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Session: 154. HIV Drug Resistance
Friday, October 6, 2017: 12:30 PM

Background. Integrase Strand Transfer Inhibitor (INSTIs) transmitted resistance has remained uncommon, estimated at 0.04%, with E157Q being the mutation most commonly identified. E157Q is thought to cause low-level resistance to raltegravir and elvitegravir but has also been the only mutation implicated in a recent case of dolutegravir treatment failure. INSTI resistance testing is not currently recommended and little data is available on clinical outcomes on INSTI therapy in the presence of E157Q, therefore we reviewed all the patients in an urban clinic in Detroit with E157Q seen on genotype to determine its clinical impact.

Methods. We reviewed the records of all Wayne State University Adult HIV clinic attendees in Detroit, Michigan who had an INSTI genotype performed between February 2014 and February 2016 to identify those with an E157Q mutation. We reviewed demographics, HIV risk factors, treatment and clinical outcomes.

Results. 292 patients had INSTI resistance testing during our study period. 24 patients (8.2%) had an E157Q mutation. These patients had a median age of 27.5 years. They were predominately male (87.5%), black (87.5%), and MSM (70.8%). Four patients had an additional mutation (N155H, T97S, L74V, and V151I). Eleven patients were treatment-naïve, consistent with transmitted E157Q drug resistance. One treatment-naïve patient had both the E157Q mutation and the T97S mutations. Of the 24 patients with E157Q, 15 were placed on an INSTI-based regimen and 6 (40%) achieved viral suppression at 12 months. 7 patients were lost to follow up at and 2 had stopped treatment at 12 months. Amongst patients adherent to INSTI based ART, there were no cases of treatment failure.

Conclusion. While our sample size was relatively small, our data suggests that E157Q is not an infrequent mutation and patients with E157Q who were started on INSTI based regimens and were adherent achieved viral suppression. This is reassuring for rapid ART start at time of HIV diagnosis with INSTI based ART without genotype data. Loss to follow up and poor adherence were seen frequently, limiting our ability to determine clinical outcomes on ART.

In short, patients with E157Q mutation have good clinical outcomes on INSTI based ART.

Disclosures. All authors: No reported disclosures.

1375. Clinical Outcomes Following the Use of Archived HIV-1 DNA Sequencing to Guide Antiretroviral Therapy Regimen Adjustment and Simplification

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Background. While favorable new antiretroviral therapy (ART) options are available for HIV disease, the Department of Health and Human Services guidelines recommend against switching suppressive regimens unless there is evidence that the new regimen will be fully active. A new assay analyzes archived HIV pro-viral DNA and can detect resistance mutations when HIV RNA is below the limit of detection, when standard genotyping (GT) is not possible. Small studies have correlated archived DNA GT to historical plasma RNA GT, but there is minimal available data on treatment outcomes when using this assay to determine antiretroviral therapy switch strategies. We evaluated clinical outcomes following ART adjustment based upon results of archived DNA GT testing.

Methods. A retrospective review of electronic medical records was performed at our medical center from October 2014 to October 2016. Inclusion criteria included age ≥ 18 years, archived DNA GT result available, ART changed after archived GT result, and follow up HIV RNA available after ART switch. Data was collected prior to and after ART switching. McNemar's test was used for categorical variables and paired t-test for continuous variables.

Results. A total of 38 patients were included. Most patients were male (89%), Caucasian (66%), had a history of AIDS diagnosis (45%), had HIV for >10 years (74%), and had baseline ART resistance (24% resistant to 1 class, 37% resistant to ≥ 2 classes). Median baseline CD4 was 532 cells/mm³. At baseline, 31 (82%) patients had HIV RNA < 50 copies/mL. Compared with baseline, 35 (92%) patients were undetectable at furthest follow up (P = 0.22). Median time to furthest follow up was 146.5 days (range 12–485). Overall, 36 (95%) patients had at least one undetectable HIV RNA after switching. None of the patients with an initial undetectable HIV RNA became detectable after switching ART. Average number of pills per day and administrations per day decreased from 3.84 to 1.97 (P < 0.001) and 1.47 to 1.05 (P < 0.001) respectively. The number of patients on protease inhibitors (PIs) decreased from 66% to 21% (P < 0.001).

Conclusion. The use of archived DNA GT to guide ART adjustment may result in maintained viral suppression while allowing for regimens with optimized long-term safety and decreased pill burden.

Disclosures. All authors: No reported disclosures.

