successful the virologic suppression will be." The World Health Organization recommends that HIV-infected individuals who are receiving cART in resource-limited settings have periodic CD4 blood cell counts in order to monitor treatment effectiveness.

"Monitoring prescription refills at the pharmacy provides a proactive approach to disease management in contrast to monitoring CD4 cell counts, which is reactive," said Bisson. "Measuring how many people adhered to their prescriptions was actually significantly better at predicting disease status at 6 and 12 months compared to the CD4 cell count." In monitoring patients who had been on treatment for longer

periods, accuracy of the measures was the same.

The study was based on data extracted from the Aid for AIDS Disease Management Programme database that covers nine countries in southern Africa. The data included pharmacy prescription refill claims for cART, CD4 blood cell count, and virus levels for over 1,900 HIV-infected adults initiating cART. The team used a method developed in part by co-author Robert Gross, MD MSCE, Assistant Professor of Medicine and Assistant Professor of Epidemiology.

After the first six months of cART therapy, 50 percent of the patients were less than perfectly adherent. Adherence is defined as the number of days covered by the submitted prescription claims divided by the number of days between cART initiation and the last refill prior to testing. For example, if claims covered 90 days but the refill interval was 100 days, adherence was scored as 90 percent. Of the patients with perfect adherence, 9 percent had higher viral loads, whereas of the patients with less than perfect adherence, 40 percent had higher viral loads.

Although the study was performed in a low-resource setting, using patient adherence data would also be useful in a high-resource setting. "Converting pharmacy refill data to a metric that is included in patient charts would help the clinician counsel the patient and could direct interventions, even in my own practice," said Bisson.

Using patient adherence data has the potential to shift the emphasis in treating AIDS away from reactively responding to proactively preventing drug resistance. Bisson cautioned however that the findings of this study need to be confirmed in other settings. This observational study was based on data that had already been collected; a prospective study is being planned that will monitor new patients as they progress through their treatment.