317. Utility of a Hepatitis C Screening Best Practice Advisory in University-based Primary Care Practices

Faith Donaghey[1]; Jessica Tuan, MD, MS[1]; Irini Agaraj[1]; Dorothy Wakefield, MS[1] and Lisa Chirch, MD, FIDSA[2]; [1]University of Connecticut School of Medicine, Newington, Connecticut; [2]University of Connecticut, Farmington, Connecticut

Session: 41. Hepatitis

Thursday, October 3, 2019: 12:15 PM

Background. Hepatitis C virus infection (HCV) is a significant health concern in the United States, impacting an estimated 3 million people. Adults born between 1945 and 1965 ("baby boomers") are 5 times more likely to have HCV infection compared with the general population. In 2012, the CDC recommended screening of adults born between 1945 and 1965. In April 2018 UConn Health transitioned from utilizing the Next Gen EHR system to Epic. At Epic launch, an HCV-screening Best Practice Advisory (BPA) was implemented, along with 13 other outpatient-based BPAs. This allowed for comparison of HCV screening rates before and after Epic launch.

Methods. Data were collected via retrospective chart review on adults born between 1945–1965 presenting to UConn primary care (PC) clinics one year prior to and 9 months post Epic launch. The BPA was set to fire for patients in the birth cohort who did not have an HCV antibody result or a history of hepatitis C in the medical record. Proportions were compared using chi-squared tests and Fisher's Exact test.

Results. The HCV screening rate among PC providers 1-year pre-BPA was approximately 7.7%. Analysis of data nine months after BPA implementation demonstrated HCV screening rates were unchanged at 7.6%. Table 1 describes initial care cascade findings. During the post-launch monitoring period, a 0.2% [270/105,431] response rate was noted (as measured by follow-up actions taken from all BPAs, Table 2). During the same period, a significantly higher response rate to the HCV-screening BPA was noted (1.2% [287/24,532], $P < 0.01$) (Figure 1).

Conclusion. The aim of this study was to improve HCV case identification and to understand the utility of a BPA in this setting. Within the first nine months, the use of an HCV-screening BPA (Figure 2) in PC clinics did not increase screening rates in adults born between 1945 -1965. Alert fatigue may contribute to low screening rates post BPA, as evidenced by the low response rates across all BPAs introduced. Our long-term goal is to gather additional data to assess the efficacy of the HCV BPA and its effects on the HCV care cascade. Modifications to BPA functionality may be indicated.

Table 1: Pre- and Post- HCV Screening BPA Implementation Data

	Pre-BPA	Post-BPA	P-Value
Total patients eligible for screening	23,922	11,059	n/a
Patients Screened with HCV Ab	1853 (7.7%)	836 (7.6%)	0.54
HCV Ab +	69 (3.7%)	24 (2.9%)	0.24
HCV RNA detectable	15 (21.7%)	3 (12.5%)	0.39
Referred for specialty care	14 (93.3%)	3 (100%)	1.00

Table 2: Possible Follow-up Actions Taken Within the HCV BPA

BPA Follow-up Actions
Screening already performed
Use Smart Set to place HCV screening lab order
Add Hep C to problem list
Patient declined

Figure 1: Best Practice Advisory Response Rate at UConn Health Outpatient Clinics

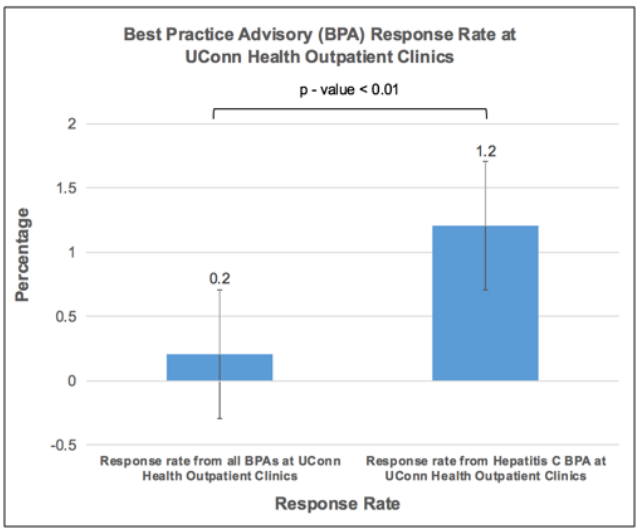
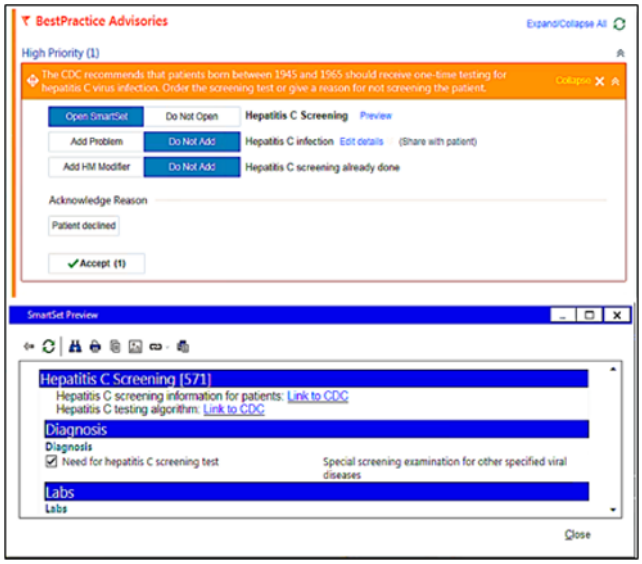