1376. Routinization of HIV & HCV Testing in the Inpatient Setting: Involvement of Residents and Nurses

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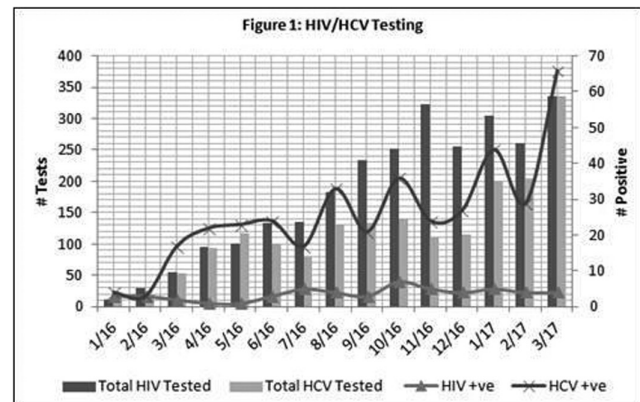
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Background. Approximately 1 in 5 and 1 in 2 of people infected with HIV and HCV respectively in the US are unaware of their infection. Risk based opt-in testing strategies result in missed or delayed diagnoses and may further stigmatize these illnesses. The use of routine opt-out testing increases test uptake and can identify patients with HIV or HCV early, resulting in improved outcomes and decreased transmission. This strategy has not yet been fully accepted or operationalized in many health care settings.

Methods. We implemented routine opt-out HIV and HCV testing for all inpatients using internal medicine resident and nurse driven screening models. Patients were eligible for each test if they had not been tested within 1 year and were not known to be infected. Residents were educated on rationale and protocols for routine opt out testing via one grand rounds lecture (January 2016) and one residency orientation lecture (August 2016). Between March and November 2016, residents were incentivized with gift cards awarded for most tests ordered. Nurses were educated through targeted forums. Instructions were distributed and placed in high traffic areas and HIV 1/2 fourth-generation Ag-Ab and HCV Ab orders were added to admission order sets. Patients were given a chance to decline after routine opt-out testing was offered and educational brochure provided, in accordance with Maryland law. Positive tests were confirmed using Western Blot initially, later changed to HIV 1/2 differentiation assay; HCV was confirmed with HCV RNA. Those with confirmed infection were linked to care.

Results. 71% of 3814 and 83% of 2219 eligible patients were tested for HIV and HCV; 54 (2%) and 390 (21%) were diagnosed with HIV and HCV respectively (Figure 1). Testing activity averaged 32 HIV and 28 HCV tests per month from January to March 2016 and increased after the noted interventions to an average of 300 HIV and 247 HCV tests per month from January to March 2017.

Conclusion. A high disease burden was found within the studied population, highlighting the benefit of routine opt out testing for HIV and HCV. Empowering residents and nurses to offer screening at time of admission is a viable strategy to scale up testing in the inpatient setting.



Disclosures. All authors: No reported disclosures.

1377. Identifying African American Women with HIV Infection in an Expanded HIV testing and Linkage to Care (X-TLC) Program in Healthcare Settings on the South and West Sides of Chicago.

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Background. Women account for 25% of HIV infections nationally, and African American (AA) women are disproportionately affected. We report important gender differences observed in an expanded HIV testing and linkage to care (X-TLC) program conducted on the South and West Sides of Chicago.

Methods. X-TLC is funded by CDPH with CDC prevention B funds. X-TLC has expanded from 3 sites to 14 sites, including acute care hospitals (academic, community), community health centers (CHCs), and family planning clinics. We report descriptive stats, group comparisons by Chi-square, and multivariate analyses adjusted for demographics.

Results. Since 2011, X-TLC has conducted 308,038 HIV screens, and 63.7% of those tested were women. Overall seroprevalence for HIV was 0.56%, and 30.5% of HIV patients identified were cis-gender women (seroprevalence 0.15%). The seroprevalence for women testing in EDs was higher (0.44%). Similar to men, only 52.9% of HIV positive women were new diagnoses. Women accounted for 28.5% of all new diagnoses,

compared with 15.4 % for Chicago overall. In 2016 X-TLC screened 91,865 persons for HIV, and 65.2 % of those tested were women. There were 193 new diagnosis and 32.1 % (62) were women, 85.7 % AA. In comparison, in 2015 there were 139 women with a new HIV diagnosis for all of Chicago. Women newly diagnosed were less likely to be linked to care (adjusted odds ratio, aOR, 0.54, 0.35–0.85). Linkage was lower for women diagnosed at CHCs (84.6 % vs. 76.3 %, $P = 0.02$). Most CHCs did not have on site HIV providers. At our site, however, women linked to care were more likely to be retained in care (aOR 0.58, 0.43–0.78). We also conduct targeted outreach testing, partner services (PS) testing, and social network strategy (SNS) testing, but women are not identified by these programs (16/171 tested women, 8 new diagnoses were men for PS; 507 tested, 471 men and 36 trans-gender women, 38 new positives, 0 cis-gender women for SNS).

