PrEP Usage Demographics Among Participants Who Were Surveyed Using Convenience Sampling at Two LGBTQ Focused Events in Pittsburgh

by

Rajeev Kishore Salunke

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This thesis was presented

by

Rajeev Kishore Salunke

It was defended on

April 13, 2020

and approved by

Committee Chair: Mackey R. Friedman, PhD, MPH, Assistant Professor, Department of Infectious Diseases and Microbiology, Graduate School of Public Health, University of Pittsburgh

Linda R Frank, PhD, MSN, CS, ACRN, FAAN, Professor, Department of Infectious Diseases and Microbiology, Graduate School of Public Health, University of Pittsburgh

Mary E Hawk, DrPH, Associate Professor, Department of Behavioral and Community Health Sciences, Graduate School of Public Health, University of Pittsburgh

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Abstract

Introduction

PrEP is defined as daily medicine taken by at-risk individuals to prevent HIV. Although an increasing number of individuals are using PrEP, more studies are needed to accurately assess the distribution of PrEP use in different populations.

Existing data suggests that PrEP usage remains low in communities that need it the most. Black and Hispanic MSM are significantly less likely to use PrEP compared to White MSM.

Objectives

This study hypothesizes that:

- i) African-Americans have lower odds of reporting past/present PrEP use compared to white individuals.
- ii) Latino/Hispanic individuals have lower odds of reporting past/present PrEP use compared to white individuals.
- iii) Individuals in the 26-35-year age-group have higher odds of reporting past/present PrEP use compared to individuals in the 18-25-year age-group.
- iv) MSM individuals have higher odds of reporting past/present PrEP use than non-MSM individuals.

Methods

Anonymous, multiple-choice questionnaires were administered at the Allies for Health+Wellbeing Booth during both events. A total of 267 individuals were surveyed.

IRB approval was not obtained prior to data collection but post hoc IRB permission to publish the data was obtained.

Results

Out of the 263 individuals included in the study, 34(12.9%) individuals were past/present PrEP users. Individuals in the 26-35-year age-group were significantly more likely to report past/present PrEP use compared to 18-25-year-olds. African-Americans were significantly more likely to report past/present PrEP use compared to White individuals. Native-Americans were significantly more likely to report past/present PrEP use compared to White individuals. Being an MSM was significantly associated with past/present PrEP usage (compared to non-MSM).

Conclusion

The public health significance of this study is that it provides a snapshot of past/present PrEP usage in the surveyed population. A PrEP to Need ratio (PnR) can be calculated with the help of this data and can be used to assess PrEP usage over time. This data can then be used as a basis to carry out more research to develop interventions to increase PrEP use in populations who are at a high risk of HIV acquisition with low rates of PrEP use. More demographic data is needed from future studies to accurately assess PrEP use.

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Preface

I would like to thank Allies for Health + Wellbeing and Ashleigh Garcia for giving me the opportunity to carry out my survey at the Allies for Health + Wellbeing booth at the Pittsburgh Pride 2019 and the Too Hot for July events. I would also like to thank Braeden Bash and Jill Maraden for their support.

I would also like to thank my committee members Dr. Frank, Dr. Friedman and Dr. Hawk for their unwavering support and encouragement throughout the course of my MPH degree. Their help, support and feedback gave me direction and helped me get this far.

1.0 HIV in the United States

Awareness about HIV/AIDS started to spread in the USA after reports of multiple cases of Kaposi's sarcoma and Pneumocystis Carinii Pneumonia in the early 1980s. By 1984, the viral origin of HIV had been established. Similar cases were also increasingly documented in other parts of the world ¹. At the end of 1990, the United States had between 628,000 to 988,000 PLWH ². Today, around 1.1 million PLWH are in the Unites States³. The number of new HIV cases diagnosed in the United States in 2017 was 38,739 4. Although the number of new cases per year has remained relatively constant since 2012 ⁴, new HIV diagnoses affect various subpopulations at different rates. The highest number of new HIV cases are seen in Black, male to male sexual contact cases. The lowest number of new HIV cases in 2017 was seen in White heterosexual women(see Figure 1 below) 4. When looking at HIV incidence data by age group, the 25-29-year age group had the highest incidence of HIV followed by the 20-24, 30-34, 35-39, 40-44, 45-49, 50-54, 55-59, 15-19, 60-64 and \geq 65-year groups in decreasing magnitudes respectively 5. While examining HIV incidence by gender the incidence in males is 4 times higher than in females⁵. The distribution of HIV incidence by race shows us that African Americans have the highest incidence of HIV followed by Hispanic/Latino, mixed races, Native Hawaiian/Pacific Islander, Native American/Alaska Native, White and Asian in decreasing order respectively ⁵ (Table 1 highlights this data in more detail).

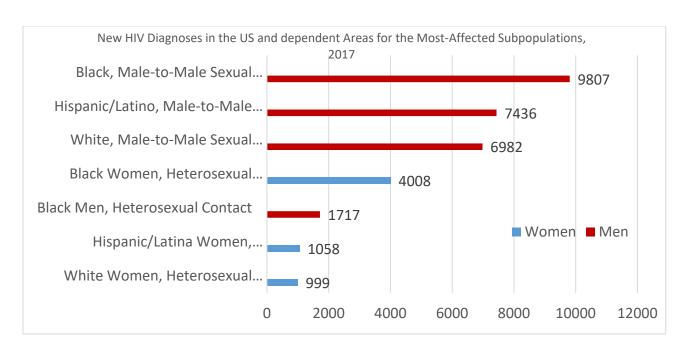


Figure 1 New HIV diagnoses in different subpopulations 2017

This figure shows the incidence of HIV in different subpopulations. The Black MSM subpopulation had the highest number of new HIV diagnoses followed by the Hispanic/Latino MSM subpopulation.⁴

Table 1 Incidence of HIV by age and race

	201	12	201	13	20:	14	20	15	20	16	2017	1
	No.	Rate										
Age at diagnosis (yr)												
<13	241	0.5	184	0.3	180	0.3	140	0.3	130	0.2	99	0.2
13-14	50	0.6	43	0.5	32	0.4	25	0.3	25	0.3	25	0.3
15-19	1919	9.0	1687	8.0	1727	8.2	1740	8.2	1700	8.0	1711	8.1
20-24	7174	31.8	7054	30.9	7370	32.2	7276	32.1	6868	30.7	6354	26.7
25-29	6459	30.2	6653	30.8	7187	32.7	7596	33.9	7930	34.6	7691	32.9
30-34	5458	26.1	5202	24.4	5451	25.3	5457	25.2	5662	25.9	5614	25.6
35-39	4161	21.3	3964	20.2	4241	21.3	4263	21.0	4224	20.3	4315	20.3
40-44	4448	21.1	3925	18.8	3793	18.4	3417	16.9	3264	16.5	2995	15.2
45-49	4290	19.8	3923	18.5	3610	17.3	3325	16.0	3098	14.8	2964	14.1
50-54	3187	14.1	2968	13.1	2899	12.9	3000	13.5	2879	13.2	2677	12.5
55-59	1924	9.3	2010	9.5	1933	9.0	1874	8.6	1886	8.6	1886	8.6
60-64	1049	5.9	1066	5.9	973	5.2	999	5.2	1078	5.5	1086	5.4
≥65	820	1.9	860	1.9	831	1.8	852	1.8	845	1.7	864	1.7
Race/ethnicity												
American Indian/Alaska Native	172	7.4	147	6.3	182	7.7	189	8.0	230	9.6	212	8.8
Asian	797	5.1	792	4.9	923	5.5	941	5.4	972	5.4	942	5.1
Black/African American	18196	46.9	17326	44.3	17533	44.4	17453	43.7	17269	42.9	16690	41.1
Hispanic/Latino	9196	17.3	8986	16.6	9549	17.3	9643	17.1	9831	17.0	9461	16.1
Native Hawaiian/ Other Pacific Islander	51	9.8	47	8.8	44	8.1	74	13.3	41	7.2	57	9.9
White	11041	5.6	10621	5.4	10581	5.3	10403	5.3	10117	5.1	10048	5.1
Multiple Races	1727	28.8	1620	26.2	1415	22.2	1261	19.2	1129	16.7	871	12.6

Diagnoses of HIV infection by year of diagnosis and selected characteristics, 2012-2017 – United States. ⁵

1.1.1 The HIV landscape of Allegheny County and Pennsylvania

There were 36,086 individuals living with HIV (PLWH) in Pennsylvania at the end of 2018²². As of December 2018, there were 26,188 male and 9,898 female PLWH in the state²². An estimated 17,723 African American, 11,049 White, 5,632 Hispanic, 1,296 multiracial, 337

Asian/Pacific and 49 Native American PLWH were present in Pennsylvania at the end of 2018 ²². While splitting the data by age group, Pennsylvania had 549, 1,672, 10,582, 11,558, 7,853, and 3,872 PLWH in the age groups of <13, 13-19, 20-29, 30-39, 40-49 and over 49 respectively, at the end of 2018²². There were 14,112 PLWH who self-identified as Men who have sex with men in Pennsylvania at the end of 2018²².

The rate of new HIV diagnosis in Pennsylvania in 2017 was 8.4 per 100,000 population²². The highest rate by county was 31.2 per 100,000 population (Philadelphia County)²². Most of the individuals diagnosed with HIV in 2017 were from Philadelphia and Allegheny Counties²². There were an estimated 2,965 PLWH at the end of 2018 in Allegheny County²². The rate of new HIV infections for 2018 in Allegheny County is 7.4 per 100,000 population²², which is below the state average of 8.4 (the rate has decreased compared to 2016, where the rate was 10.8 per 100,000 population)²². There were 85 new HIV cases and 28 new AIDS cases in Allegheny County in 2018²³.

