practices. Overall, targeted harm reduction services could be beneficial in the screening and prevention of HCV exposure amongst PWID.

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

1051. Rapid onset of seroprotection rates in young adults immunized with a tri-antigenic hepatitis B virus (HBV) vaccine compared to a mono-antigenic HBV vaccine

Timo Vesikari, MD, PhD[1]; Joanne M. Langley, MD[2]; Nathalie Machluf, PhD[3]; Johanna Spaans, BSc, MSc[4]; Bebi Yassin-Rajkumar, n/a[5]; Dave Anderson, PhD[6]; Vlad Popovic, MD[6]; Francisco Diaz-Mitoma, MD[6]; [1]Nordic Research Network, Tampere, Pirkanmaa, Finland; [2]Canadian Center for Vaccinology, Dalhousie University, IWK Health Centre and Nova Scotia Health Authority, Halifax, NS, Canada, Halifax, Nova Scotia, Canada; [3]SciVac Ltd, Rehovot, HaMerkaz, Israel; [4]VBI Vaccines Inc., Ottawa, ON, Canada; [5]Sponsor, Ottawa, ON, Canada; [6]VBI Vaccines, Cambridge, MA

PROTECT and CONSTANT Study Groups

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Background. Hepatitis B (HBV) remains a significant public health risk with an estimated 240-350 million people chronically-infected with HBV worldwide. In the US, rates of new HBV infections are highest among individuals aged 30-39 years, highlighting the elevated risk in adults. Moreover, CDC reported that in 2017 only 34.3% of US adults aged 19-49 years were vaccinated against HBV. Younger adults who are at-risk of HBV infection, through exposure in the workplace or home (e.g. healthcare workers, public service sector workers, those living with HBsAb-positive individuals), through travel to countries with high HBV prevalence, or through exposure as a result of high-risk behavior (e.g. injection drug use, risk through sexual transmission), need a highly effective and safe HBV vaccine with a rapid onset of seroprotection.

Seroprotection Rates from Phase 3 Studies

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Figure 1:

Seroprotection Rates (SPR %)

Defined as percent of participants with anti-HBs titers ≥ 10 mIU/mL

Studies	Study Arm	N	Month 3	Month 6	Month 7	Month 12
PROTECT Phase 3 : US, EU, CAN	TAV	145	76.0%	87.2%	99.2%	97.5%
	MAV	154	37.0%	39.0%	91.1%	87.1%
CONSTANT Phase 3 : US, EU, CAN	TAV	2,126		90.4%	99.3%	98.7%
	MAV	712		51.6%	94.8%	92.4%
SG-005-05 Phase 3 : Vietnam	TAV	120		98.3%	100.0%	99.1%
	MAV	117		81.2%	98.3%	98.2%
38-13-040 Phase 3 : Russia	TAV	50	95.9%	100.0%	100.0%	
	MAV	49	87.2%	89.4%	97.9%	
SciB018 Phase 4 : Israel	TAV	88	98.8%	98.8%	100%	100%

Methods. Four phase 3 studies assessing kinetics of seroprotection rates (SPR; anti-HBs ≥ 10 mIU/mL) in adults aged 18-45 years, vaccinated at months 0, 1 and 6 with 10 µg of tri-antigenic HBV vaccine (TAV) *vs.* 20 µg of a mono-antigenic HBV vaccine (MAV) were completed between 2008 & 2020: (1) PROTECT study in US, Europe, and Canada, n = 299; (2) CONSTANT study in US, Europe and Canada, n = 2,838; (3) SG-005-05 study in Vietnam, n = 349; (4) 38-13-040 study in Russia, n = 99. One phase 4, single-arm study was conducted with 10 µg of TAV in adults aged 20-40 years: SciB018 study in Israel, n = 83.

