Prescription of HIV Pre-Exposure Prophylaxis and HIV Incidence in a Cohort of Women with Severe Mental Illnesses in the U.S.

AT THE FOREFRONT
UChicago Medicine

Samuel R. Bunting, MD, MS,[1*] Max Hyman, BS,[2] & Aniruddha Hazra, MD[3,4]

1. Department of Psychiatry and Behavioral Neuroscience, University of Chicago Medicine, Chicago, IL, USA, **samuel.bunting@bsd.uchicago.edu**
2. Center for Health and the Social Sciences, University of Chicago, Chicago, IL, USA
3. Chicago Center for HIV Elimination, University of Chicago Medicine, Chicago, IL, USA
4. Section of Infectious Disease and Global Health, Department of Medicine, University of Chicago Medicine, Chicago, IL, USA

Background

- Approximately 20% of new HIV diagnoses in the U.S. are made among women[1]
- Severe mental illnesses (SMI) like schizophrenia, schizoaffective disorder, and bipolar disorder are associated with elevated HIV incidence especially among women[2]
- Experiences of stigma/discrimination, transactional sex, and socioeconomic disadvantage further exacerbate HIV risk in SMI[3]
- Daily antiretroviral medication as HIV pre-exposure prophylaxis (PrEP) up to 99% effective with both oral and long-acting injectable (LAI) formulations (cabotegravir, lenacapavir)[4,5]
- Pre-exposure prophylaxis (PrEP) is only prescribed to an estimated 2.1% of the women with a likely PrEP indication in the U.S.[6]
- Prescription of PrEP to women with SMI has not been investigated and represents a critical gap in understanding in the HIV prevention response
- Only a single study investigating prescription, finding < 1% of people with BD *or* schizophrenia prescribed PrEP between 2013-2018 but did *not* stratify by diagnosis or gender[7]

Methods

- Claims-based analysis using the MarketScan commercial claims database of fully-adjudicated medical and pharmacy claims for privately insured Americans
- Data years 2010-2023. Cohort entry at any year.
- Inclusion Criteria:
  - Two outpatient claims on different dates or one inpatient claim with an SMI diagnosis code applying previously reported algorithm[8]
    1. Bipolar disorder (type I or II)
    2. Schizophrenia (any subtype)*
    3. Schizoaffective disorder (any subtype)*

    *Combined for analysis (schizophrenia spectrum)
  - Female sex (binary coded in MarketScan)
  - Age ≥ 14 years old
  - At least 6-months of continuous medical and prescription drug coverage prior to index date
- **Index date** (inclusion in cohort): Date of second outpatient or first inpatient claim with SMI diagnosis code
- Exclusion Criteria:
  - Two outpatient claims or one inpatient claim for an HIV diagnosis code *prior* to index date
  - >28 days of HIV treatment regimen; single 28-day prescription assumed post-exposure prophylaxis (PEP) *prior* to index date
  - Hepatitis B diagnosis as oral PrEP regimens also approved for HepB treatment, creating a possible confounding effect
- Covariates:
  - Demographic: Marital status, age, geography and region of residence, relation to primary policy holder
  - Clinical: STI encounters (chlamydia, gonorrhea, trichomoniasis, syphilis), follow-up outpatient care (psychiatry, OBGYN, primary care), psychiatric hospitalizations, use of long-acting injectable (LAI) antipsychotics/anti-cravings, substance (stimulant, opioid) use disorders
- **Primary Outcomes:**
  - New HIV diagnosis: Two outpatient claims or one inpatient claim with HIV diagnosis code *and/or* >31 days of antiretrovirals for HIV treatment (excluded PEP)
  - PrEP Prescription (≥1mo): At least 30 days of oral PrEP *without* concurrent prescription of a third antiretroviral (PEP)
  - PrEP to need Ratio (PnR): Ratio between incidence of enrollees prescribed PrEP and enrollees diagnosed with HIV per year (per 100,000), measure of adequacy of scale up
- Logistic regression model for each outcome fully adjusting for all relevant clinical and demographic covariates

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Results

- 241,910 women with SMI in cohort (Table 1) between 2010-2023
  - 221,407 with bipolar disorder; 20,503 with schizophrenia
- Total of 123 *new* HIV diagnoses
  - Bipolar disorder: 101; Schizophrenia: 22
- 330 women with SMI prescribed ≥1mo of PrEP (0.40%)
  - Bipolar disorder: 293; Schizophrenia: 37
- Mean age 34.7 (*SD* = 2.87) years
- Mean cohort duration of 3.23 years

Table 1. Sample demographics, outcomes, and logistic regression results.