Conclusion. More women than men were offered and/or accept HIV screening in healthcare settings. The proportion of seropositive women identified was higher than the national average. X-TLC is reaching a large proportional of AA women with HIV unaware of their status. Other testing strategies will rarely identify cis-gender women with HIV infection. Gender differences in linkage to and retention in care will require strategies targeted at women.

Disclosures. J. P. Ridgway, Gilead FOCUS: Grant Investigator, Grant recipient; N. Glick, Gilead FOCUS: Grant Investigator, Grant recipient; D. Pitrak, Gilead Sciences FOCUS: Grant Investigator, Grant recipient

1378. Making a Big Impact on Expanding HIV Inpatient Testing with a Small EHR Modification

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Friday, October 6, 2017: 12:30 PM

Background. The CDC estimates over 1.2 million Americans are living with HIV and, of those, approximately 14% are unaware of their HIV-positive status. Since 2014, most hospitals adopted some form of Electronic Health Records (EHR) and the Centers for Medicare & Medicaid Services extended Medicare coverage for annual HIV screenings. Despite these developments, there has been limited progress in expanding HIV testing in inpatient settings. The present study was conducted at Jersey City Medical Center (JCMC) in an effort to expand HIV testing by implementing EHR modification in the form of testing prompts.

Methods. This study began on January 1, 2016 at JCMC, a teaching hospital that passed all lab work orders through an EHR system. The number of daily orders for HIV screenings was recorded for 145 consecutive days before EHR modification ($n = 145$) to establish baseline data.

EHR modification occurred on the 146th day of the study (May 25, 2016). This modification featured testing prompts displaying CDC guidelines for screening patients over the age of 18 for HIV whenever a physician ordered lab work for admitted patients. Orders for HIV screenings on this transitional date were excluded from analysis.

After EHR modification was completed, the number of daily orders for HIV screenings was recorded for an additional 145 consecutive days ($n = 145$) for comparison. Testing data was available for all 145 consecutive days before and 145 consecutive days after EHR modification.

Results. Since the beginning of this study—before testing prompts were implemented—JCMC inpatient units ordered an average of 8.53 ($SD=3.25$) HIV screenings per day. The average number of daily orders for HIV screenings increased twofold after EHR modification ($M=17.39$, $SD=4.26$), $t(288) = 19.90$, $P < .001$. JCMC identified 86 HIV-positive and linked over 90% of these patients to care.

Conclusion. Conventional HIV screening methods in the inpatient setting might not be sufficient at detecting most HIV-positive cases. By implementing testing prompts in its EHR system to encourage increased testing for HIV, Jersey City Medical Center was able to increase the number of individuals aware of their HIV status and link them to care as needed.

Disclosures. T. Nguyen, Gilead FOCUS: Employee, Grant recipient

1379. Can an HIVSmart! App-optimized Self-Testing Strategy be Operationalized in Canada?

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Session: 155. HIV Testing

Friday, October 6, 2017: 12:30 PM

Background. Although HIV self-tests are recommended by the WHO, they are not yet approved in Canada. Service delivery gaps such as linkages to counseling and care remain unachieved by offering self-tests without adequate support. In this first Canadian study, we evaluated the feasibility of operationalizing an innovative HIVSmart! app-optimized oral HIV self-testing strategy in men who have sex with men (MSM), presenting at a large sexual health clinic in Montreal.

Methods. Between July 2016 to February 2017, participants were offered the OraQuick In-Home HIV Test, and a tablet installed with the HIVSmart! app, at a private office in the clinic to simulate an unsupervised home environment. With the HIVSmart! app, participants independently performed and interpreted self-tests, and were linked to in-person post-test counseling and care. Self-test results were confirmed by laboratory tests (p24, Western Blot, RNA as needed).

Results. The mean age of the 451 participants was 34 years (18–73); 85% were well educated (beyond high school, $n = 371/438$); 53% (230/438) were frequent testers (past 6 months), and 13% were on PrEP (52/451). 99% (417/422) of participants found the HIVSmart! app helpful in guiding them through the self-testing procedure; 93% (418/451) of participants interpreted their tests accurately; and 94% (395/419) stated they would recommend the app-optimized self-testing strategy to their partners. Feasibility (completion rate of self-testing) was 93% (419/451), and acceptability of the strategy was high at 99% (451/458). All HIV self-test negative participants (448/451, 100%) were counseled following the self-test. Three participants self-tested positive, were confirmed HIV positive (0.7% prevalence), and were rapidly linked to care with a physician.