Results. In all five studies, vaccination with TAV achieved SPRs of 87.2-100.0% at month 6 after 2 doses and 99.2-100.0% at month 7 after 3 doses, compared to 39.0-89.4% and 91.1-98.3% achieved with MAV at months 6 and 7, respectively (Fig 1). Moreover, as demonstrated with the data available from two of the controlled studies, TAV induced SPRs of 76.0%-95.9% at month 3 after 2 doses compared to 37.2%-87.2% with MAV. No major safety signals were observed, and adverse events were well-balanced and consistent with the known vaccine safety profiles.

Conclusion. Tri-antigenic HBV vaccine (TAV) has demonstrated its ability to rapidly, consistently, and safely elicit high SPRs in younger adults across different regions of the world.

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1052. Serologic vs. molecular testing for screening for hepatitis C virus infection in patients with hematologic malignancies with and without prior hematopoietic cell transplant recipients.

Harrys A. Torres, MD[1]; Georgios Angelidakis, MD[2]; Ying Jiang, MS[3]; Minas Economides, MD[2]; Marcel Yibirin, MD[2]; Robert Orlowski MD, MD[4]; Richard Champlin, MD[5]; Srdan Verstovsek, MD[6]; Issam I. Raad, MD[7]; Issam I. Raad, MD[7]; [1]Departments of Infectious Diseases, Infection Control and Employee Health, Gastroenterology, Hepatology and Nutrition,, houston, Texas; [2]Departments of Infectious Diseases, Infection Control and Employee Health, houston, Texas; [3]MD Anderson Cancer Center, Houston, TX; [4]Lymphoma/Myeloma, houston, Texas; [5]Stem Cell Transplantation,, houston, Texas; [6]Leukemia, housotn, Texas; [7]The University of Texas MD Anderson Cancer Center, Houston, Texas

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Background. The prevalence of chronic hepatitis C virus (HCV) infection in patients with cancer in the U.S. has been reported to be 1.5% overall and up to 10.6% in specific subgroups. Testing for antibody to HCV (anti-HCV) is a low-cost diagnostic method in widespread use worldwide; however, the optimal screening test for HCV in cancer patients has not been established. We sought to identify the optimal screening test for HCV in patients with hematologic malignancies and/or prior hematopoietic cell transplant (HCT).

Methods. New patients who were seen at the Lymphoma/Myeloma, Leukemia, and Stem Cell Transplant clinics at MD Anderson Cancer Center (02/11/2019-11/5/2019) were simultaneously screened for HCV with serologic (antibody to HCV [anti-HCV]) and molecular (HCV RNA) assays. Anti-HCV testing was performed by using the ARCHITECT Anti-HCV assay and HCV RNA testing was performed by using the Cobas HCV test. The agreement between the two tests was evaluated using Cohen's kappa statistic and McNemar's test. All tests were two-sided with a significance level of 0.05.

Results. A total of 214 patients were enrolled in the study, of whom 127 (59%) were men (Table), One hundred forty-nine patients (70%) had a lymphoid neoplasm, 65 (30%) had a myeloid neoplasm, and 15 (7%) underwent HCT. Ninety-three patients (43%) had progressive disease. Three patients (1.4%) had positive anti-HCV, and two (0.9%) had positive HCV RNA. The overall percentage agreement was 99.5% (95% CI, 97.4% to 99.9%). Of the 3 patients with positive anti-HCV, 2 had positive and 1 had negative HCV RNA. There were no cases of seronegative HCV infection. The positive percentage agreement was 66.7% (95 CI, 20.8% to 93.9%), and the negative percentage agreement was 100.0% (95% CI, 98.2% to 100.0%). Cohen's Kappa coefficient was 0·80 (95% CI, 0.41 to 1.00, $p < 0·0001$), indicating substantial agreement between anti-HCV and HCV RNA tests for diagnosis of HCV infection.

Conclusion. The diagnostic yield for screening for chronic HCV infection in heavily immunocompromised cancer patients is similar for serologic and molecular testing. The use of anti-HCV, a diagnostic method with low cost, in patients with cancer would contribute to the World Health Organization's goal of HCV elimination worldwide.