Between 2009 and 2017, the annual number of reported new HIV infections in Allegheny County were between 100 and 142 ²⁴. In 2017, the majority (around 80%) of new HIV infections occurred in males, and the most common age group affected was 20-29 years ²⁴. African American males had a higher incidence rate (44.4 per 100,000 population) of HIV infection as compared to white males (8 per 100,000 population) ²⁴. In women, 70% of new HIV infections were in African American women (14 out of 20 new infections in 2017) ²⁴. In 2017, around 61% of new HIV infections occurred in men who have sex with men ²⁴.

There were 26 newly diagnosed AIDS cases in Allegheny County in 2017 ²⁴. Eighty one percent (21 out of 26) of the newly diagnosed individuals were male, half (13 out of 26) of the new AIDS cases were in whites and 42% (11 out of 26) were in African Americans ²⁴.

1.2 PrEP

Pre-Exposure Prophylaxis (PrEP) for HIV is medication intended to be taken by HIV negative individuals to prevent the acquisition of HIV ⁶. PrEP use has been predicted to reduce the sexual transmission of HIV by 99% when used daily ⁶. When taken consistently, PrEP has also been shown to reduce the risk of HIV transmission by 74% in individuals who inject drugs ⁶. On July 12th, 2012 the Food and Drug Administration (FDA) approved Truvada as pre-exposure prophylaxis for HIV ⁷. As of now, Truvada and Descovy (approved in October 2019) are the only FDA approved drugs for PrEP. According to the CDC, PrEP is recommended for:

- i) Serodiscordant couples⁶
- ii) Individuals not in mutually monogamous relationships with someone who recently tested negative for HIV 6.
- iii) Gay/bisexual men who have had condomless anal sex in the past 6 months 6.
- iv) Gay/bisexual men who have been diagnosed with a sexually transmitted infection in the past 6 months ⁶.
- v) Heterosexual males who report inconsistent condom use with partners of unknown HIV status ⁶..
- vi) Individuals at a substantial risk of HIV infection (individuals who inject drugs or women with bisexual male partners)⁶.
- vii) . PrEP is also recommended for people who have injected drugs in the past 6 months and have shared needles or have been in drug treatment in the past 6 months ⁶.

Since it has been proven to be extremely effective when taken daily, it is important to make PrEP and other HIV prevention modalities easily accessible to populations at the highest risk

of HIV acquisition (Black MSM, MSM). PrEP should always be used with a condom as it does not offer any protection against other sexually transmitted infections such as chlamydia and gonorrhea ⁶.

1.2.1 Barriers and Facilitators of PrEP

Barriers

PrEP has an effectiveness of 99% when taken daily ⁶. This makes it an indispensable tool in preventing HIV. The uptake, adherence and use of PrEP unfortunately, is rife with barriers. Barriers of PrEP uptake and use can be subdivided into two types, structural barriers and individual barriers ⁸.

Some of the structural barriers to PrEP uptake include lack of access to PrEP, stigma surrounding PrEP, the cost of PrEP and lack of provider knowledge or prescribing providers. PrEP is only available by prescription; only certified clinicians can prescribe PrEP. Even after PrEP use has been initiated, regular clinician access is required for periodic blood testing (HIV testing and kidney function test) and follow up. Therefore, lack of access to a provider can impede PrEP use. Telemedicine can overcome these barriers by bringing PrEP to the people. The availability of online PrEP (NuRX, Plushcare) and TelePrEP has the potential to improve PrEP uptake using telemedicine, thus putting more people in touch with PrEP providers.

Stigma is another important barrier to consider. Often, PrEP users experience stigma from members of the society and even some healthcare providers. Stigma is usually experienced from healthcare providers and members of the society⁸. According to a study done by Jaiswal et al, stigma experienced from healthcare providers pertained mainly to concerns about talking to a doctor about their sex life. Stigma experienced from members of the society came from concerns

of being perceived as HIV positive by others and having to explain their use of PrEP to others (family, romantic and sexual partners, and religious communities). Stigma is divided into experienced and anticipated stigma ⁸. Anticipated stigma from family, romantic and sexual partners, and religious communities negatively affects PrEP uptake and use⁸. Stigma of associating PrEP with HIV and having multiple sexual partners also played a role in negatively affecting PrEP use.

The cost of PrEP is another barrier to consider. For the uninsured, PrEP costs 1844.75 dollars for a 30-day supply^{10,26} (for both Truvada and Descovy). This puts it out for reach for many subpopulations, particularly those that are at high risk for HIV acquisition¹⁰. Medication assistance programs can be used by uninsured individuals who lack prescription drug coverage to get PrEP for free ⁴⁸.Although PrEP is covered by most insurance plans and state-funded Medicaid schemes, the cost follow up bloodwork is not. Paying for follow up tests poses yet another barrier to continued PrEP use⁴⁹.

The dearth of prescribing providers has led to a barrier to PrEP prescriptions. A lack of clear guidelines on who should prescribe PrEP has also led to confusion between primary care providers and HIV specialists, thus leading to more barriers to PrEP uptake ⁸.

Some individual barriers to PrEP use are side effects of the drug, lack of PrEP awareness, lack of one's risk perception and concerns about events/situations that might occur while taking PrEP ^{8,11}.

The adverse effects encountered while taking PrEP deter some from taking or sticking to PrEP⁸. According to a study done by Holloway et al. that used an online survey to gather data on PrEP uptake, adherence and discontinuation among 761 young MSM in California form July 2015 to August 2015, 21 individuals discontinued PrEP. The top reasons for PrEP discontinuation

included being concerned about long term consequences of PrEP use (33.3%), being unable to afford a prescription for PrEP (28.6%), using other strategies to reduce HIV risk (23.8%), forgetting to take PrEP everyday (23.8%) and being unable to afford the required medical visits for PrEP (19%)³⁹. The top reason that deterred individuals from using PrEP was concern about side effects.

Glidden et al studied the symptoms, side effects and adherence in PrEP users during the first 3 months of the iPrEX Open label extension (OLE) study (an 18-month open label, multi-site PrEP cohort taking daily PrEP). Out of 1092 participants that were studied for side effects of PrEP, there were 56 (5%) interruptions in PrEP dispensations. PrEP discontinuation was temporary in 22 participants and permanent in 34. The most common adverse effects reported to cause discontinuation of PrEP were nausea/abdominal pain, diarrhea, skin problems/itching, headache and flatulence ⁴⁵.

Golub et al. studied the effect of barriers and facilitators of PrEP acceptability and PrEP adherence motivation. The study was carried out among MSM and transgender women divided into 2 groups- those willing and those unwilling to take PrEP. The participants were then given a list of PrEP use barriers to rate according to importance. The study stated that concerns about the long-term effects of PrEP on health and concerns about side effects were rated as most important by both groups¹¹. A greater percentage of those who were unwilling to take PrEP deemed the barriers as important¹¹. Expectations to indulge in anal sex, HIV medications not working if one becomes HIV positive and having to explain their PrEP use to others were also some other barriers that were important (a greater percentage of those who were unwilling to take PrEP deemed these barriers as important)¹¹.

There are also some logistical barriers to PrEP use. Regularly seeing a provider and getting a blood test (HIV testing and Kidney Function test) every 3 months, makes PrEP unappealing to some.

Taking a pill every day is also cumbersome enough for some individuals to not consider PrEP to prevent HIV.

Facilitators

There are few factors that enhance overall PrEP usage especially among sexual minority men (gay, bisexual men and other MSM) and transgender women^{8,11}. Sexual health counseling, high risk perception, increased pleasure associated with condomless sex, not having to pay for PrEP and access to free sexual health care/monitoring while on PrEP are some of the facilitators to PrEP use^{8,11}.

When part of support for the use of PrEP, counseling about sexual health was found to promote PrEP use. It has been noted that men who have sex with men are more willing to use PrEP when offered in conjunction with one on one counselling⁸. Viewing oneself as an individual with a high risk of HIV acquisition increases the odds of using PrEP¹¹. The desire to engage in condomless sex makes individuals seek out alternate HIV prevention modalities like PrEP or PEP, which increases an individual's willingness to use PrEP¹¹. Being part of an insurance plan that provides PrEP for free is a huge incentive for high risk individuals to use PrEP. Additional care provided, such as treatment for STIs like gonorrhea and chlamydia, testing for STIs and sexual counseling while obtaining PrEP can be an appealing reason to initiate and continue PrEP use^{8,11}.

1.3 PrEP Awareness

When individuals are unaware of PrEP, they cannot make the informed decision of using PrEP. Being unaware of the existence of an HIV prevention modality puts many subpopulations at a higher risk of HIV acquisition, especially when PrEP has proven to be extremely effective.

Awareness of PrEP has remained low despite being available commercially since 2012. Although PrEP awareness has increased since it was available (especially among MSM)¹⁹, levels of awareness are still low in individuals of color (compared to white individuals), individuals over the age of 40 (compared to those below the age of 40)^{32,33,34}. Unfortunately, awareness is the lowest in Black MSM and transgender women^{33,34}.

Figure 2 ¹³ shows the levels of PrEP awareness, discussion with healthcare providers, and usage among White, Hispanic and African American MSM in 23 urban areas in the year of 2017.

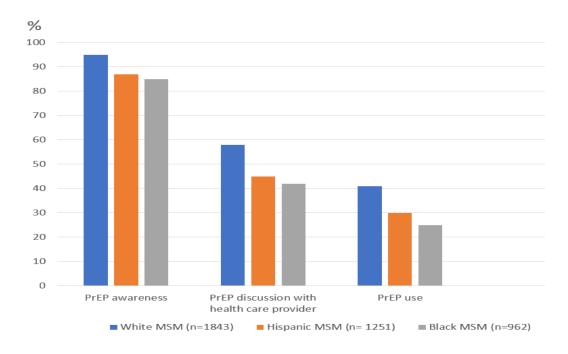


Figure 2 PrEP awareness, discussion and use in White, Latino and African American MSM

Figure 2 shows the levels of PrEP awareness, discussion and usage among White, Hispanic and African American MSM in 23 urban areas. 13

1.4 PrEP Use in the United States

PrEP was marketed to the US market as a once-a day pill taken to prevent HIV. Truvada (approved for PrEP in 2012) and Descovy (approved for PrEP in 2019), both made by Gilead Sciences are the only medications available for preexposure prophylaxis against HIV.