Figure 2: Hepatitis C Screening Best Practice Advisory



Disclosures. **All authors:** No reported disclosures.

318. Tenofovir Alafenamide (TAF) vs. Tenofovir Disoproxil Fumarate (TDF) in Hispanic/Latinx and Black Participants: Efficacy, Bone and Renal Safety Results from a Pooled Analysis of 7 Clinical Trials

Edwin DeJesus, MD[1]; Jaime Federico Andrade Villanueva, MD[2]; Jose Ramon Arribas Lopez, MD[3]; Cynthia Brinson, MD[4]; Gordon Crofoot, MD[5]; Eric S. Daar, MD[6]; Ellen Koenig, MD[7]; Daniel Podzamczer, MD, PhD[8]; Moti Ramgopal, MD, FACP, FIDSA[9]; Jorge Santana, MD[10]; Lizette Santiago, MD[11]; Pablo Tebas, MD[12]; Carmen Zorrilla, MD1[3]; Susan Guo, PhD[14]; Ya-Pei Liu, PhD[14]; Lijie Zhong, PhD[14]; Diana M. Brainard, MD[15]; Christoph C. Carter, MD[15]; Lauren Temme, PharmD[14] and Moupali Das, MD[15]; [1]Orlando Immunology Center, University of Central Florida College of Medicine, Orlando, Florida; [2]Hospital Civil de Guadalajara, Guadalajara, Jalisco, Mexico; [3]Hospital Universitario La Paz, Madrid, Madrid, Spain; [4]Central Texas Clinical Research, Austin, Texas; [5]Crofoot Research Center, Houston, Texas; [6]Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center, Torrance, California; [7]Instituto Dominicano de Estudio Virologicos – IDEV, Santo Domingo, Distrito Nacional, Dominican Republic; [8]Hospital Bellvitge, Barcelona, Catalonia, Spain; [9]Midway Research Center, Ft. Pierce, Florida, [10]University Puerto Rico School of Medicine, San Juan, Puerto Rico, [11]HOPE Clinical Research, San Juan, Puerto Rico, [12]University of Pennsylvania, Philadelphia, Pennsylvania, [13]Maternal Infant Study Center (CEMI), San Juan, Puerto Rico, [14]Gilead Sciences, Foster City, California, [15]Gilead Sciences Inc., Foster City, California

Session: 42. HIV Complications: Bone Complications

Thursday, October 3, 2019: 12:15 PM

Background. People of color are underrepresented in clinical trials. TAF has shown improved renal and bone safety vs. TDF. We pooled 7 studies to evaluate efficacy/safety of TAF vs. TDF for ART initiation/switch in Hispanic/Latinx and Black participants.

Methods. Data from Hispanic/Latinx and Black adults who initiated/switched to TAF or TDF in 7 randomized trials (2 treatment-naïve, 5 suppressed switch) were analyzed. TAF-based regimens (elvitegravir/cobicistat/emtricitabine [FTC]/TAF, rilpivirine/FTC/TAF, FTC/TAF, or bictegravir/FTC/TAF) were compared with TDF-based regimens. Virologic suppression (VS; HIV-1 RNA < 50 c/mL, FDA snapshot) and % change in bone mineral density (BMD) and renal tubular biomarkers urine β-2-microglobulin (B2M):creatinine (Cr) ratio and retinol binding protein (RBP):Cr ratio are reported at W96.

