Protocol Title: Persistent elevation of liver transaminases following HCV virologic cure among HCV mono-infected and HIV/HCV co-infected adults

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Summary: A strong body of evidence supports the benefits of HCV cure, including improvement in survival among those achieving sustained virologic response (SVR), the virologic surrogate for cure. However, a subset of patients treated for HCV demonstrate progression of liver fibrosis despite SVR, and higher fibrosis progression rates have been observed among HIV-infected patients who achieve SVR compared to HIV-uninfected patients. Additionally, a few recent studies have reported that 12-35% of all patients demonstrate persistent elevation of liver alanine aminotransferase levels following SVR, for which the long-term clinical implications remain unclear. Of note, higher rates of aminotransferase elevations have been observed among HIV-infected patients following SVR, independent of alcohol use and liver fibrosis stage.

Primary Objective: To compare rates of liver transaminase elevation after sustained virologic response (SVR) among HIV/HCV co-infected and HCV mono-infected patients.

Secondary Objectives:
1. To assess risk factors for persistent transaminase elevation after SVR among HIV/HCV co-infected and HCV mono-infected patients.
2. To evaluate etiologies of persistent transaminase elevation after SVR among HIV/HCV co-infected and HCV mono-infected patients.
3. To determine whether persistent transaminase elevation after SVR is associated with antiretroviral therapy and HIV viral suppression among HIV/HCV co-infected patients.
4. To compare rates of liver-related clinical outcomes among HIV/HCV co-infected and HCV mono-infected patients with persistent transaminase elevation after SVR.

Objective of Internship: complete analysis, work with GI fellow to write up abstract for scientific meeting and manuscript

Scope of Work: This is a descriptive analysis of HIV/HCV co-infected and HCV mono-infected adults who achieve virologic cure of HCV at Duke. Specifically, rates of persistent liver transaminase elevations following SVR-12 will be compared between HIV/HCV co-infected patients and HCV mono-infected patients, and clinical predictors and outcomes associated with persistent transaminase elevations will be assessed. Frequency counts and percentages will be used to describe categorical variables; means and standard deviations will be used to describe contiguous variables. Comparisons among groups will employ Fisher’s exact test or chi-square test for categorical variables, and Student’s t-test for continuous variables. Multivariable regression analyses will be performed by a biostatistician in collaboration with the Duke Center for AIDS Research and Duke Clinical Research Institute. Of note- this project was started by CFAR/DCRI biostats but not completed.