Table. Characteristics of the study population (n=214)

Table. Characteristics of the study population (n=214)

Characteristic	Value
Median age, (range, years)	64 (27-84)
Male sex	127 (59%)
Race	
White	180 (84%)
Black	18 (8%)
Asian	9 (4%)
Native American	1 (0.5%)
Other	6 (3%)
Hematologic neoplasm	
Lymphoid [a]	149 (70%)
Myeloid [b]	65 (30%)
HCT	15 (7%)
Allogeneic	3/15 (20%)
Autologous	12/15 (80%)
Anti-HCV positive	3 (1%)
HCV RNA positive	2/3 (67%)
HCV RNA negative	1/3 (33%)
HCV RNA positive	2 (1%)
Anti-HCV positive	2/2 (100%)
Anti-HCV negative	0/2
Seronegative HCV infection [c]	0
HCV genotype	
1b	2/2 (100%)

Data are median (range) or n (%).

HCT=hematopoietic cell transplant; HCV=hepatitis C virus.

[a] Lymphoid neoplasms included the following categories based on the 2016 World Health Organization classification: mature B-cell neoplasms and Hodgkin lymphoma.

[b] Myeloid neoplasms included the following categories based on the 2016 World Health organization: myeloproliferative neoplasms, myelodysplastic/myeloproliferative neoplasms, myelodysplastic syndromes, acute myeloid leukemia, and related neoplasms, and B-lymphoblastic leukemia/lymphoma.

[c] Seronegative HCV infection: negative anti-HCV test, positive HCV RNA test.

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1053. The Ecological Relationship Between County-Level HCV Case Rates and Office-Based Buprenorphine in Ohio.

Daniel L. Brook, BS[1]; Shibani Chettri, MPH[1]; Angela Hetrick, MPH[1]; Adams L. Sibley, MPH[2]; Christine Schalkoff, MSPH[2]; Kathryn Lancaster, MPH, PhD[1]; Vivian Go, PhD[2]; David Kline, PhD[3]; William Miller, MD, PhD, MPH[1]; [1]The Ohio State University, Columbus, Ohio; [2]University of North Carolina at Chapel Hill, Chapel Hill, North Carolina; [3]The Ohio State Univeristy, Columbus, Ohio

Session: P-48. Hepatitis

Background. The United States is experiencing an epidemic of hepatitis C virus (HCV) infections due to injection drug use, especially in rural areas. Counties may be expanding access to buprenorphine, an evidence-based treatment that has been shown to reduce injection drug use, to control the HCV epidemic. We assessed the county-level relationship between HCV rates in 2013-2015 and office-based buprenorphine prescribing in 2018 in Ohio. We also assessed if this relationship varied between rural and urban counties.

Methods. We fit crude and adjusted negative binomial models to assess the relationship between HCV incidence rates in 2013-2015 and office-based buprenorphine prescribing capacity and frequency in Ohio in 2018. We examined effect measure modification of this relationship by rural-urban status using an interaction term.

Results. We found that a 1% higher acute HCV rate was associated with an 18% (95% Confidence Interval [CI]: -3%, 44%) higher office-based buprenorphine prescribing capacity and an 22% (95% CI: -4%, 55%) higher office-based buprenorphine prescribing frequency. We found that a 1% higher total HCV rate was associated with a 239% (95% CI: 179%, 317%) higher office-based buprenorphine prescribing capacity and a 273% (95% CI: 183%, 405%) higher office-based buprenorphine prescribing frequency. We found no evidence of effect measure modification by rural-urban status.

Conclusion. Counties across Ohio may have expanded access to office-based buprenorphine in response to high rates of total HCV. Expansion of office-based buprenorphine may be less associated with acute HCV rates due to the low frequency with which these cases are seen in outpatient settings.