PrEP must be prescribed by a clinician after an appointment where the individual receiving PrEP will be provided guidance on how to use PrEP. Counseling on safe sex practices is also provided. The individual must then take PrEP daily and return for blood testing –(HIV testing and Kidney function test) every three months. Online PrEP options, with online clinician appointments and at-home blood tests (NuRx, Plushcare, etc.) can also be used when convenient ^{43,44}.

According to the CDC, around 1.1 million individuals can potentially benefit from HIV prevention strategies like PrEP ¹⁷, but in 2017, only 118,249 individuals used PrEP²⁷ (Figure 3 shows the number of individuals who can benefit from PrEP, broken down by race ¹⁷).

PrEP use is slowly starting to increase in the United States⁴². One cross-sectional study of population level data, using data from a national health data company estimated that the number of PrEP users had increased from 765 users in 2012 to 118,249 in 2017 ²⁷. According to a study done by the CDC in 2017, 35% of gay and bisexual men at risk for HIV were using PrEP ⁴². The distribution of PrEP use, however, is not uniform across different states and subpopulations.

PrEP to Need ratio (PnR) is defined as the number of PrEP users divided by the number of new HIV diagnoses. A lower PnR indicates an unmet PrEP need. In examining differences in PnR, across country, southern states have lower PnR compared to the rest of the US ²⁷.

Estimated N	lumber of adults	who could poten States, 2015	tially benefit fron	n PrEP, United
	Gay, bisexual, or other men who have sex with men	Heterosexually active adults	Persons who inject drugs	Total by race/ethnicity
Black/African American, non-Hispanic	309,190	164,660	26,490	500,340
Hispanic/Latino	220,760	46,580	14,920	282,260
White, non-Hispanic	238,670	36,540	28,020	303,230
Total who could potentially benefit from PrEP	813,970	258,080	72,510	1,144,550

Figure 3 Number of adults who could potentially benefit from PrEP

Estimated number of adults who could potentially benefit from PrEP, United States, 2015.¹⁷

One study that used the National Prescription database to quantify PrEP use among MSM in urban areas showed an increase in PrEP use from 6% to 36% between 2012 and 2016 ¹⁴. Another study that looked at PrEP use in African American MSM between the years of 2014 and 2017 using serial cross sectional survey assessments at Black Gay Pride events in 6 cities reported that PrEP use among African American MSM increased from 4.5% (in 2014) to 15.5% (in 2017)¹⁹. Despite these increases, PrEP use remains low among gay and bisexual men of color⁴².

According to the CDC, prevalence of HIV in communities is an important factor that can influence the likelihood of developing an HIV infection¹⁵, which is why increasing the use of PrEP in high risk subpopulations and communities (populations mentioned in Figure 3) is crucial to prevent new HIV infections.

Although the South accounts for more than half of the new HIV diagnoses, only 30% of all PrEP users are from the South ¹⁶. New York, Washington D.C, Massachusetts, Rhode Island

and Washington had the highest number of PrEP users in 2017 ¹⁶. The rate of PrEP use in the Northeast was double that of the other regions (West, South and Midwest) ¹⁶.

The number of male PrEP users outnumber female PrEP users by a factor of 16. Males account for around 94% of total PrEP users ¹⁶. Figure 4 shows the distribution of PrEP use between males and females ¹⁸.

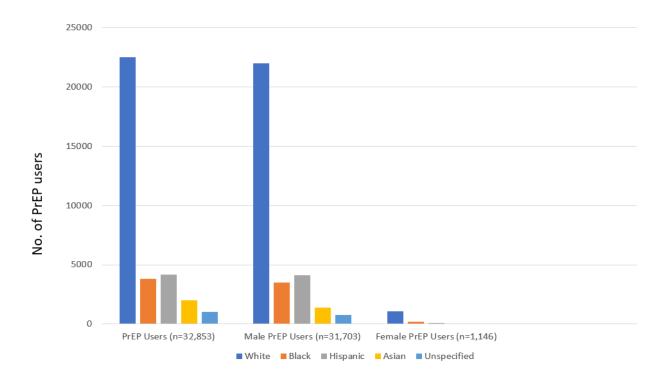


Figure 4 Number of male and female PrEP users

This figure shows the number of male and female PrEP users¹⁸

Individuals in the age group of 25-34 had the greatest number of PrEP users followed by the 35-44,45-54, 18-24, 55-64 and ≥65 age groups respectively ¹⁸. This pattern mimics the HIV incidences in these groups ⁵. Table 2 describes the distribution of PrEP use among the genders and different age groups ¹⁸.

Table 2 PrEP use by gender and age group between 2014-2016

	Year no (%)		
Characteristic	2014	2015	2016
Total	13,748 (100)	38,879 (100)	78,360 (100)
SEX			
Male	12,624 (91.8)	36,845 (9438)	74,639 (95.3)
Female	1,110 (8.1)	2,012 (5.2)	3,678 (4.7)
Unknown/Missing	14 (0.1)	22 (0.1)	43 (0.1)
Age Group (yrs)			
16-17	22 (0.2)	29 (0.1)	64 (0.1)
18-24	953 (6.9)	3,223 (8.3)	7,382 (9.4)
25-34	4,687 (34.1)	14,766 (38.0)	30,959 (39.5)
35-44	3,825 (27.80)	10,156 (26.1)	19,989 (25.5)
45-54	2,845 (20.7)	7,564 (19.5)	13,913 (17.8)
55-64	1,080 (7.9)	2,543 (6.5)	5,046 (6.4)
≥65	336 (2.4)	598 (1.5_	1,007 (1.3)

Annual number of persons aged \geq 16 years prescribed HIV preexposure prophylasix, by selected characteristics – IQVIA* longitudinal prescription database, United States, 2014-2016. 18

1.5 Correlates of PrEP Use

There are multiple factors indirectly associated with the usage of PrEP (factors that don't directly affect the access and use of PrEP but those that can help predict PrEP use). Some of these are residential instability in the recent past (negatively associated with PrEP usage), current health coverage, got tested for HIV in the past 6 months, having a higher income, higher

education levels (college degree and up)^{19,20,21}. The number of male sexual partners an individual has, has also been shown to significantly predict PrEP use (higher number of male sexual partners increased the likelihood of PrEP use)^{19,21}. Studying the correlates of PrEP use can shed some light on some of the disparities that exist with PrEP usage. Using this knowledge, interventions can be developed to improve PrEP uptake in subpopulations with low PrEP usage. Optimizing the way PrEP is promoted, to target groups with low PrEP usage (but high HIV risk) is one such intervention.

According to Mayer, et al. (2016), prior use of post exposure prophylaxis, or PEP (medications used to prevent HIV acquisition, taken after potential exposure, usually for 28 days) was shown to significantly predict PrEP use²¹. The use of PEP in the past also meant that these individuals were more likely to be aware of PrEP through clinician counseling (provided during their visit to acquire PEP)²¹. Prior PEP users were also seen as an important subpopulation for targeted PrEP use promotions²¹. A history of sexually transmitted infections (STIs) was also associated with increased PrEP use²¹ (STI counseling by healthcare providers could be contributing factor to PrEP knowledge and use at the time of STI diagnosis).

Okafor, et al. (2017), who conducted a study to assess correlates of PrEP use among MSM in Los Angeles between February 2015 and January 2017, noted that having sex with an HIV positive partner was shown to significantly predict recent PrEP use²⁰. The use of poppers (alkyl nitrate-based substances ingested through inhalational route for recreational purposes) was also shown to significantly predict PrEP use²⁰. Popper use was also associated with other activities that put individuals at a high risk of HIV acquisition, like condomless anal sex²⁰.

Being 'out' to one's doctor and colleagues was also shown to be associated with higher rates of PrEP usage²⁰. However, the study used participants with prior involvement in studies

related to PrEP use facilitation which the authors claim could have inflated the rate of PrEP use in the study population.²⁰.

According to Eaton, et al. (2018), drug use in the recent past was more likely to be reported by PrEP users (compared to non-PrEP users)¹⁹. Eaton et al found that the use of stimulants (cocaine, methamphetamines and ecstasy) was shown to significantly predict PrEP use; this finding was rather worrisome, as these substances may have a negative impact on medication adherence¹⁹.

1.6 PrEP Adherence

One study that used semi-structured interviews involving MSM to determine factors affecting adherence noted that disruptions in daily routine and use of alcohol and methamphetamines was associated with low PrEP adherence rates³⁶. This study also stated that long-acting PrEP agents can improve adherence rates in the future³⁶. Another study (a systematic review) noted that social factors such as stigma, low risk perception, low decision-making power, an unacceptable dosing regimen, side effects and the logistics of daily life were all factors that hampered PrEP adherence³⁷.

One demonstration project and safety study reported that the most common reason for missing pills were participants 'forgetting to take the pill', 'being away from home' and 'being busy with other things' ³⁸.

1.7 Public Health Significance

There is a dearth of studies describing the demographics of PrEP usage in Pittsburgh and Allegheny County. City- and County- level data can help streamline efforts to optimize PrEP usage by pointing out populations with high HIV risk and low PrEP uptake. PrEP use data demonstrating the differences in PrEP use among different subpopulations exclusively in Pittsburgh are scarce. This study aims to provide some information on PrEP usage in different demographic subpopulations in Pittsburgh and fill in that gap. The data from this study can then be used in projects targeting increased PrEP use in these subpopulations.

