predictive value for vaccine failure. We retrospectively analyzed the relationship of calculated globulin (CG) levels with HBV vaccine response in the U.S. Military HIV Natural History Study (NHS).

Methods. NHS is a longitudinal observational cohort of DoD active duty and beneficiaries with HIV infection, enrolling since 1986. Inclusion criteria was: (1) no current or past HBV or hepatitis C infection (2) HBV vaccination after positive HIV date, (3) available post-vaccination follow-up serum HBV surface antibody (HBAb) test, (4) CD4 cell count, HIV RNA viral load (VL), and protein levels within 90 days prior to the last vaccine dose. Using a standard approach, CG levels were derived by subtracting the albumin level from total protein. Variables were analyzed using uni- and multivariate logistic regression model.

Results. Data from 674 eligible participants were analyzed. Subjects were 87% male, 44% Caucasian, 41% African-American. At time of last vaccine dose, median values were age, 34 yrs; CD4 cells/μL, 515; nadir CD4 cells/μL, 318. 51% were receiving ART and VL was <400 copies/ml in 51%. Overall, HBV vaccine response rate was 54%. Among CG quartiles, HBV vaccine response was 70%, 60%, 40% and 44% from lowest to highest quartile respectively (P < 0.001). In the multivariate analysis, CD4 cell count and vaccine dose (per 100 cells) were significantly associated with vaccine response (Table).

Conclusion. CG levels at time of last dose independently predicted successful HBV vaccine response in HIV-infected persons. These data suggest B-cell dysfunction, characterized by higher CG levels, may be clinically significant regardless of VL and CD4 cell count.

Table 1. Comparison of laboratory characteristics between coinfected and mono-infected patients

| Characteristics | HIV+ (n = 471) | HIV+/HBsAg + (n = 47) | p |
|-----------------|----------------|-----------------------|---|
| WHO Clinical Stage | | | |
| Stage I (%) | 210 (45.5) | 22 (46.8) | | |
| Stage II (%) | 138 (29.9) | 14 (29.8) | | |
| Stage III (%) | 109 (23.6) | 10 (21.3) | | |
| Stage IV (%) | 4 (0.9) | 1 (2.1) | 0.848 |
| Median platelets count | 226 (177 – 269) | 212 (176 – 266) | 0.278 |
| Median CD4+ T – cell count, cells/mm3 (IQR) | 363 (204 – 508) | 327 (131 – 462) | 0.203 |
| Median ALT (IQR) | 21.4 (16.0 – 30.1) | 26.2 (18.0 – 35.0) | 0.054 |
| Median AST (IQR) | 28.8 (22.1 – 38.1) | 29.4 (26.0 – 39.8) | 0.244 |
| HBV DNA, IU/mL Median (IQR) | 1484 (244 – 727,292) | < 20 % | 45 (96.7) |
| APRI | 10 (21.7) | ≥ 20 % | 24 (52.2) |
| < 0.50 % | 12 (26.1) | ≥ 20 < 20 000 ( %) | 2 (4.3) |
| FIB-4 | 44 (95.6) | < 2.0 | | |
| >3.25 | 2 (4.4) | >3.25 | | |

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2224. Longterm Evaluation of Hemoglobin A1c Following Hepatitis C Therapy in Patients with and without HIV Co-infection

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Background. Historically, eradication of HCV with interferon-based treatments was linked with decreased incidence of diabetes. While viral clearance with direct acting agents (DAAs) may be associated with acute decreases in fasting glucose levels and hemoglobin A1c (HbA1c), there remains a need for larger prospective studies to address the longterm impact of sustained viral response (SVR) achieved with DAAs on glucose metabolism.

Methods. Prospective longitudinal cohort study of 251 subjects with chronic HCV (100% genotype 1a/b, 31% HIV+, 17% diabetes) evaluated pre- and post-DAA therapy with median follow-up of 28 mos. Change in HbA1c, glucose, lipid and transaminase levels were compared based on SVR, HIV, diabetes status and fibrosis stage.

Results. There was no difference in change in HbA1c between subjects who achieved SVR (n = 241) compared with those who did not. Mean change in HbA1c did not differ from zero (-0.02 ± 0.53%) for those with SVR. Further, when subjects were grouped based on HIV, diabetes or fibrosis stage, there were no significant differences in changes in HbA1c or glucose following SVR. Subjects with HIV had smaller reductions in transaminase values (change ALT –33.3 ± 51 IU/L HIV+ vs. –47.8 ± 45 IU/L HIV-, P = 0.0007). Following SVR, total and LDL cholesterol increased (P = 0.0002 and P = 0.0003, respectively) whereas triglyceride levels decreased (P = 0.008).