Conclusion. The HIVSmart! app-optimized strategy was feasible, and highly accepted by an educated, frequently testing, urban MSM population of Montréal. With the app, participants were able to interpret their test results accurately and were rapidly linked to care. Innovations like HIVSmart! which engage, aid, and facilitate linkages to care, can be adapted to suit the needs of many populations in Canada and internationally, maximizing global impact through reverse innovation.

Disclosures. All authors: No reported disclosures.

1380. A Randomized Trial of Bictegravir or Dolutegravir with Emtricitabine and Tenofovir Alafenamide (F/TAF) Followed by Open Label Switch to Bictegravir/F/TAF Fixed Dose Combination

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Session: 156. HIV: Antiretroviral Therapy

Friday, October 6, 2017: 12:30 PM

Background. Integrase strand transfer inhibitors (INSTIs) are widely recommended for initial HIV-1 treatment. Bictegravir (BIC, B) is a novel, once-daily INSTI with potent antiviral activity being developed in coformulation with emtricitabine and tenofovir alafenamide (F/TAF).

Methods. In this Phase 2 study, treatment naïve, HIV-infected adults were randomized 2:1 to receive blinded treatment with BIC or dolutegravir (DTG) coadministered with open label F/TAF (200/25 mg). After all participants completed 48 weeks, they were unblinded and switched to a single fixed-dose combination tablet of B/F/TAF 50/200/25 mg. The proportion of participants with HIV-1 RNA <50 copies/mL (c/mL) was assessed at Week (W) 24 and W48 of the blinded phase and 12 weeks after switching to open label B/F/TAF (W72).

Results. Of 98 participants enrolled in the blinded treatment phase, 65 were randomized to BIC+F/TAF and 33 to DTG+F/TAF. Most were male, had asymptomatic HIV infection, with median HIV-1 RNA 4.4–4.5 log₁₀ c/mL. The proportion of subjects with HIV-1 RNA <50 c/mL at W24 was 97% for the BIC arm and 94% for the DTG arm, and at W48 was 97% and 91%, respectively (Table). All 92 participants who completed the blinded phase were switched to B/F/TAF at W60. At W72 or 12 weeks after switching to open-label B/F/TAF, 99% (91/92) maintained HIV-1 RNA <50 c/mL (98% prior BIC arm [$N = 62$]; 100% prior DTG arm [$N = 30$]) and one individual withdrew prior to the analysis. No viral resistance was detected in participants treated with BIC. No participants discontinued open label B/F/TAF due to an adverse event, there were no treatment-related serious adverse events and no deaths. One individual on BIC previously discontinued due to an adverse event of urticaria following the W24 visit.

Conclusion. All participants switched from DTG+F/TAF to open-label B/F/TAF maintained virologic suppression, with none discontinuing due to adverse events. During 72 weeks of follow-up, no treatment-emergent resistance to any components was detected in participants taking B/F/TAF. B/F/TAF demonstrated durable virologic suppression in naïve patients through W72 and was safe and effective after switching from DTG + F/TAF; further study in treatment naïve and experienced populations is warranted.

Table.

N (%)	Week 24 ^a		Week 48 ^b		Week 72	
	BIC + F/TAF (n=65)	DTG + F/TAF (n=33)	BIC + F/TAF (n=65)	DTG + F/TAF (n=33)	B/F/TAF from BIC + F/TAF (n=62)	B/F/TAF from DTG + F/TAF (n=30)
HIV-1 RNA < 50 copies/mL	63 (97)	31 (94)	63 (97)	30 (91)	61 (98)	30 (100)
HIV-1 RNA ≥ 50 copies/mL	2 (3)	2 (6)	1 (2)	2 (6)	0	0
HIV-1 RNA ≥ 50 copies/mL in the analysis window	1 (2)	1 (3)	0	1 (3)	0	0
Discontinued study drug due to lack of efficacy	0	0	0	0	0	0
Discontinued study drug due to other reason ^c and last HIV-1 RNA ≥ 50 copies/mL	1 (2)	1 (3)	1 (2)	1 (3)	0	0
No virologic data in the analysis window	0	0	1 (2)	1 (3)	1 (2)	0

a Difference in percentages (BIC+F/TAF vs DTG+F/TAF) at Week 24: 2.9% (-8.5% to 14.2%); $p=0.50$

b Difference in percentages (BIC+F/TAF vs DTG+F/TAF) at Week 48: 6.4% (-6.0% to 18.8%); $p=0.17$

c Other reasons include subjects who discontinued study drug due to investigator's discretion, withdraw consent, lost to follow-up, noncompliance with study drug, protocol violation, pregnancy, and study termination by sponsor.