Results. The pooled population (N = 5,825) included 1138 Hispanic/Latinx and 1324 Black participants. Treatment-naïve participants (n = 1,733) were 15% female, 25% Black, 19% Hispanic/Latino, with median age 34 years, HIV-1 RNA 4.6 $\log_{10}$ c/mL, CD4 405 cells/mm^3. Switch participants (n = 4,092) were 13% female, 22% Black, 20% Hispanic/Latino, median age 45 years, CD4 653 cells/mm^3. There was no difference in VS rate with TAF vs. TDF in any group. VS rate (TAF vs. TDF) in naïve participants: 88% vs. 84% (Hispanic/Latinx); 78 vs. 79% (Black); 87% vs. 85% (overall). VS (TAF vs. TDF) was well maintained in switch participants: 91% both arms (Hispanic/Latinx); 86% vs. 87% (Black); 90% vs. 88% (overall). TAF and TDF were well tolerated with few discontinuations due to adverse events (0.6–2%) in all groups. At W96 there was less impact on renal biomarkers in all groups initiating TAF ($P < 0.001$; table), and decreases in BMD were smaller ($P < 0.005$; table) vs. TDF. All groups switching from TDF to TAF experienced decreases in tubular proteinuria and improvements in BMD (both $P < 0.001$; table) at W96.

Conclusion. Hispanic/Latinx and Black participants who initiated/switched to TAF had significantly improved bone and renal parameters vs. TDF, with similar VS rates at W96. Efficacy and biomarkers were similar to the overall study population. These data in >2,400 Hispanic/Latinx and Black PLH demonstrate noninferior efficacy and safety advantages with TAF vs. TDF.

Table: Renal Urine Biomarkers and Bone Mineral Density Through Week 96

Treatment-Naive Participants									
	Hispanic/Latinx Participants			Black Participants			All Participants		
Biomarker, % Change at W96	TAF-Based (n=167)	TDF-Based (n=167)	p-value	TAF-Based (n=223)	TDF-Based (n=213)	p-value	TAF-Based (n=866)	TDF-Based (n=867)	p-value
RBP:Cr	21.6 (-16.3, 83.5)	68.3 (15.0, 171.2)	<0.001	19.6 (-17.2, 69.4)	55.8 (-3.3, 167.8)	<0.001	13.8 (-18.8, 66.1)	74.2 (10.4, 192.2)	<0.001
B2M:Cr	-28.4 (-52.3, 6.1)	29.3 (-21.4, 223.6)	<0.001	-34.0 (-62.4, 3.2)	2.8 (-48.8, 132.3)	<0.001	-32.1 (-61.0, 4.2)	33.5 (-27.8, 230.7)	<0.001
Spine BMD	-1.0 (-2.8, 1.1)	-2.1 (-4.5, 0.0)	0.003	-0.9 (-3.0, 1.8)	-2.5 (-4.7, -0.3)	<0.001	-0.9 (-3.1, 1.1)	-2.8 (-5.0, -0.5)	<0.001
Hip BMD	-1.0 (-2.5, 0.6)	-2.5 (-4.6, -0.2)	<0.001	-1.0 (-3.1, 0.7)	-3.4 (-5.7, -1.3)	<0.001	-0.9 (-2.8, 1.0)	-3.6 (-5.5, -1.2)	<0.001
Switch Participants									
	Hispanic/Latinx Participants			Black Participants			All Participants		
Biomarker, % Change at W96	TAF-Based (n=472)	TDF-Based (n=332)	p-value	TAF-Based (n=485)	TDF-Based (n=403)	p-value	TAF-Based (n=2291)	TDF-Based (n=1801)	p-value
RBP:Cr	11.6 (-36.8, 73.2)	51.7 (2.1, 118.0)	<0.001	11.0 (-21.6, 60.5)	56.4 (2.4, 169.8)	<0.001	-2.3 (-42.0, 46.7)	61.2 (6.3, 162.2)	<0.001
B2M:Cr	-15.4 (-68.7, 49.0)	42.2 (-15.9, 168.5)	<0.001	-3.2 (-48.6, 30.9)	32.7 (-25.8, 169.7)	<0.001	-25.8 (-71.1, 20.6)	53.0 (-21.9, 191.9)	<0.001
Spine BMD	1.7 (-0.5, 3.8)	-0.2 (-2.0, 2.3)	<0.001	2.2 (-0.1, 4.2)	0.0 (-2.0, 2.1)	<0.001	1.8 (-0.4, 4.1)	-0.1 (-2.3, 2.2)	<0.001
Hip BMD	1.7 (0.0, 3.4)	-0.3 (-1.6, 1.3)	<0.001	1.9 (0.4, 3.4)	-0.3 (-1.9, 1.4)	<0.001	1.8 (0.2, 3.4)	-0.5 (-2.1, 1.2)	<0.001

Data are presented as median (Q1, Q3); p-values were from Wilcoxon rank sum test (renal urine biomarkers) or ANOVA (BMD).