	Sample	**HIV**			**Any PrEP (≥1 mo.)**		
Diagnosis	*n* (%)	*n* (%[b])	aOR (95%CI)	*p*	*n* (%[b])	aOR (95%CI)	*p*
Bipolar Disorder	221,407 (91.5)	101 (82.1)	*Ref.*		293 (88.8)	*Ref.*	
Schizophrenia	20,503 (8.47)	22 (17.9)	1.73 (1.06, 2.82)	**.03**	37 (11.2)	1.02 (0.71, 1.46)	.93
Married							
No	167,136 (69.1)	91 (74.0)	*Ref.*		294 (89.1)	*Ref.*	
Yes	74,774 (30.9)	32 (26.0)	0.74 (0.41, 1.33)	.31	36 (10.9)	0.62 (0.38, 1.02)	.06
Age Group (years)							
13-24	73,245 (30.3)	44 (35.8)	*Ref.*		200 (60.6)	*Ref.*	
25-34	55,165 (22.8)	21 (17.1)	0.41 (0.19, 0.90)	**.03**	67 (20.3)	0.67 (0.41, 1.10)	.12
35-44	48,001 (19.8)	23 (18.7)	0.48 (0.22, 1.05)	.07	44 (13.3)	0.59 (0.34, 1.01)	**.05**
45-54	40,407 (16.7)	24 (19.5)	0.58 (0.26, 1.27)	.17	15 (4.55)	0.26 (0.13, 0.51)	**<.001**
55+	25,092 (10.4)	11 (8.94)	0.52 (0.21, 1.27)	.15	4 (1.21)	0.14 (0.05, 0.41)	**<.001**
Geography							
Urban	198,624 (82.1)	107 (87.0)	*Ref.*		291 (88.2)	*Ref.*	
Rural	29,595 (12.2)	9 (7.32)	0.58 (0.29, 1.15)	.12	21 (6.36)	0.57 (0.36, 0.89)	**.01**
Missing	13,691 (5.66)	7 (5.69)	1.89 (0.77, 4.63)	.17	18 (5.45)	0.59 (0.35, 1.02)	.06
Region							
Northeast	35,807 (14.8)	23 (18.7)	*Ref.*		63 (19.1)	*Ref.*	
North Central	51,029 (21.1)	23 (18.7)	0.70 (0.39, 1.26)	.23	67 (20.3)	0.61 (0.43, 0.87)	**.01**
West	108,735 (44.9)	60 (48.8)	0.90 (0.55, 1.47)	.67	146 (44.2)	0.66 (0.49, 0.90)	**.01**
South	44,212 (18.3)	16 (13.0)	0.61 (0.32, 1.17)	.14	50 (15.2)	0.66 (0.46, 0.97)	**.03**
Unknown	2,127 (0.88)	1 (0.81)	0.42 (0.05, 3.69)	.43	4 (1.21)	3.59 (1.16, 11.2)	**.03**
Relation to Policyholder							
Self (employee)	110,861 (45.8)	58 (47.2)	*Ref.*		116 (35.2)	*Ref.*	
Spouse	63,716 (26.3)	29 (23.6)	0.94 (0.51, 1.72)	.85	29 (8.79)	0.69 (0.40, 1.18)	.18
Child/Other Dependent	67,333 (27.8)	36 (29.3)	0.34 (0.16, 0.71)	**<.001**	185 (56.1)	0.88 (0.55, 1.40)	.59
High-Risk Sexual Behavior Claim[c]							
No	235,974 (97.5)	112 (91.1)	*Ref.*		260 (78.8)	*Ref.*	
Yes	5,936 (2.45)	11 (8.94)	2.24 (1.15, 4.36)	**.02**	70 (21.2)	4.01 (3.00, 5.36)	**<.001**
Chlamydia							
No	240,435 (99.4)	121 (98.4)	*Ref.*		319 (96.7)	*Ref.*	
Yes	1,475 (0.61)	2 (1.63)	1.01 (0.23, 4.37)	.99	11 (3.33)	1.13 (0.59, 2.16)	.72
Gonorrhea							
No	240,661 (99.5)	121 (98.4)	*Ref.*		314 (95.2)	*Ref.*	
Yes	1,249 (0.52)	2 (1.63)	1.00 (0.23, 4.41)	.99	16 (4.85)	1.89 (1.09, 3.29)	**.02**
Trichomoniasis							
No	239,595 (99.0)	117 (95.1)	*Ref.*		307 (93.0)	*Ref.*	
Yes	2,315 (0.96)	6 (4.88)	2.18 (0.91, 5.23)	.08	23 (6.97)	2.50 (1.58, 3.96)	**<.001**
Syphilis							
No	241,377 (99.8)	119 (96.7)	*Ref.*		323 (97.9)	*Ref.*	
Yes	533 (0.22)	4 (3.25)	6.89 (2.45, 19.4)	**<.001**	7 (2.12)	3.27 (1.48, 7.21)	**<.001**
Outpatient Follow Up Care							
Primary Care or OBGYN	80,750 (33.4)	32 (26)	*Ref.*		83 (25.2)	*Ref.*	
