Session: 148. HIV: General Epidemiology
Friday, October 4, 2019: 12:15 PM

Background. While Germany has a long tradition in HIV research with many well-established regional cohorts, there was a lack of collaborative efforts toward harmonized data collection and biobanking, both key strategies for efficient translational research projects. Key challenges are heterogeneity of data systems and privacy concepts, of existing study and data collection protocols, and sample collection, storage, and sharing.

Methods. In 2013, we established the Translational Platform HIV (TP-HIV) with support of the German Centre for Infection Research (DZIF) as a collaboration between university hospitals and specialized HIV care centers throughout Germany. After assessing the individual needs of all partner sites, we have taken comprehensive action to create a common platform for collaboration in all research stages. We developed protocols, rules of operation, biobanking strategies, and privacy concepts for all collaborating partner sites. Patients infected with HIV (PLWH) who sign the informed consent for the TP-HIV are pro- and retrospectively included in the cohort.

Results. To date, the TP-HIV infrastructure is implemented at 27 member sites from 11 cities, potentially extending to more than 20,000 patients currently treated for HIV across Germany. Facing the special needs in the German research environment, the TP-HIV established a unique data- and biomaterial collection allowing expedited translational research and reduce project overheads, regulatory burden, and data security regulations for investigators. By active surveillance, rapid access to individual patient groups such as patients with acute HIV infection, TP-HIV is an ideal platform for early phase clinical trials with new drug candidates. Researchers with clinical, biological, epidemiological, and statistical expertise have been brought together within the TP-HIV, which enables an effective translational chain from bench to bedside and back. New collaborations have been established with currently 23 active study protocols.

Conclusion. The TP-HIV has demonstrated to be a powerful tool for generating and testing research hypotheses in PLWH. In the future, we will work to further expand our network and address the pressing needs in the German research environment.

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1270. Population-Based Estimates of PrEP Access in Oregon, 2012–2016

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Session: 149. HIV: Prevention
Friday, October 4, 2019: 12:15 PM

Background. PrEP is an important HIV prevention modality. Population-based metrics of PrEP uptake and access are critical to the evaluation of public health efforts to increase PrEP use.

Methods. Using the Oregon All Payers All Claims administrative dataset, we determined the number of unique individuals at least 16 years of age starting PrEP, defined as at least one prescription of >30 days of Truvada, each year from 2012–2016. People with HIV or hepatitis B were excluded. We created two metrics of PrEP access in 2016: the number of individuals starting PrEP per 100K population and the number of individuals with a PrEP prescription in each of the four quarters of 2016 per 100K population (i.e., prevalent users). Using public health surveillance data, we created three metrics of PrEP need in 2016: the number of HIV diagnoses per 100K population; the number early syphilis and gonorrhea diagnoses per 100K population; and the number of acute or chronic hepatitis C diagnoses among patients aged 16–30 years per 100K population. We calculated six metrics of PrEP access-to-need by dividing each of the access measures by the need measures.

Results. The number of individuals with a new PrEP prescription increased from 8 in 2012 to 571 in 2016. Most new PrEP users were men, aged 25–34 years, identified as white, lived in an urban area, had commercial insurance, and had an internal medicine PrEP prescriber. In 2016, there were 17.2 PrEP starts and 9.9 individuals with a PrEP prescription in all four quarters of 2016 per 100K population. There were 6.7 HIV cases, 136.0 early syphilis and gonorrhea cases, and 109.1 acute and chronic hepatitis C cases per 100K population. Per HIV diagnosis, there were 2.6 PrEP starts and 1.5 prevalent users. However, there were 0.13 PrEP starts and 0.07 prevalent users per early syphilis and gonorrhea diagnosis and 0.16 PrEP starts and 0.09 prevalent users per hepatitis C diagnosis. Women, people aged 16–24, people of color, and people in rural areas experienced lower PrEP access-to-need.