Roth et.al used data from a local organization in Pittsburgh (AIDS Free Pittsburgh/AFP) to conduct a serial cross-sectional analysis of PrEP awareness in Allegheny county ⁴¹. The survey, conducted by AFP, was made available to several organizations to distribute among their client and patient bases. Out a total of N=2036 surveys that were collected, 191 were analyzed (incomplete/incorrect responses, individuals who were categorized as females, those who identified as straight cisgender males and those who self-identified as HIV positive were excluded). The study found gender and sexual orientation to be significant predictors of PrEP awareness. Individuals above the age of 55 were significantly less likely to be aware of PrEP compared to 18-24-year-old individuals, gender non-conforming individuals were found to be less aware of PrEP compared to males (bivariate analysis only). Multiracial individuals were more aware of PrEP compared to White individuals (bivariate analysis only). Being African American/Asian was not significantly associated with PrEP awareness compared to Whites.

Studies like this can help us identify populations with low PrEP use and thus develop strategies to combat it. Demographic data on PrEP use is constantly needed to assess the

penetration of PrEP as a preventive modality. Low rates of PrEP use uncovered from data collection can then be addressed by interventions that increase PrEP awareness and use.

Close monitoring of PrEP users can help unearth new problems that occur with PrEP usage and distribution. New side effects of the drug, problems with PrEP access, problems with insurance policies, problems with adherence and many other barriers can be assessed with data collected at the city and county level. This data can then be used by the Allegheny County Health Department to resolve these issues by developing appropriate policies and interventions, aimed at future PrEP users.

The aim of this study is to analyze whether significant differences exist in the levels of past or present PrEP use among different demographics like age, race, gender in the study population (individuals at the Pittsburgh Pride 2019 and Too Hot for July 2019 who took the survey) and within the MSM subpopulation and compare this to national statistics. This study hypothesizes that:

- i) Individuals that identify as African American have lower odds of reporting past or present PrEP use when compared to white individuals.
- ii) Individuals that identify as Latino/Hispanic have lower odds of reporting past or present PrEP use when compared to white individuals.
- iii) Individuals in the 26-35-yearage group have higher odds of reporting past or present PrEP use when compared to individuals in the 18-25-year age group.
- iv) Individuals who identify as MSM have higher odds of reporting past or present PrEP use than those who do not identify as MSM.

Updated PrEP use data is needed to assess parameters such as PrEP to Need ratios in different populations. The findings of this study can be used as a guide for future research on PrEP use statistics(like calculating the PrEP to Need ratios in different populations) in Pittsburgh and Allegheny County. PrEP use data can then be used to develop targeted strategies and interventions to increase PrEP awareness and use in sociodemographic groups with low reported PrEP use and high HIV risk, and address PrEP use differences.

1.8 Public Health Implications

i) <u>Training of healthcare professionals</u>:

- a) Pinto et al mentions the purview paradox, which was found to be a major barrier to PrEP uptake⁵¹. According to the paradox, HIV specialists do not see HIV negative patients often, whereas PCPs, who often see high-risk HIV negative patients are not trained in providing PrEP⁵¹. Training PCPs to correctly prescribe PrEP can dramatically improve uptake.
- b) Increasing awareness and positive PrEP attitudes among non-prescribing providers (staff at HIV test sites and AIDS service organizations) can help educate and link clients to locations offering PrEP⁵¹.

ii) <u>Funding for Services</u>:

- a) Advocating for expansion of health insurance that covers PrEP⁵⁰
- b) Increasing funding to medication assistance programs⁵⁰

c) Funding medication costs, adherence and counseling/monitoring services (like Telemedcine/telePrEP)⁵⁰

iii) Structural changes to increase access:

- a) Stigma experienced from some healthcare providers is a barrier to PrEP use⁸. Cultural competency training to address bias against PrEP users should be integrated into existing competency training regimens. Maloney et al conducted online focus groups to assess stigma in healthcare that prevent MSM from seeking PrEP information and prescriptions from their PCPs⁵⁰. A common theme among most participants was the need for a non-judgmental relationship with the PCP before disclosure of one's sexual orientation and sexual health discussions including HIV prevention and PrEP⁵⁰. This highlights the need to address stigma to facilitate sexual discussions with their patients.
- b) Increasing the number of PrEP providing facilities in locations with low PrEP uptake can improve PrEP uptake.
- c) Paying for PrEP was found to be a major barrier to many MSM according to Jaiswal et al⁸. Reducing the cost of PrEP and introduction of generic options for PrEP can help alleviate these barriers.

iv) *Policy changes*:

a) Medication policies put in place by private insurance companies exacerbate barriers to PrEP implementation⁵¹. Policies that require prior authorization paperwork and strict requirements regarding completion of tests prior to authorization and prescription renewal impede PrEP implementation and use⁵¹.

- A change to such policies to ones that provide easy PrEP access is essential in improving PrEP implementation and use.
- b) Putting policies in place to combat the purview paradox to improve PrEP uptake⁵¹. Policies that mandate PCPs to prescribe PrEP can positively impact PrEP implementation.

2.0 Methods

The study, a non-randomized questionnaire-based survey that utilized convenience sampling at two LGBTQ focused events, viz the Pittsburgh Pride 2019 and Too Hot for July 2019 was conducted to describe the demographic distribution of past or present PrEP usage of those individuals who visited the Allies for Health + Wellbeing booth at these events. The paper surveys were completely anonymous and were completed at the booth by the individual using a clipboard.. IRB approval was not sought before conducting the survey and gathering the data but post hoc approval to use the data from the IRB was obtained (no IRB numbers are provided for post hoc approvals). The letter of approval from the IRB can be found in the appendix.

The survey was administered by two volunteers stationed at the Allies for Health + Wellbeing booth at both events. Volunteers at the stall were pointing visitors to complete the survey after their visit. The Too Hot for July event took place on the 6th of June 2019 at the Ace Hotel and the Pittsburgh Pride took place on the 8th and 9th of June 2019 at Ft. Duquesne Blvd, Pittsburgh, PA.

2.1.1 Demographic Measures

The focus of this study was to describe the demographic distribution of past or present PrEP usage in the individuals surveyed. Table 3 shown below shows the questions asked in the survey. The survey asked questions about the participants' age, sex at birth, gender identity, sexual preference, sexual orientation, past or present PrEP use discontinuation status and race.

2.1.2 Outcome Measure

Past or present PrEP use was assessed using one question with four options (only one response allowed). The question "Have you ever used PrEP (Pre-Exposure Prophylaxis)/
Truvada? Had the following four options: "Yes (more than 6 months ago)", "Yes (in the past 6 months)", "Yes (I am currently on PrEP)" and "No". Individuals selecting the following options

— Yes (more than 6 months ago), Yes (in the past 6 months) and Yes (I am currently on PrEP)

was put into the past/present PrEP use category. Anyone selecting 'No' was put into the No past/present PrEP use category.

		PrEP Us	age Survey	L	
		(All responses wi	II remain anony	mous)	
What is your age?					
O 18-25	O 26-35	O 36-45		O 46-55	O 55+
What sex were you	assigned at birth?				
O Female	O Ma	le	O Other		
M/h-+ i Cd-					
What is your Gende Female		ole responses allo ale			□ Non Conforming
			□ Non – bi	nary	☐ Non – Conforming
Other					
What is your sexual	nreference? (Mult	tinle recnances al	lowed)		
wilat is your sexual	preference: (with	tipie responses ai	ioweuj		
∏ Female	ПМа	le	∏ Transgend	er Men	□ Transgender Women
☐ Female ☐ Other		le	☐ Transgend	er Men	☐ Transgender Women
		le	□ Transgend	er Men	☐ Transgender Women
					☐ Transgender Women
□ Other	cribe your sexual o		ltiple respons	es allowed)	☐ Transgender Women
☐ Other	cribe your sexual o	orientation? (Mu	Itiple respons	es allowed)	☐ Transgender Women
☐ Other How would you des	cribe your sexual o	orientation? (Mu sbian	Itiple respons	es allowed)	☐ Transgender Women
☐ Other How would you des	cribe your sexual o	orientation? (Mu sbian ner	Itiple respons	es allowed)	☐ Transgender Women
□ Other How would you desc □ Gay □ Straight	cribe your sexual o	orientation? (Mu sbian ner	Itiple response Bise:	es allowed)	
Other How would you described Gay Straight Have you ever used	cribe your sexual o	orientation? (Mu sbian ner	Itiple response Bise:	es allowed) xual	
Other How would you described Gay Straight Have you ever used O Yes (more than 6	cribe your sexual o	orientation? (Mu sbian ner	Itiple response Bise: Truvada? O Yes (in t	es allowed) xual	
Other How would you described Gay Straight Have you ever used O Yes (more than 6	cribe your sexual of Les Oth PrEP (Pre-Exposur months ago) y on PrEP)	orientation? (Mu sbian ner ————————————————————————————————————	Itiple response Bise: Truvada? O Yes (in t	es allowed) xual	
Other How would you described Gay Straight Have you ever used O Yes (more than 6	cribe your sexual of Less Oth PrEP (Pre-Exposur months ago) y on PrEP) sing PrEP? If so, W	orientation? (Mu sbian ner re Prophylaxis)/ T	ltiple response Bise: ruvada? O Yes (in t	es allowed) xual	onths)
Other How would you described Gay Straight Have you ever used O Yes (more than 6 O Yes (I am current) Did you ever stop used O Yes	cribe your sexual of Less Oth PrEP (Pre-Exposur months ago) y on PrEP) sing PrEP? If so, W	orientation? (Mu sbian ner re Prophylaxis)/ T	ltiple response Bise: ruvada? O Yes (in t	es allowed) xual he past 6 mo	onths)
Other How would you described Gay Straight Have you ever used O Yes (more than 6 O Yes (I am current) Did you ever stop use O Yes	cribe your sexual of Less Oth PrEP (Pre-Exposur months ago) y on PrEP) sing PrEP? If so, W	orientation? (Mu sbian ner ————————————————————————————————————	ltiple response Bise: Truvada? O Yes (in t	es allowed) xual he past 6 mo	onths)
□ Other How would you described Gay □ Straight Have you ever used O Yes (more than 6 O Yes (I am current) Did you ever stop use O Yes	cribe your sexual of Less Oth PrEP (Pre-Exposur months ago) y on PrEP) sing PrEP? If so, W	orientation? (Mu sbian ner re Prophylaxis)/ T	ltiple response Bise: Truvada? O Yes (in t	es allowed) xual he past 6 mo	onths) No Hawaiian/Pacific Islander
Other How would you described Gay Straight Have you ever used O Yes (more than 6 O Yes (I am current) Did you ever stop use O Yes	cribe your sexual of Les Oth PrEP (Pre-Exposur months ago) y on PrEP) sing PrEP? If so, W	orientation? (Mu sbian ner ————————————————————————————————————	ltiple response Bise: Truvada? O Yes (in t	es allowed) xual he past 6 mo	onths)