Disclosures. **All authors:** No reported disclosures.

319. SWORD 1 and 2: Switch from TDF Containing Regimen to DTG+RPV Maintains Bone Mineral Density and Decreases Bone Turnover Markers Over 148 Weeks

Lesley Kahl, BSc, Hons I, PhD[1]; Grace A McComsey, MD[2]; Monica Coronado Poggio, MD[3]; Sergio Lupo, MD, PhD[4]; Joss de Wet, MBChB, CCFP[5]; David A. Parks, MD[6]; Brian Wynne, MD[1]; Martin Gartland, PhD[1]; Kostas Angelis, PhD[7]; Alicia Aylott, MSc[7]; Michael Cupo, PhD[8]; Kati Vandermeulen, MSc[9]; Jean A. van Wyk, MB, ChB[1] and Kimberly Smith, MD[1]; [1]ViiV Healthcare, Brentford, UK; [2]University Hospitals of Cleveland and Case Western Reserve University, Cleveland, Ohio; [3]Hospital Universitario La Paz, Madrid, Spain; [4]CAICI Institute, Rosario, Santa Fe, Argentina; [5]University of British Columbia Canada, Vancouver, BC, Canada; [6]Central West Healthcare, St. Louis, Missouri; [7]GlaxoSmithKline, London, UK; [8]GlaxoSmithKline, Collegeville, Pennsylvania; [9]Janssen R&D, Beerse, Antwerpen, Belgium

Session: 42. HIV Complications: Bone Complications
Thursday, October 3, 2019: 12:15 PM

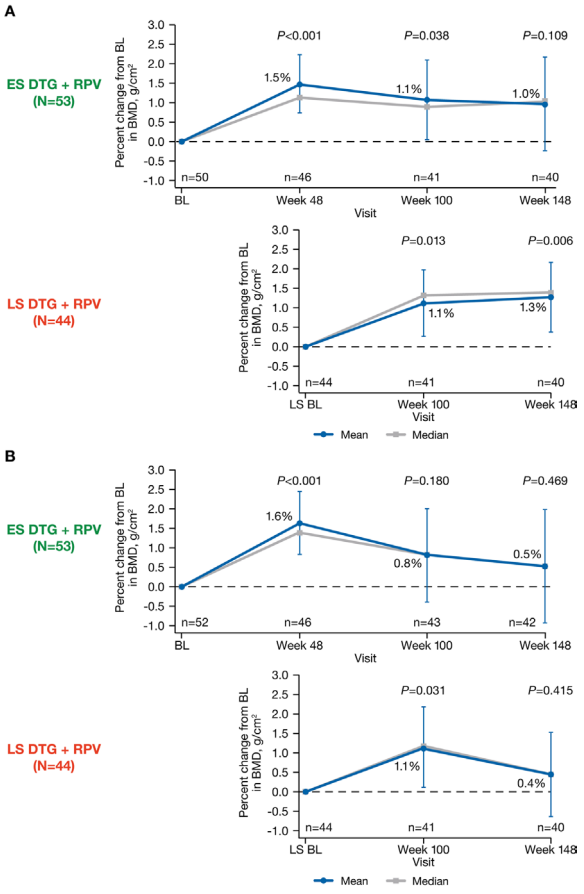
Background. HIV infection and antiretroviral therapy (ART), particularly tenofovir (TDF), is associated with loss of bone mineral density (BMD). The SWORD studies demonstrated noninferiority of the 2-drug regimen (2DR) dolutegravir (DTG) + rilpivirine (RPV) to continuing current triple-therapy ART (CAR) at 48 weeks and continued viral suppression on DTG+RPV through Week 148. A substudy of SWORD 1 and 2 evaluated a change in BMD by DEXA for those participants who switched from triple ART containing TDF to DTG+RPV. The primary analysis reported at 48 weeks showed a significant increase in total hip and lumbar spine BMD and a significant decrease in bone turnover markers in patients receiving DTG+RPV compared with CAR. Here we present data through Week 148.

Methods. HIV-infected adult patients with HIV-1 RNA < 50 c/mL received ART containing TDF for ≥6 months prior to randomization to DTG+RPV (Early Switch group, ES) or CAR on Day 1 (Baseline, BL) through Week 48 in SWORD-1/2. CAR patients suppressed at Week 48 switched to DTG+RPV at Week 52 (Late Switch group, LS). Hip and lumbar spine BMD were measured by DEXA scans read centrally. Secondary endpoints include a change in BMD and bone turnover markers through Week 148.