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1054. A Randomized Controlled Trial of Hepatitis B virus (HBV) Revaccination among Men Who Have Sex with Men and Were Born in the Era of Universal Neonatal HBV Immunization

Yi-Chia Huang, n/a[1]; Hsin-Yun Sun, MD[2]; Yu-Chung Chuang, n/a[3]; Sung-Hsi Huang, n/a[4]; Wen-Chun Liu, MS[2]; Yi-Ching Su, MS[2]; Sui-Yuan Chang, PhD[2]; Chien-Ching Hung, PhD[2]; [1]National Taiwan University Hospital Biomedical Park Hospital, Hsinchu County, Hsinchu, Taiwan; [2]National Taiwan University Hospital, Taipei, Taipei, Taiwan; [3]National Taiwan University Hospital and National Taiwan University College of Medicine, Taipei, Taipei, Taiwan; [4]1. Department of Internal Medicine, National Taiwan University Hospital Hsinchu Branch, 2. Department of tropical medicine and parasitology, National Taiwan University College of Medicine, Hsinchu, Hsinchu, Taiwan

Session: P-48. Hepatitis

Background. People who have lost anti-HBs antibody decades after neonatal vaccination but are at high risk of acquiring HBV are recommended to undergo HBV revaccination. The optimal revaccination strategy remains unknown, however. We aimed to compare the efficacy of revaccination with standard- (20-μg) vs double-dose (40-μg) of HBV vaccine among men who have sex with men (MSM).

Methods. MSM aged ≥ 20 years who had undergone HBV vaccination at birth and tested negative for HBsAg and anti-HBc with anti-HBs titer < 10 mIU/ml were randomized to receive standard- or double-dose HBV vaccine (1:1 ratio with a block size of 4) at weeks 0, 4, and 24. Plasma HIV RNA < 50 copies/ml for ≥ 6 months was required for HIV-positive MSM. The primary endpoint was the proportion of participants achieving anti-HBs ≥ 10 mIU/ml at week 28. The secondary endpoints were high-titer response (≥ 100 mIU/ml) at weeks 28 and 48, serological response at week 48, and adverse events (AE).

Results. From Sep 2017 to Jun 2020, 161 HIV-positive and 77 HIV-negative MSM were enrolled. The serological response at week 28 was 86.2% for the standard-dose group and 94.9% for the double-dose group (p=0.070). The proportion of high-titer response was higher for the double-dose group than the standard-dose group at 28 weeks (84.6% vs 70.1%, p=0.041). The respective serological response and high-titer response at week 48 were 81.3% and 58.7% for the standard-dose group vs 94.2% and 78.3% for the double-dose group (p=0.023 and p=0.013, respectively). In generalized estimating equations model, double-dose HBV revaccination (aOR, 1.7; 95% CI, 1.1-2.8) and baseline anti-HBs ≥ 2.5 mIU/ml (aOR, 7.5; 95% CI, 4.3-13.5) were associated with high-titer responses. HIV infection was not associated with serological response (aOR, -1.2; 95%CI, -2.47-1.60) and high-titer response (aOR, -1.1; 95%CI, -1.95-1.49). The double-dose group had a higher rate of local AEs (27.2% vs 38.7%, p=0.118). One (0.8%) severe AE occurred in the double-dose group, which resolved without sequelae.

Table 1. Baseline characteristic of participants

	Standard dose (n=119)	Double dose (n=119)	p-value
Baseline characteristics			
Age, mean (SD)	27.4 (3.1)	27.4 (3.3)	0.881
Anti-HBs titer at baseline, <2.5 mIU/ml, n (%)	76 (36.1)	78 (34.5)	0.786
HIV infection, n (%)	80 (67.2)	81 (68.1)	0.890
Syphilis, n (%)	29 (24.4)	47 (39.5)	0.012
HCV, n (%)	5 (4.2)	10 (8.5)	0.194