Figure 5 Questions from the survey

2.2 Analytic Sample

The study included individuals who visited the Allies for Health + Wellbeing both at the 2 events and agreed to take the survey. A total of 267 individuals took the survey. Four completed questionnaires were excluded for selecting 2 genders in the gender identity question. Out of 263 surveys, 34 reported current or past PrEP use (229 individuals had never used PrEP). Responses by transgender individuals were determined by assessing the option choices in the sex assigned at birth and gender identity questions. Responses by men who have sex with men were determined by assessing the option choices in the sex assigned at birth and sexual preference questions (any individual who selected their sex at birth as male and had male as one of the options in the sexual preference question, regardless of other choices was considered as MSM).

2.3 Data Analysis

The purpose of this study was to analyze differences in past or present PrEP use within age groups, race, gender, and HIV transmission groups; and to conduct within-group analyses of past or present PrEP use differences by race/ethnicity among MSM. This study hypothesizes that:

- i) Individuals that identify as African American have lower odds of reporting past or present PrEP use when compared to white individuals.
- ii) Individuals that identify as Latino/Hispanic have lower odds of reporting past or present PrEP use when compared to white individuals.

- iii) Individuals in the 26-35-yearage group have higher odds of reporting past or present PrEP use when compared to individuals in the 18-25-year age group.
- iv) Individuals who identify as MSM have higher odds of reporting past or present PrEP use than those who do not identify as MSM.

The different demographics included were age, race, gender and MSM status. . A total of 263 surveys were analyzed. Predictor variables for the outcomes were age, race, gender, and MSM status. The use of PrEP was the outcome variable. Independent demographic factors that were significantly associated with past or present PrEP use were determined by performing Chi-Square and Fisher's Exact tests (used with nominal variables with a small sample size with an expected value of < 5). Odds ratios with one predictor and one outcome were determined by using bivariate logistic regression. Past or present PrEP use rates were then compared by every demographic factor (one by one), controlling for all other factors. This was conducted using multivariable logistic regression which then produced adjusted odds ratios (aOR), which were then used to determine the association of different demographic covariates with past or present PrEP use. The purpose of these tests was to determine possible demographic associations of past or present PrEP use within the sampled population and the MSM subpopulation.

The results obtained from chi square tests and logistic regression analyses were used to determine associations of PrEP use within the study population and the study MSM population. Then, comparisons will be drawn between the results of the study and National PrEP use statistics.

Stata SE 15.0 (StataCorp LP, College Station, TX) was used to perform all statistical analyses.

Replies to the "Have you ever stopped using PrEP? If so, why?" question were grouped together by common themes. Three broad themes emerged among the replies, viz. 'side effects', 'being in a past or relationship' and 'other'. Any reply that mentioned a side effect as the reason for past or present PrEP discontinuation was categorized as 'Side effects'. Replies that mentioned being in a relationship (either currently or in the past) as the reason for past or present PrEP discontinuation were categorized as 'being in a past or present relationship'. All other replies were categorized as 'other'.

3.0 Results

Population characteristics of the individuals included in the study are described in the tables below (Table 3 and Table 4). Out of the total 267 individuals who took the survey, only 34 (12.7%) had reported past or present PrEP use. The tables below (Tables 3 and 4) divides the entire study population and the MSM subpopulation based on past or present PrEP use and demographic characteristics. Chi square and/or Fisher's exact test values corresponding to the effect of sociodemographic variable categories on past/present PrEP use are also given.

Gender, race and MSM vs non-MSM categories were found to be significantly associated with past or present PrEP use. While looking at gender distribution of the population, 46.7% (n=123) were categorized as cisfemales (individuals who were assigned as female at birth and currently identify themselves as female), 39.5% (n=104) were categorized as cismales (individuals who were assigned as male at birth and currently identify themselves as male), 5.7% (n=15) identified themselves as non-binary on the survey, 2.6% (n=7) identified themselves as non-conforming, 1.9% (n=5) were categorized as transgender female (individuals who were assigned as male at birth and currently identify themselves as female) and 3.4% (n=9) were categorized as transgender male (individuals who were assigned as female at birth and currently identify themselves as male). The survey population distribution by race was as follows: 18.6% (n=49) identified as African American, 1.5% (n=4) identified themselves as Native American, 2.6% (n=7) self-identified as Asian, 2.2% (n=6) self-identified as Latino/Hispanic, 6.8% (n=18) selected the Mixed Race option for the race question, 1.9% (n=5) selected the 'Other' race category and 66.1% (n=174) identified themselves as White. There were 82 (31.17%) individuals categorized as men who have sex with men (individuals who were assigned as male at birth,

selected male in the sexual preference question regardless of other replies and identified themselves male, non-conforming or non-binary were considered as MSM for this study).

Age group was not found to be significantly associated with past or present PrEP use. The age distribution of the surveyed population was as follows: 44.8% (n=118) of the individuals surveyed were in the 18-25 year age group, 30% (n=79) were in the 26-35 year age group, 16.3% (n=43) were in the 36-45 year age group, 4.1% (n=11) were in the 46-55 year age group and 4.5% (n=12) were in the 55+ age group.

Age was not found to be a significant predictor of past or present PrEP use (χ^2 = 6.44, Fisher's exact p value = 0.117). PrEP use proportions for the different age groups were - No PrEP use: 109 (92.37%) | PrEP use: 9 (7.62%) | Total: 118 for the 18-25 year age group; No PrEP use: 64 (81.01%) | PrEP use: 15 (18.98%) | Total: 79 for the 26-35 year age group; No PrEP use: 36 (83.72%) | PrEP use: 7 (16.27%) | Total: 43 for the 36-45 year age group; No PrEP use: 9 (81.81%) | PrEP use: 2 (18.18%) | Total: 11 for the 46-55 year age group and No PrEP use: 11 (91.66%) | PrEP use: 1 (8.33%) | Total: 12 for the 55+ year age group.

Gender was found to be a significant predictor of past or present PrEP use (χ^2 = 45.02, Fisher's exact p value = 0.000). PrEP use proportions for the different gender categories were - No PrEP use: 123 (100%) | PrEP use: 0 (0%) | Total: 123 for the cisfemale category; No PrEP use: 77 (74.03%) | PrEP use: 27 (25.96%) | Total: 104 for the cismale category; No PrEP use: 14 (93.33%) | PrEP use: 1 (6.66%) | Total: 15 for the non-binary category; No PrEP use: 6 (85.71%) | PrEP use: 1 (14.28%) | Total: 7 for the non-conforming category; No PrEP use: 3 (60%) | PrEP use: 2 (40%) | Total: 5 for the transgender female category and No PrEP use: 7 (77.77%) | PrEP use: 2 (22.22%) | Total: 9 for the transgender male category.

Race, was also found to be a significant predictor of past or present PrEP use (χ^2 = 23.25, Fisher's exact p value = 0.000). PrEP use proportions for the different race categories were - No PrEP use: 36 (73.46%) | PrEP use: 13 (26.53%) | Total: 49 for the African-American category; No PrEP use: 2 (50%) | PrEP use: 2 (50%) | Total: 4 for the Native-American category; No PrEP use: 5 (71.42%) | PrEP use: 2 (28.57%) | Total: 7 for the Asian category; No PrEP use: 4 (66.66%) | PrEP use: 2 (33.33%) | Total: 6 for the Latino/Hispanic category; No PrEP use: 18 (100%) | PrEP use: 0 (0%) | Total: 18 for the mixed category; No PrEP use: 4 (80%) | PrEP use: 1 (20%) | Total: 5 for the other category and No PrEP use: 160 (91.95%) | PrEP use: 14 (8.04%) | Total: 174 for the white category.

Being part of the MSM population was found to be a significant predictor of past or present PrEP use ($\chi^2 = 53.29$, p = 0.000). PrEP use proportions were No PrEP use: 53 (64.63%) | PrEP use: 29 (35.36%) |Total: 82 for the MSM category; No PrEP use: 176 (97.23%) | PrEP use: 5 (2.76%) |Total: 181 for the non-MSM category.

Within the MSM subpopulation, no demographic variable (age, gender or race) was found to significantly predict past or present PrEP use ($\chi^2=4.04$, p = 0.400 for age group; $\chi^2=0.376$, p = 0.829 for gender and $\chi^2=11.47$, p = 0.075 for race) . PrEP use proportions for the different age categories within the MSM population were - No PrEP use: 16 (66.66%) | PrEP use: 8 (33.33%) |Total: 24 for the 18-25-year category; No PrEP use: 16 (59.25%) | PrEP use: 11 (40.74%) |Total: 27 for the 26-35-year category; No PrEP use: 8 (53.33%) | PrEP use: 7 (46.66%) |Total: 15 for the 36-45-year category; No PrEP use: 4 (66.66%) | PrEP use: 2 (33.33%) |Total: 6 for the 46-55-year category and No PrEP use: 9 (90%) | PrEP use: 1 (10%) |Total: 10 for the 55+ category.