Results. Following switch to DTG+RPV significant increases were observed for total hip in the ES and LS groups through 100 weeks with a non-significant increase at Week 148 in ES (Figure 1a). Lumbar spine BMD significantly increased from BL at 48 weeks post switch, remained increased, though not significantly from BL through Week 148 (Figure 1b). The BMD of the LS group was similar to that of the ES group through 100 weeks exposure. The majority of patients remained in their pre-switch T-score category or improved a category for both hip and spine through Wk148 (Table 1). Through Wk148, BMI increased minimally and bone turnover markers significantly decreased ($P < 0.001$ to 0.042 across markers) from BL/LS BL except Type I Collagen C-Telopeptide at Wk148 in the LS group ($P = 0.279$).

Conclusion. Switch to the DTG+RPV 2DR was associated with sustained improvements in BMD through Week 148, along with a reduction in bone markers. The favorable effects on skeletal health were observed despite the ageing of study patients and other factors decreasing BMD. A switch to DTG+RPV in suppressed patients provides a robust option for preserving bone health while continuing suppressive HIV treatment.

Figure 1. (A) Percent Change From Baseline (BL)/Late Switch Baseline (LS BL) in Total Hip BMD (g/cm²). **(B)** Percent Change From BL/LS BL in Lumbar Spine BMD (g/cm²).



Mean % change and 95% CI data are shown in blue. Median data are shown in gray. *P* values are from 1-sample 2-sided *t*-test for % change from BL/LS BL. BL, baseline; BMD, bone mineral density; ES, early switch; LS, late switch; LS BL, Late Switch baseline – the latest pre-switch assessment.

Table 1a. Change From Baseline (BL) /Late Switch Baseline (LS BL) in T-score Category for Total Hip Through Week 148

	ES DTG + RPV (N=53)			LS DTG + RPV (N=44)	
Shifts from BL/LS BL	**Week 48**	**Week 100**	**Week 148**	**Week 100**	**Week 148**
n	46	41	**40**	41	**40**
Improvement					
From Osteopenia to Normal	3 (7%)	2 (5%)	**2 (5%)**	5 (12%)	**3 (8%)**
No change					
From Normal to Normal	32 (70%)	27 (66%)	**26 (65%)**	29 (71%)	**28 (70%)**
From Osteopenia to Osteopenia	11 (24%)	11 (27%)	**11 (28%)**	6 (15%)	**8 (20%)**
Deterioration					
From Normal to Osteopenia	0	1 (2%)	**1 (3%)**	1 (2%)	**1 (3%)**

BL, baseline; LS BL, Late Switch baseline - the latest pre-switch assessment; ES, early switch; LS, late switch; n, number of subjects with T-score total hip data at BL/LS BL and week of interest.
Normal: T-score > −1. Osteopenia: −2.5 < T-score ≤ −1.

Table 1b. Change From Baseline (BL) /Late Switch Baseline (LS BL) in T-score Category for Lumbar Spine Through Week 148

	ES DTG + RPV (N=53)			LS DTG + RPV (N=44)	
Shifts from BL/LS BL	**Week 48**	**Week 100**	**Week 148**	**Week 100**	**Week 148**
n	46	43	**42**	41	**40**
Improvement					
From Osteopenia to Normal	3 (7%)	4 (9%)	**1 (2%)**	1 (2%)	**2 (5%)**
From Osteoporosis to Osteopenia	1 (2%)	1 (2%)	**1 (2%)**	1 (2%)	**0**
From Severe Osteoporosis to Osteoporosis	2 (4%)	1 (2%)	**2 (5%)**	0	**0**
No change					
From Normal to Normal	26 (57%)	23 (53%)	**23 (55%)**	26 (63%)	**26 (65%)**
From Osteopenia to Osteopenia	14 (30%)	12 (28%)	**14 (33%)**	12 (29%)	**9 (23%)**
From Severe Osteoporosis to Severe Osteoporosis	0	1 (2%)	**0**	1 (2%)	**1 (3%)**
Deterioration					
From Osteopenia to Osteoporosis	0	1 (2%)	**1 (2%)**	0	**2 (5%)**

BL, baseline; LS BL, Late Switch baseline - the latest pre-switch assessment; ES, early switch; LS, late switch; n, number of subjects with T-score lumbar spine data at BL/LS BL and week of interest.
Normal: T-score > −1. Osteopenia: −2.5 < T-score ≤ −1. Osteoporosis: −3.5 < T-score ≤ −2.5. Severe osteoporosis: T-score ≤ −3.5.

Disclosures. **All authors:** No reported disclosures.