Conclusion. Access metrics based on prevalent users (a measure of longer-term adherence to PrEP), STI diagnoses (a measure of HIV acquisition risk), and HCV diagnoses among those less than 30 years of age (a measure of need among people who inject drugs) may provide a more complete assessment of PrEP access-to-need than those based on PrEP starts and HIV diagnoses.

Figure. Number of PrEP starts per year, Oregon, 2011-2016.

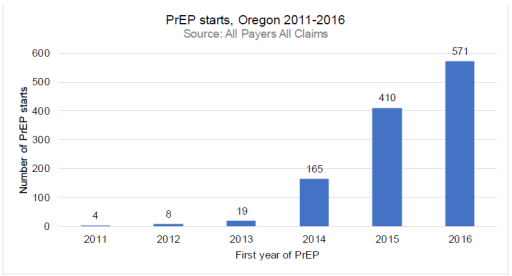

Table. PrEP access to PrEP need by selected characteristics, Oregon, 2016.

	PrEP starts per HIV diagnosis	PrEP starts per STI diagnosis	PrEP starts per HCV diagnosis[a]	Prevalent users per HIV diagnosis	Prevalent users per STI diagnosis	Prevalent users per HCV diagnosis[a]
Overall	2.6	0.13	0.16	1.5	0.07	0.09
Sex/gender						
Men	2.7	0.18	0.28	1.6	0.11	0.17
Women	1.4	0.02	0.02	0.4	0.01	0.01
Age						
16-24	2.1	0.05		0.7	0.02	
25-34	3.4	0.14		1.6	0.06	
35-44	2.3	0.17		1.6	0.11	
45-54	2.2	0.23		1.8	0.19	
55+	1.8	0.25		1.3	0.18	
Race/ethnicity[b]						
Hispanic, any race	0.3	0.02	0.12	0.1	0.01	0.03
Non-Hispanic white	0.8	0.04	0.05	0.6	0.03	0.04
Non-Hispanic black	0.7	0.02	0.27	0.3	0.01	0.11
American Indian/Alaskan Native	0.5	0.03	0.05	0	0	0
Asian	0.6	0.06	0.16	0.2	0.02	0.06
Native Hawaiian/Pacific Islander	0	0	0	0	0	0
Region						
Portland metro area	3.5	0.17	0.33	2.1	0.10	0.19
Balance of state	1.2	0.06	0.05	0.6	0.03	0.03

PrEP, pre-exposure prophylaxis; HCV, hepatitis C virus; STI, sexually transmitted infection (includes early syphilis and gonorrhea).

[a]Among people aged 16-30 years.

[b]Based on 27% of sample with complete race/ethnicity data.

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1271. Pre-Exposure Prophylaxis (PrEP) Awareness and Uptake Between Men Who Have Sex with Men and Men Who Have Sex with Men and Women

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Session: 149. HIV: Prevention
Friday, October 4, 2019: 12:15 PM

Background. Men who have sex with men are disproportionately impacted by HIV in the United States and may benefit most from pre-exposure prophylaxis (PrEP). However, differences may exist between men who only have sex with men (MSM) and men who have sex with both men and women (MSMW). MSMW may experience more barriers to accessing PrEP and may act as a potential bridge population for transmitting HIV to female sex partners. Differences in PrEP awareness and use between MSM and MSMW are unknown.

Methods. We evaluated all MSM and MSMW presenting to the Rhode Island Sexually Transmitted Diseases (STD) clinic and PrEP clinic from 2013–2017. Demographics and behavioral information were reviewed. Bivariate analyses were performed to present distributions of demographic and behavioral characteristics by sexual behavior. Logistic regression was conducted to explore associations between PrEP awareness/use and sexual behavior. Confounding variables were identified using the directed acyclic graphs (DAGs) and *a priori*.