PrEP use proportions for the different gender categories within the MSM population were No PrEP use: 49 (64.47%) | PrEP use: 27 (35.52%) |Total: 76 for the cismale category; No PrEP use: 3 (75%) | PrEP use: 1 (25%) |Total: 4 for the non-binary category and No PrEP use: 1 (50%) | PrEP use: 1 (50%) |Total: 2 for the non-conforming category.

PrEP use: 12 (42.85%) | PrEP use: 9 (57.14%) |Total: 21 for the African-American category; No PrEP use: 1 (33.33%) | PrEP use: 2 (66.66%) |Total: 3 for the Native-American category; No PrEP use: 1 (33.33%) | PrEP use: 2 (66.66%) |Total: 3 for the Asian category; No PrEP use: 1 (33.33%) | PrEP use: 2 (66.66%) |Total: 3 for the Asian category; No PrEP use: 0 (0%) | PrEP use: 2 (100%) |Total: 2 for the Latino/Hispanic category; No PrEP use: 4 (100%) | PrEP use: 0 (0%) |Total: 4 for the mixed category; No PrEP use: 4 (100%) | PrEP use: 0 (0%) |Total: 4 for the other category and No PrEP use: 31 (68.88%) | PrEP use: 14 (31.11%) |Total: 45 for the white category.

Out of the 34 past or present PrEP users, 15 (44.1% of PrEP users) answered the question 'Did you ever stop using PrEP? If so, Why?' as 'Yes'. Out of the 15 responses, 14 (41.1% of PrEP users) individuals filled out the blank space stating their reason for stopping PrEP. One individual who answered 'Yes', left the blank empty and one individual left an obscure response – 'CWOC'. The 14 responses were as follows: 'stomach problems'; 'the dreams'; 'I have no sex life!'; 'scary'; 'have a partner'; 'GI side effect'; 'irritation'; 'prostate cancer'; 'depression; not having sex'; 'side effects/adjusting'; 'relationship'; 'in a long term relationship'; 'Dr. would not renew, all tests were good, now have a PCP that prescribes PrEP' and 'CWOC'. Being in a relationship and side effects were the most common reasons for stopping PrEP. The responses were divided into 3 main categories: "side effects", "being in a past or present relationship" and "other".

Table 3 Characteristics of the individuals who took the survey, divided by past or present PrEP use. N=263

Demographic Variable	PrEP Use(%)	No PrEP Use(%)	Total	p and χ²-values
A CE				
AGE				p = 0.117 (FE)
				χ^2 Value : 6.44
18-25	9 (7.62%)	109 (92.37%)	118	χ ναιας : 0.44
26-35	15 (18.98)	64 (81.01%)	79	
36-45	7 (13.95%)	36 (86.04%)	43	
46-55	2(18.18%)	9 (81.81%)	11	
	, ,			
55+	1 (8.33%)	11 (91.66%)	12	
GENDER				
				p = 0.000 (FE)
				χ^2 Value : 45.02
Cis-Female	0 (0%)	123 (100%)	123	
Cis-Male	27 (25.96%)	77 (74.03%)	104	
Non-Binary	1 (6.66%)	14 (93.33%)	15	
Non-Conforming	1 (14.28%)	6 (85.71%)	7	
Transgender Female	3 (60%)	2 (40%)	5	
Transgender Male	2 (22.22%)	7 (77.77%)	9	
RACE				
				p = 0.000 (FE)
				χ^2 Value : 23.25
African American	13 (26.53%)	36 (73.46%)	49	
Native American	2 (50%)	2 (50%)	4	
Asian	2 (28.57%)	5 (71.42%)	7	
Latino/Hispanic	2 (33.33%)	4 (66.66%)	6	
Mixed	0 (0%)	18 (100%)	18	
Other	1 (20%)	4 (80%)	5	
White	14 (8.04%)	160 (91.95%)	174	
MSM vs Non-MSM				
				$p = 0.000 (\chi^2)$
				χ^2 Value : 23.25
MSM	29 (35.36%)	53 (64.63%)	82	
Non- MSM	5 (2.76%)	173 (97.23%)	181	

Table 4 Characteristics of the MSM population who took the he survey, divided by past or present PrEP use. N=82

Demographic Variable	PrEP Use(%)	No PrEP Use(%)	Total	p and χ²-values
AGE				
1102				$p = 0.40 (\chi^2)$
				χ^2 Value : 4.04
18-25	8 (32%)	16 (68%)	24	
26-35	11 (46.66%)	16 (59.25%)	27	
36-45	7 (46.66%)	8 (53.33%)	15	
46-55	2(33.33%)	4 (66.66%)	6	
55+	1 (10%)	9 (90%)	10	
GENDER				
				$p=0.829 (\chi^2)$
				χ^2 Value : 0.376
Cis-Male	27 (34.17%)	49 (64.47%)	76	
Non-Binary	1 (25%)	3 (75%)	4	
Non-Conforming	1 (50%)	1 (50%)	2	
RACE				
				$p = 0.075 (\chi^2)$
				χ^2 Value : 11.47
African American	9 (42.8%)	12 (57.14%)	21	
Native American	2 (66.66%)	1 (33.33%)	3	
Asian	2 (66.66%)	1 (33.33%)	3	
Latino/Hispanic	2 (100%)	0 (0%)	2	
Mixed	0 (0%)	4 (100%)	4	
Other	0 (0%)	4 (100%)	4	
White	14 (30.43%)	31 (69.56%)	45	

3.1 Regression Analysis

Full sample bivariate regression analyses

The relationship between age, gender, race, MSM status, within MSM demographics (age, gender and race) and past or present PrEP use was analyzed using bivariate and multivariable logistic regression. Odds ratios (OR) and adjusted odds ratios (aOR) with corresponding 95% confidence intervals of the analyses for the entire study population (N=263) are shown in Table 5 and ORs and those for analyses within the MSM population are shown in Table 6. Since there were no past or present PrEP users in the cis gendered female and mixed-race categories, the outputs for their respective ORs and aORs were empty.

Using the 18-25-year age group as the age reference category, the 26-35 year age group had significantly higher odds of reporting past or present PrEP use than the 18-25-year age group in the bivariate regression analysis (OR = 2.83; 95% CI: 1.17, 6.85). The 36-45, 46-55 and 55+ age groups were not significantly more likely to report past or present PrEP use than individuals in the 18-25-year age group (OR = 2.35; 95% CI: 0.81, 6.77; OR = 2.69; 95% CI: 0.50, 14.38; OR = 1.10; 95% CI: 0.12, 9.51 respectively).

Using cis gendered males as the gender reference category, the non-binary, non-conforming and transgender female categories were not significantly more likely to use PrEP (in the past or the present) than cis gendered males (OR = 0.20; 95% CI: 0.025, 1.62; OR = 0.47; 95% CI: 0.05, 4.12; OR = 4.27; 95% CI: 0.67, 26.99 respectively). Individuals in the transgender male category were not significantly more likely to report past or present PrEP use than cis gendered males in the bivariate regression analysis (OR= 0.81; 95% CI: 0.15, 4.16).

The White race category was used as the reference group that other races were compared with. The African American and Native American race categories had significantly higher odds

of reporting past or present PrEP use than the White race category in the bivariate regression analysis (OR = 4.12, 95% CI: 1.78, 9.53; OR = 11.42, 95% CI: 1.49, 87.42 respectively). Latino/Hispanic individuals had marginally significant higher odds of using PrEP (in the past or present) when compared to White individuals in the bivariate analysis (OR = 5.71, 95% CI: 0.965,33.99). According to the bivariate analysis, individuals in the Asian and Other race categories were not significantly more likely to use PrEP (in the past or present) than individuals in the White race category (OR = 4.57, 95% CI: 0.81, 25.74; OR = 2.85, 95% CI: 0.29, 27.33 respectively). Since there were no past or present PrEP users in the Mixed-Race category, the output for OR was empty.

The individuals who were categorized as MSM had significantly higher odds of reporting past or present PrEP use compared to those individuals not in the MSM category in the bivariate analysis. (OR = 19.26, 95% CI: 7.10, 52.22).

Within-MSM bivariate regression analyses

The within MSM bivariate analyses were carried out using the same reference categories for age, gender and race as previously mentioned (The 18-25-year age group for age, the cis male category for gender and the white race category for race). The 26-35, 36-45, 46-55 and 55+ year old age groups were not significantly more likely to report past or present PrEP use than individuals in the 18-25 year age category (OR =1.37, 95% CI: 0.43, 4.31; OR = 1.75, 95% CI: 0.46, 6.56; OR = 1.00, 95% CI: 0.14, 6.67; OR = 0.22, 95% CI: 0.02, 2.07 respectively).

Individuals in the non-binary and non-conforming gender categories were also not significantly more likely to use PrEP (in the past or present) than individuals in the cis male

category in the within MSM analysis (OR = 0.60; 95% CI: 0.059, 6.10 and OR = 1.81; 95% CI: 0.10, 30.18 respectively).

Since there were no past or present PrEP users in the cis-female and transgender male categories, the output for OR was empty.

African-American, Native American and Asian individuals were also not significantly more likely to report past or present PrEP use than White individuals in the within MSM analysis (OR = 1.66; 95% CI: 0.56, 4.84; OR = 4.42; 95% CI: 0.37, 52.99; OR = 4.42; 95% CI: 0.37, 52.99 respectively).