OBGYN Only	4,663 (1.93)	1 (0.81)	0.79 (0.11, 5.85)	.82	3 (0.91)	0.53 (0.17, 1.67)	.28
Psychiatry Only	13,534 (5.59)	5 (4.07)	1.31 (0.50, 3.43)	.59	6 (1.82)	0.52 (0.23, 1.21)	.13
Psych & PCP OR OBGYN	120,572 (49.8)	70 (56.9)	0.89 (0.57, 1.39)	.62	228 (69.1)	1.39 (1.06, 1.82)	**.02**
Other Providers	22,391 (9.26)	15 (12.2)	2.87 (1.51, 5.48)	**<.001**	10 (3.03)	0.58 (0.29, 1.13)	.11
Psychiatric Hospitalizations							
0	196,796 (81.4)	74 (60.2)	*Ref.*		74 (60.2)	*Ref.*	
1	5,420 (2.24)	13 (10.6)	4.92 (2.67, 9.05)	**<.001**	13 (10.6)	0.94 (0.46, 1.92)	.86
2	4,801 (1.98)	3 (2.44)	1.30 (0.41, 4.18)	.66	3 (2.44)	0.89 (0.42, 1.91)	.77
3	4,761 (1.97)	3 (2.44)	1.31 (0.41, 4.22)	.65	3 (2.44)	1.27 (0.67, 2.42)	.46
≥4	30,132 (12.5)	30 (24.4)	1.84 (1.14, 2.98)	**.01**	30 (24.4)	1.66 (1.26, 2.20)	**<.001**
LAI Agent Use[d]							
No	238,390 (98.5)	119 (96.7)	*Ref.*		119 (96.7)	*Ref.*	
Yes	3,520 (1.46)	4 (3.25)	0.73 (0.26, 2.08)	.56	4 (3.25)	0.87 (0.47, 1.59)	.65
Comorbid Stimulant Use Disorder							
No	234,219 (96.8)	104 (84.6)	*Ref.*		104 (84.6)	*Ref.*	
Yes	7,691 (3.18)	19 (15.4)	2.78 (1.55, 4.98)	**<.001**	19 (15.4)	1.50 (1.01, 2.24)	**.05**
Comorbid Opioid Use Disorder							
No	231,977 (95.9)	106 (86.2)	*Ref.*		298 (90.3)	*Ref.*	
Yes	9,933 (4.11)	17 (13.8)	1.63 (0.90, 2.95)	.10	32 (9.70)	1.42 (0.92, 2.18)	.11
Follow Up Duration (yrs)	-	-	1.16 (1.09, 1.23)	**<.001**	-	1.27 (1.21, 1.33)	**<.001**

Regression analyses control for year of cohort entry (2010 – 2023).

a. Column percentage; b. Row percentage; c. Z-codes; d. LAI agents included LAI antipsychotics and LAI anti-craving agents.

- PrEP to need ratio (PnR):
  - Bipolar disorder: 0.71 (2010) – 3.70 (2022)
  - Schizophrenia: 0 (2010) – 2.50 (2022)
  - National: 0.45 (2012) – 3.89 (2022)

Conclusions & Future Directions

- PrEP use among women with SMI was very low (<1%) however did exceed the percentage of women newly diagnosed with HIV in this cohort
- Women with SMI face unique barriers to care that increase the chance of acquiring HIV and impede access to PrEP
- PrEP has been available in the U.S. for > 10 years but uptake has lagged among women
- Connection between encounter for syphilis and HIV incidence supports the need for screening for both STIs and HIV in psychiatric care
- Psychiatric care, both acute and subacute, serves as a routine point of contact with the healthcare system and may support integration of PrEP
- Psychiatric hospitalization associated with greater odds of PrEP prescription which may be a feature of more frequent healthcare contact
- Privately insured population may not be fully representative of all women with SMI in the U.S., further study with public insurance data is needed

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