Results. Of 1,795 male individuals, 84% (1,504) were MSM, and 16% (291) were MSMW. The median age of our study population was 29 (interquartile range [IQR]: 23–42). When compared with MSM, MSMW were more likely to be non-White (33% vs. 28%), uninsured (54% vs.46%), self-report more sexual partners in the past 12 months (median 6 [IQR: 3–9]: vs. 4 [IQR:2–10]), use intranasal cocaine (21% vs. 12%), and engage in selling (6% vs. 2%) or buying sex (12% vs. 4%, all $P < 0.05$). MSMW were also less likely to have a previous HIV test (77% vs. 89%) compared with MSM. MSMW were 59% (adjusted odds ratio [aOR]: 041, 95% confidence interval [CI]: 0.31–0.55) less likely to be aware of PrEP and 17% (aOR: 0.83, 95% CI: 0.41–1.66) less likely to report ever using PrEP after adjusting for age, race/ethnicity, and self-reported HIV risk.

Conclusion. Despite engaging in higher risk behaviors, MSMW were significantly less likely to be aware of or use PrEP compared with MSM. Future PrEP interventions are needed to target this potentially high-risk bridge population.

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1272. Feasibility and Successful Enrollment in Proof-of-Concept Trials to Assess Safety and Efficacy of a Broadly Neutralizing Monoclonal Antibody, VRC01, to Prevent HIV-1 Acquisitionin in Uninfected Individuals

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Session: 149. HIV: Prevention
Friday, October 4, 2019: 12:15 PM

Background. The Antibody-mediated Prevention (AMP) trials (HVTN 704/HPTN 085 and HVTN 703/HPTN 081) are the first efficacy trials to evaluate whether VRC01, a broadly neutralizing antibody (bnAb) that targets CD4 binding site of HIV envelope, prevents HIV acquisition in uninfected individuals. In these ongoing trials, 10 intravenous (IV) infusions of VRC01 are given every 8 weeks over a period of 2 years. We report on interim operational feasibility, enrollment and safety.

Methods. Participant recruitment was enhanced by extensive community engagement and education. Eligible participants were randomly assigned 1:1:1 to 10mg/kg, 30mg/kg of VRC01 or saline placebo. HVTN 704/HPTN 085 enrolled high-risk men (MSM) and transgender (TG) individuals who have sex with men at 26 sites in United States, Peru, Brazil, and Switzerland. HVTN 703/HPTN 081 enrolled high-risk heterosexual women at 20 sites in Botswana, Kenya, Malawi, Mozambique, South Africa, Tanzania, and Zimbabwe. HIV testing occurs monthly.

Results. In October 2018, the AMP trials completed enrollment of 4,625 participants. Enrollment met or exceeded targets throughout the trial period, peaked at 298 participants/month, and was slowed mid-trial to allow for sufficient drug supply at trial sites. In HVTN 704/HPTN 085, 2701 (target $N = 2700$) MSM/TG participants 18–50yrs were enrolled with median age of 28; 99% born male; 90% identified as male gender and 5% TG female. Race/ethnicity was 32% White, 15% Black and 57% Hispanic/Latino/a. 28% had a sexually transmitted infection (STI) including gonorrhea (GC), chlamydia (CT) or syphilis at enrollment. In HVTN 703/HPTN 081,1924 (target $N = 1900$) women 18–40yrs were enrolled with median age of 26;100% were born female (53% female gender, 47% gender not assessed); 99% were Black. 26% had a STI at enrollment including GC, CT, trichomonas or syphilis. Overall 36,945 infusions have been given so far with no serious procedural complications due to IV administration. Retention and adherence to the rigorous study schedule (monthly visits for 2 years) remain within an acceptable range.

Conclusion. The AMP trials have exceeded enrollment of target populations and are maintaining high rates of retention. With exceptional safety and operational feasibility, they are paving the way for future large-scale bnAb trials for HIV prevention and/or treatment.

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1273. Reasons for Disengagement in Care among Individuals Receiving Pre-Exposure Prophylaxis (PrEP) from a Sexual Health Clinic

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Session: 149. HIV: Prevention
Friday, October 4, 2019: 12:15 PM

Background. Pre-exposure prophylaxis (PrEP) effectively reduces HIV acquisition, but its efficacy depends on continued engagement through periods of high and low risk. Persistence in HIV prevention care has been low in real-world settings. In our program, 32% of patients are lost to care after their first visit and only 35% of patients are retained at their planned third visit. Reasons for low persistence in care are poorly described.