Conclusion. The current study failed to identify sustained benefits in glucose or HbA1c in HCV treated patients, irrespective of HIV, diabetes or fibrosis stage. HIV infection blunted improvements in transaminase levels related to SVR. While HbA1c
2225. Real-world Effectiveness of Ledipasvir/Sofosbuvir (LDV/SOF) for 8 weeks in Patients Coinfected with HCV and HIV-1
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Background. Real world cohorts (RWC) have demonstrated excellent efficacy of LDV/SOF for 8 weeks in HCV mono-infected patients. Real world effectiveness data of LDV/SOF for 8 weeks in HIV/HCV coinfected patients is emerging from several multiple single-center and multicenter prospective and retrospective cohorts. The aim of this study was to describe the effectiveness of the single tablet regimen of LDV/SOF for 8 weeks in HCV genotype (GT) 1 patients with HIV/HCV coinfected patients. The prospective trials include data from Ain et al (investigator sponsored and Isaakov et al (registration trial). The RWC include the Deutsche Hepatitis C-Register, Madrid Coinfection Registry (Madrid-CoRe), Veterans Affairs HCV Registry, and Slim et al, representing diverse patient populations from Europe and US. Baseline characteristics and efficacy were analyzed.
Methods. In this descriptive analysis, data from two prospective studies, one investigator sponsored and 1 registration trial, one prospective RWC, three retrospective RWC of LDV/SOF for 8 weeks in HIV/HCV coinfected patients were compared. RWC were based on willingness to participate and had at least 15 HCV coinfected patients. The prospective trials include data from Ain et al (investigator sponsored) and Isaakov et al (registration trial). The RWC include the Deutsche Hepatitis C-Register, Madrid Coinfection Registry (Madrid-CoRe), Veterans Affairs HCV Registry, and Slim et al, representing diverse patient populations from Europe and US. Baseline characteristics and efficacy were analyzed.
Results. The majority of the 294 patients included in this descriptive analysis were GT 1, treatment naïve (TN), noncirrhotic (NC), and had a HCV viral load < 6 million. The prospective cohorts enrolled 79 patients with the following baseline characteristics: mean age (43 years), male (66%), white (8%), and GT 1a (41%). The RWC studies assessed enrolled 215 patients with the following overall baseline characteristics: mean age (54 years) male (84%), white (82%), and GT 1a (75%) in those that reported demographics. The overall SVR12 from six diverse real world and post-marketing cohorts was 94% (277/294). The individual study results are presented in Table 1.
Conclusion. This analysis of diverse cohorts from the EU and US yielded high SVR rates similar to SVR rates seen in multiple RW monoinfected cohorts and supports the use of LDV/SOF in TN, NC GT 1 HIV/HCV coinfected patients with a baseline HCV viral load < 6 million.
Table 1. Clinical trials and RWC with LDV/SOF for 8 weeks in HIV/HCV coinfection

| Study          | Treatment (a) | SVR12 (%) |
|----------------|--------------|-----------|
| Ain et al      | Prospective LDV/SOF x 8 weeks | 20 18 90* |
| Russian cohort | Prospective LDV/SOF x 8 weeks | 59 57 97* |
| Madrid-CoRe    | Prospective LDV/SOF x 8 weeks | 93 85 91**|
| VA (Backens et al) | Retrospective LDV/SOF x 8 weeks | 31 30 97** |
| DHC-R (Buggisch et al) | Retrospective LDV/SOF x 8 weeks | 76 73 96** |
| Slim et al     | Retrospective LDV/SOF x 8 weeks | 15 14 93** |

(a) SVR12: Sustained Virological Response 12 weeks; *Intention to Treat; ** Per Protocol;

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Background. Studies have documented more rapid progression of HCV-associated liver fibrosis in patients co-infected with HIV. However, the natural history of HCV infection in both mono-infected and HIV co-infected patients remains high variability. The patterns of progression in HIV/HCV coinfected patients are not fully characterized. Given the invasiveness of serial liver biopsies, Fibrosis-4 score (FIB-4) is increasingly used. We used FIB-4 to study the natural history of liver fibrosis progression among co-infected patients and evaluated predictors of progression to cirrhosis over 5 years prior to treatment with direct acting agents (DAAs).
Methods. Study subjects were selected from HIV/HCV co-infected patients receiving care at Yale-New Haven Hospital from February 2014 through April 2016 without advanced fibrosis 5 years prior to study entry; Annual FIB-4 scores dating back 5 years were calculated from the most recent FIB-4 score or the last FIB-4 prior to DAA treatment initiation. Patients were further categorized based on FIB-4 progression over the course of 5 years. Univariate and multivariable logistic regression models were used to examine factors associated with FIB-4 progression.
Results. There were 93 men 65 men and 28 women; mean age of 56.7 years. Over 5 years, 25 (26.9%) had FIB-4 progress to >3.25 and 68 (73.1%) had FIB-4 remain <3.25. Demographic variables, clinical variables (HIV viral load, CD4 count) and co-morbid conditions such as diabetes and hyperlipidemia did not differ significantly between those whose FIB-4 stayed below 3.25 and those whose FIB-4 progressed to above 3.25 in univariate and multivariable logistic regression models.
Conclusion. In this study of 93 HIV/HCV coinfected patients without baseline advanced fibrosis, 26.9% progressed to advanced fibrosis over the course of 5 years. We did not identify any statistically significant factors that predicted those who were more likely to progress, although clinically relevant factors such as absence of HIV viremic control, low CD4 count, and lack of statin use showed a trend towards significance and should be assessed in future studies in a larger cohort. Our findings highlight the importance of prioritizing all patients with HCV/HIV co-infection for HCV treatment.