Full sample multivariable regression analyses

The same reference groups were used in the multivariable analysis of the entire study population and the within MSM population (18-25 year for age, cis gender males for gender, White for race, non-MSM individuals for the MSM vs non-MSM category).

In the multivariable analysis, none of the age groups were significantly more likely to use PrEP (in the past or present) compared to the reference group i.e the 18-26 year age group (aOR = 2.05; 95% CI: 0.68, 6.11, aOR = 2.34; 95% CI: 0.61, 9.03; aOR = 2.09; 95% CI: 0.30, 14.36; aOR = 0.27; 95% CI: 0.02, 2.91 for the 26-35, 36-45, 46-55 and 55+ age groups respectively). Multivariable analysis of the gender category revealed that individuals in the non-binary and non-conforming categories were not significantly more likely to report past or present PrEP use than the reference group i.e cis-males (aOR = 0.70; 95% CI: 0.06, 7.59 and aOR = 1.79; 95% CI: 0.10, 32.33 respectively). Since there were no past or present PrEP users in the cis gendered female category, the output for aOR was empty. The aOR outputs for the transgender female and

transgender male categories were non-estimable due to small sample sizes in their respective categories.

African American individuals were significantly more likely to report past or present PrEP use compared to white individuals (aOR= 3.25; 95% CI: 1.21, 8.72). Past or present PrEP use in Latino/Hispanic individuals was marginally more significant when compared to white individuals (aOR= 17.87; 95% CI: 0.94, 336.70). Individuals in the Native American race category were not significantly more likely to use PrEP (in the past or present) in the multivariable analysis than the reference group i.e White individuals (aOR = 6.35, 95% CI: 0.53, 74.98). Multivariable analysis for individuals in the Asian and Other race categories were not significantly more likely to report past or present PrEP use than individuals who were White (aOR = 3.61, 95% CI: 0.27, 47.51 and aOR = 0.78, 95% CI: 0.07, 8.19 respectively). Since there were no past or present PrEP users in the Mixed-Race category, the output for aOR was empty. Individuals who were categorized as MSM had significantly higher odds of reporting past or present PrEP use compared to those individuals not in the MSM category in the multivariable analysis. (aOR = 54.35, 95% CI: 8.78, 336.28).

Within-MSM multivariable regression analyses

In the within MSM multivariable analyses none of the age groups (26-35, 36-45, 46-55 and 55+) were significantly more likely to report past or present PrEP use compared to the reference group i.e the 18-26 year age group (aOR = 1.24; 95% CI: 0.38, 4.00, aOR = 1.80; 95% CI: 0.47, 6.91; aOR = 1.25; 95% CI: 0.18, 8.71; aOR = 0.23; 95% CI: 0.02, 2.22 for the 26-35, 36-45, 46-55 and 55+ age groups respectively).

Multivariable analysis of the gender category in the MSM population revealed that individuals in the non-binary and non-conforming categories were not significantly more likely to report past or present PrEP use than cis males (aOR = 0.71; 95% CI: 0.06, 7.46 and aOR = 1.66; 95% CI: 0.09, 29.21 respectively).

Multivariable analysis of the race category in the MSM population revealed that individuals in the African American, Native American and Asian categories were not significantly more likely to report past or present PrEP use than white individuals (aOR = 1.63, 95% CI: 0.55, 4.80; aOR = 4.31, 95% CI: 0.35, 52.15; aOR = 4.73, 95% CI: 0.33, 66.07 respectively).

Table 5 Odds ratios (OR) and adjusted Odds ratios (aOR) from bivariate and multivariable logistic regression models assessing associations between age, gender, race, MSM status (predictors) and PrEP Use (outcome) among individuals who answered surveys at 2 LGBTQ focused events in Pittsburgh, 2019 (n=263)

Demographic Variable	PrEP Use OR (95% CI)	PrEP Use aOR (95% CI)		
AGE				
NGL				
18-25	REF	REF		
26-35	2.83 (1.17, 6.85)	1.60 (0.52, 4.94)		
36-45	2.35 (0.81, 6.77)	2.10 (0.55, 8.00)		
46-55	2.69 (0.50, 14.38)	1.73 (0.25, 11.92)		
55+	1.10 (0.12, 9.51)	0.26 (0.02, 2.63)		
GENDER				
Cis-Male	REF	REF		
Cis-Female	Empty (No PrEP Use)	Empty (No PrEP Use)		
Non-Binary	0.20 (0.025, 1.62)	0.70 (0.06, 7.54)		
Non-Conforming	0.47 (0.05, 4.12)	1.76 (0.09, 31.58)		
Transgender Female	4.27 (0.67, 26.99)	3.66 (0.33, 39.66)		
Transgender Male	0.81 (0.15, 4.16)	Non- estimable		
RACE				
White	REF	REF		
African American	4.12 (1.78, 9.53)	2.43 (0.87, 6.78)		
Native American	11.42 (1.49, 87.42)	5.78 (0.48, 68.4)		
Asian	4.57 (0.81, 25.74)	3.56 (0.28, 44.8)		
Latino/Hispanic	5.71* (0.96, 33.99)*	19.07 (0.852, 426.567)		
Mixed	Empty (No PrEP Use)	Empty (No PrEP Use)		
Other	2.85 (0.29, 27.33)	0.94 (0.08, 10.27)		
MSM vs Non-MSM				
Non-MSM	REF	REF		
MSM	51.85 (12.03, 223.44)	75.75 (11.29, 507.92)		

There were a total of 263 survey responses analyzed (n=263). The Odds Ratio values (OR) were derived using bivariate logistic regression, while the adjusted Odds Ratio values (aOR) were derived using Multivariable logistic regression (all other demographic factors were controlled for). Base variables labeled REF were used as a reference that other variables were compared to. # :denotes marginal significance. Values in **bold** are significant. Non- estimable results were due to very few individuals in that category and empty results were due to that category having no (zero) past or present PrEP users

Table 6 Odds ratios (OR) and adjusted Odds ratios(aOR) from bivariate and multivariable logistic regression models assessing associations between age, gender, race (predictors) and PrEP Use (outcome) among MSM who answered surveys at 2 LGBTQ focused events in Pittsburgh, 2019 (n=82)

Demographic Variable	PrEP Use OR (95% CI)	PrEP Use aOR (95% CI)
ACE		
AGE		
18-25	REF	REF
26-35	1.85 (0.61, 5.61)	1.50 (0.47, 4.77)
36-45	1.85 (0.49, 6.94)	2.01 (0.52, 7.75)
46-55	1.06 (0.15, 7.06)	1.49 (0.21, 10.42)
55+	0.23 (0.02, 2.19)	0.25 (0.02, 2.46)
GENDER		
Cis-Male	REF	REF
Cis-Female	Empty (No PrEP Use)	Empty (No PrEP Use)
Non-Binary	0.60 (0.059, 6.10)	0.71 (0.06, 7.52)
Non-Conforming	1.81 (0.10, 30.18)	1.72 (0.09, 30.65)
Transgender Female	5.44 (0.539, 54.92)	3.71 (0.34, 39.80)
Transgender Male	Empty (No PrEP Use)	Empty (No PrEP Use)
RACE		
White	REF	REF
African American	2.28 (0.82, 6.32)	2.13 (0.75, 6.00)
Native American	4.57 (0.38, 54.65)	4.87 (0.40, 58.86)
Asian	4.57 (0.38, 54.65)	3.96 (0.31, 49.73)
Latino/Hispanic	Empty (No MSM Users)	Empty (No MSM Users)
Mixed	Empty (No MSM Users)	Empty (No MSM Users)
Other	Empty (No MSM Users)	Empty (No MSM Users)

4.0 Discussion

PrEP use is still low among subpopulations that need it the most in the United States^{12,13}. This study aimed to shed light on the demographic distribution of past or present PrEP use in the surveyed sample and draw comparisons to national PrEP use statistics. Further studies on distribution and long-term trends of PrEP use are required to deploy appropriate interventions to increase uptake. The results show that at the two events in Pittsburgh, African American individuals, Native Americans, and men who have sex with men were more likely to have used PrEP in the past or currently use PrEP when compared to their corresponding reference groups (although the limited sample size and the method of sampling used, viz. convenience sampling, mean that these results cannot be generalized).

Individuals in the 26-35 age group were significantly more likely to have used PrEP in the past or currently be on PrEP compared to their counterparts in the 18-25-year age group according to the results from the bivariate regression analysis (OR = 2.83, 95% CI: 1.17, 6.85) [although the limited sample size and the method of sampling used, viz. convenience sampling, mean that these results cannot be generalized]. In comparison, the CDC states that, PrEP usage has been higher in the 25-34-year age category when compared to the 18-24-year age group 18, which is similar to the results in my study. One study, done by Holloway et al, showed similar findings where individuals in the age group of 25-29 had significantly more PrEP users than individuals in the 18-24-year-old age group.³⁹

According to this study ,men who have sex with men were significantly more likely to report past or present PrEP use as compared to those who were not in the MSM category, this represents one of the most important populations that PrEP is geared towards, according to the

CDC⁶ (although the limited sample size and the method of sampling used, viz. convenience sampling, mean that these results cannot be generalized).

Within the MSM population, 21 individuals were African American, out of which 9 individuals (42.85%) were past or present PrEP users. 45 individuals were White, 14 (31.11%) of these individuals were past or present PrEP users. Out of the 2 Latino/Hispanic MSM, 2 (100%) were PrEP users (although the limited sample size and the method of sampling used, viz. convenience sampling, mean that these results cannot be generalized).

Kuhns et al conducted a longitudinal study of HIV risk in young MSM (N=394). The study (conducted between December 2014 and January 2016) showed that only 4.7% of Black young MSM had ever used PrEP. Past or present PrEP use in White, Hispanic and Other races were 29.5%, 11.7% and 6.9% respectively. Past or present PrEP use was the lowest among Black young MSM ⁴⁶.