Methods. We identified all MSM who started PrEP between July 2015 and June 2018 at a sexual health clinic in an urban academic medical center in New York and had not had a visit in ≥6 months. We called patients between July 2018 and January 2019; those who were English speaking were given the option to complete an online questionnaire about current PrEP status, reasons for disengagement, and social and behavioral determinants of health (SBDH).

Results. Up to 710 patients were eligible for the study; over 700 calls were made. 125 participants agreed to participate and 57 (46%) completed the questionnaire. 24 patients (42%) were still actively taking PrEP. The most common reasons for starting PrEP were fear of getting HIV (58%), high self-perceived HIV risk (28%), and recommendations from friends (26%). Among those no longer taking PrEP, the most common reasons for discontinuation were cost/insurance issues (32%), lower perceived HIV risk (18%), concern about long-term side effects (12%), and trouble attending every-3-month appointments (12%). For those stopping due to lower perceived risk, 40% were in a monogamous relationship, 60% were less sexually active, and 20% always used a condom or did not engage in receptive anal intercourse. 56% of patients had at least 1 major life event in the preceding 3 months, including loss of a job (25%), breakup with a partner (12%), illness or death of a family member (11%), or unstable housing (8%). 47% used drugs or alcohol before sex in the past month including 39% not on PrEP.

Conclusion. Reasons for engagement, disengagement, and re-engagement are highly variable at the individual level. Cost and insurance issues were common in spite if clinic resources available to cover the cost of visits and medications. Life trauma was common. Individualized interventions to address SBDH may be required to engage and retain individuals in HIV prevention care.

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1274. The PrEP Care Continuum Among an Uninsured Patient Population

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Session: 149. HIV: Prevention
Friday, October 4, 2019: 12:15 PM

Background. Despite the clear preventive benefits of HIV Pre-Exposure Prophylaxis (PrEP), uptake among populations at highest risk of HIV acquisition has been limited by lack of health insurance and access to care. In March 2018 we opened a free PrEP clinic for those without insurance. We provide HIV prevention services, following the CDC guidelines, with PrEP case manager navigation, medical management, and medication for at-risk individuals free of charge.

Methods. Half-day clinics were organized on a twice-monthly basis with supervision provided by two infectious disease specialists and several other licensed providers/fellows, with supporting case managers and medical assistants. Medical students were enlisted to help organize and manage patient visits. All patient visits were preceded by discussion with case managers to document insurance status, followed by a sexual history and general physical examination by medical students and supervisory licensed providers. We performed all laboratory testing, diagnostics, and follow-up visits per CDC guidelines.

Results. From March 2018 to 2019, 193 self-identified at-risk patients scheduled an appointment; 157 unique patients were seen and all deemed eligible for PrEP per CDC guidelines. Of those eligible for PrEP, 140 (89%) received a prescription and started emtricitabine/tenofovir and 115 (73%) remain in care with ≥2 visits completed. Of the 25 no longer in care at our clinic, 6 have insurance or Medicaid (2 continue to be seen in our insured PrEP Clinic), 1 reports no HIV risk factors, and 1 is over-income for pharmacy patient assistance. Patients enrolled in clinic are largely male (145, 92%); 74% age ≤ 34, a disproportionate fraction belonging to a minority racial/ethnic group (67, 43%), with a majority Latinx (60, 38%). A total of 48 STI cases were identified, mostly rectal chlamydia, rectal and pharyngeal gonorrhea 39 (81%), and 9 (19%) cases of syphilis, and no new HIV or HCV infections. At the first visit, 17% of our patients have an STI and at subsequent visits 22% have a new STI.

Conclusion. Implementation of a free PrEP clinic for uninsured patients is a feasible and effective strategy to reach key populations at risk for HIV. STI rates are high in our population and increased after starting PrEP.