The rates of past or present PrEP usage in White MSM (in Kuhn's study) are similar to this study, but the rates in African American and Latino individuals are different. Past or present PrEP use was higher in African American and Latino/Hispanic MSM when compared to White MSM in this study. The above-mentioned study looked at PrEP usage rates in the cities of Houston and Chicago, which may differ from rates of PrEP usage in Pittsburgh.

According to a study by Finlayson et al which looked at PrEP use among MSM in 20 urban areas between 2014 and 2017 prevalence of PrEP use in MSM is 35% in 2017¹⁴. This is similar to the prevalence of MSM PrEP use in the population used in this study (39.5%).

More studies need to be conducted to assess the distribution and impact of PrEP usage in different subpopulations. The data from these studies can then help identify subpopulations in

need of increased PrEP and guide interventions that can increase PrEP usage effectively in these subpopulations.

In the study there were no cis-gendered female past or present PrEP users, which is consistent with CDC data stating that PrEP awareness and PrEP use is very low among females when being compared to data for males^{13,18}. Since PrEP is also meant to be used by heterosexual women who have condomless sex with partners of unknown HIV status⁶, concentrating efforts to promote PrEP use among women can be a possible step to prevent new HIV cases in the future. According to the CDC, African American women have the highest rates of new HIV infections and low rates of PrEP use among women ^{5,18}, therefore promoting PrEP use among African American women with appropriately targeted interventions can increase PrEP usage.

With the increasing HIV incidence rates in some subpopulations, especially African American and Latino/Hispanic MSM, PrEP usage must increase drastically in these subpopulations to put a dent in the incidence of HIV and avoid possible outbreaks.

To ensure that PrEP is successful in the future, simultaneous data collection and interventions that target increased PrEP use aimed at PrEP needy populations must be carried out. PrEP to Need ratios can then be calculated to assess PrEP's impact on reducing new HIV cases. A parallel increase in PrEP use and the PrEP to Need ratio could be an indication of PrEP use leading to a decrease in the number of new HIV cases. According to a study done by Siegler et. al, the first step in calculating PrEP to Need ratios is to calculate the number of PrEP users and determine the distribution of PrEP use among different populations²⁷. PrEP to Need ratios of a particular region carried out periodically can give us trends on the effect of PrEP on new HIV cases.

Since PrEP along with other HIV preventive modalities are essential in the fight to eradicate HIV/AIDS, complete integration and recognition of PrEP as an effective HIV prevention modality is essential. Steps must also be taken to eradicate barriers to PrEP usage. Increasing access to PrEP, reducing the stigma surrounding PrEP, decreasing the costs associated with PrEP and educating medical professionals to increase PrEP prescription are some barriers that need to be addressed.

Increasing insurance cover to improve PrEP usage can overcome the most important barrier to PrEP, the cost. The production of the generic version of Truvada (once Truvada's patent expires in 2021) should increase PrEP coverage. The production of long acting PrEP medications in the future can address issues with adherence (for example taking a shot once in three months or having a depot version of PrEP implanted could vastly improve adherence vs taking one pill a day)³⁶.

Being in a relationship and side effects due to PrEP were the most common reasons for PrEP discontinuation in the study. The management of said side effects has the potential to improve PrEP adherence. Five out of 15 (33.3%) of the individuals who discontinued PrEP did so due to side effects. This is similar to the percentage of people who discontinued PrEP due to concern of side effects in a study done by Holloway et al (33.3%) on 761 young MSM in California from July 2015 to August 2015 ³⁹.

This study has its share of limitations. The use of convenience sampling limits the generalizability of this study. Since the surveys took place at events that were LGBTQ focused, rates of past or present PrEP use and awareness were probably higher at these events compared to real-world overall rates, thus skewing the results of the study towards higher levels of past or present PrEP usage.

Not including individuals below the age of 18 also potentially eliminated past or present PrEP users below that age group (FDA approved the use of Truvada in adolescents in 2018²⁵). Factors such as education level, income and health insurance can also influence the use of PrEP, unfortunately these factors were not controlled for in this study. Stigma associated with the personal nature of some of the survey questions could have also introduced a potential reporting bias.

HIV status of the individual was unknown due to patient privacy/identity concerns, as being HIV positive would eliminate an individual from participating in this study since HIV positive individuals cannot use PrEP. Future research can include the HIV status of individuals in the study to accurately identify individuals who are PrEP eligible.

The study did not account for individuals who may have taken the survey more than once. Individuals who may have filled out duplicate surveys while attending both Pride days and/or the Pride and the Too Hot for July events were not accounted for.

The study also did not track the number of individuals who declined the survey.

The population of this study was predominantly on the younger side. This could be attributed to the fact that the Too Hot for July event attracts a much younger crowd, skewing the population curve. The sample size of the study is also a limitation. A smaller sample size increases the margin of error and decreases generalizability.

To improve on this study, future works should include a population that is more representative of the venue in which the study is being carried out in. This can be achieved by time-location sampling of the venue (a probabilistic method used to collect data on hard to reach populations – like MSM, who can be found at identifiable locations)⁴⁰.

5.0 Conclusion

PrEP is not being used by subpopulations that need HIV prevention the most. Subpopulations with the highest HIV incidences are not seeing increase in PrEP usage to levels that can positively impact HIV incidence rates.

To assess the impact of PrEP on the community, data on PrEP usage is needed. There is limited data on PrEP usage patterns among different demographic subgroups in Pittsburgh. This study attempts to gather data on the demographic distribution of past or present PrEP use in Pittsburgh and compare it to national PrEP usage to fill in the gaps due to limited local data. PrEP to Need ratios can be calculated using PrEP usage statistics to determine the impact of PrEP on new HIV cases. The data in this and other similar studies is essential in calculating PnRs. The data from this study can also be used to assess trends in PrEP usage when paired with data from other studies looking at PrEP use over the years.

Despite its limitations, this study aims to provide information on demographic variables that may be significantly associated with PrEP use.

Convenience sampling was used for its cost effectiveness and ease of use properties.

Studies in the future can expand on this project by utilizing a larger sample size, acquiring a sample that is representative of the population being studied and filter out ineligible participants with more precision. The data in this study can be used as a point of reference for future studies that aim to gather data on PrEP use in Pittsburgh.

To improve on this study, future works should include a population that is more representative of the venue in which the study is being carried out in. This can be achieved by time-location sampling of the venue (a probabilistic method used to collect data on hard to reach

populations – like MSM, who can be found at identifiable locations)40. Calculation of PrEP to need ratios for Pittsburgh is also a logical next step. Other recommendations for similar studies in the future would be to include the HIV status of individuals involved and use electronic surveys that are easier to use and provide more privacy to survey participants.

PrEP for HIV is still a relatively new modality used in HIV prevention. With time and the appropriate effective intervention strategies to improve usage, PrEP will have a positive impact on HIV incidence levels.

Appendix IRB Approval



3500 Fifth Avenue 8uite 100 Pittsburgh, PA 15213 412-383-1480 Pay: 412-383-1508

July 23, 2019

Rajeev Salunke MPH Candidate Infectious Diseases and Microbiology- MIC Graduate School of Public Health University of Pittsburgh 130 DeSoto Street Pittsburgh, PA 15261

Re: Unanticipated Problem - Human Subject Research without IRB Approval

Dear Mr. Salunke:

On July 12, 2019, IRB Committee F discussed your submission of a reportable event regarding human subject research without prior IRB approval.

In brief, you reported that you distributed and collected a survey to identify the population using Pre-exposure prophylaxis (PrEP) at the Pittsburgh Pride and another local LGBT event in order to compare it to the population that is at the highest risk of developing HIV.

Printed surveys were handed out to the attendees at the Too Hot for July event and the Pittsburgh Pride Parade from the Allies for Health and Wellbeing stall. The surveys did not request any identifying information. In addition to surveying people visiting the Allies stall, surveys were handed out to people in the performance event space at the Too Hot for July event only (all surveys at the Pittsburgh Pride were given to people visiting the Allies Stall). The Too Hot for July event took place on the 6th of June 2019 at the Ace Hotel and the Pittsburgh Pride took place on the 8th and 9th of June 2019 at Ft. Duquesne Blvd. A total of 268 people were surveyed.

You reported that you did not seek IRB approval to conduct this study because you believed that it met the criteria for IRB exemption. The committee agreed that while this protocol likely would have been deemed to be exempt from Federal Regulations for the Protection of Human Research Subjects, this does not mean that the protocol was exempt from IRB review.

After reviewing all of the available information, the Committee concluded that this Reportable Event did not represent serious or continuing non-compliance in accordance with University of Pittsburgh policies or federal regulations, nor did it meet the definition of an unanticipated problem involving risk to subjects or others. However, the committee requests that you successfully complete the "Responsible Conduct of Research" course and the "Social<u>Behavioral-Educational</u>" Human Subject course through the Collaborative Institutional Training Institute (CITI). Please submit proof of completion to Joseph Madia (jvml 5@pitt.edu) by September 1, 2019.

The IRB approves of the use this data, however please note that it is your ethical responsibility to disclose to any potential publisher of this research that all data was acquired without IRB approval.

This matter is now considered to be closed.

Sincerely,

Richard Guido, MD Chair, Institutional Review Board University of Pittsburgh guidrs@mail.magee.edu

CC:

Mackey R Friedman, PhD, MPH
Assistant Professor, Infectious Diseases and Microbiology
Keystone Building, c/o HPCP, Pittsburgh, PA 15213
mrf9@pitt.edu

Kelly Dornin-Koss, MPPM, RN, CCRC
Co-Director, Research Conduct and Compliance Office
Director, Education and Compliance Office for Human Subject Research
kldl@pitt.edu

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