

Is PrEP for Me?

Utilizing Longitudinal HIV Testing and Diagnosis Data To Inform The Creation Of An Algorithm For Pre-exposure Prophylaxis Use

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LOS ANGELES LGBT CENTER

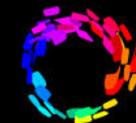
PRESENTATION OUTLINE

- Background of the Los Angeles LGBT Center
- Snapshot of our HIV Testing Protocol
- Review of Longitudinal HIV Studies
- Review of Pre-Exposure Prophylaxis Background and Guidelines
- Study Objectives
- Inclusion Criteria, Theory, and Variable Selection
- Survival Analysis Methods and Results
- Risk Score Methods and Results
- Limitations and Strengths
- Policy Implications



THE LOS ANGELES LGBT CENTER

- Founded in 1969
- Offers a range of services including
 - HIV and STD Testing
 - Primary and HIV Medical Care
 - Trans* Healthcare
 - Drop-In Services for Homeless Youth
 - Work Placement
 - Performing Arts
 - Legal Services
 - Senior Services
- Two Locations for Medical Services
 - McDonald-Wright Building in Hollywood
 - Center WeHo in West Hollywood



LOS ANGELES LGBT CENTER

HIV TESTING AT THE CENTER

- In 2015, the Center tested approximately 13,000 unduplicated individuals for HIV.
- The Center diagnosed 279 HIV infections in 2015.
- Unique from other clinics
 - Full panel of Sexually Transmitted Infection (STI) tests encouraged
 - Behavioral Risk Assessment
 - STI treatment
 - Disease Intervention Specialist Services
 - Offers nPEP and PrEP, often free of charge



PATIENT FLOW

- Patient comes into the clinic and checks in with the front desk staff
- The patient is seen by an HIV/STI testing counselor to assess the reason for visit (STI screening, treatment, etc.) and answer an 82-item risk assessment
- The patient is sent to the lab for blood draw and pharyngeal swab and asked to self-collect urine and rectal specimens
- Patient waits in waiting room until HIV test result is ready
- Patient is called back and disclosed the result
- Whole visit takes approximately 1.5 hours



ORIGINAL STUDY OBJECTIVES IN 2011

- The Medical and Research Director of the Los Angeles LGBT Center wanted to create a standardized mechanism to assess longitudinal HIV risk among the HIV testing clientele.
- Using an HIV risk assessment, we would be able to:
 - Inform someone of their HIV risk in a quantifiable way
 - Discuss their risk relative to others
 - Develop an action plan and provide referrals to reduce their risk behaviors



LONGITUDINAL HIV RISK (MENZA 2009)

- In 2009, Menza et al. published a study in *Sexually Transmitted Diseases* that used survival analysis to create a longitudinal HIV risk score for Seattle MSM.
- They found the following correlates of HIV infection at follow-up:
 - Age Group
 - Race/Ethnicity
 - STI Test Results
 - STI History
 - Methamphetamine Use
 - Nitrates Use
 - Number of Sex Partners
 - Type of anal sex

Has your patient/client used methamphetamine or inhaled nitrites (poppers) in the prior 6 months?	If yes, add 11 points If no, add 0 points	_____
Does your patient/client report unprotected anal intercourse with a partner of positive or unknown HIV status in the prior year?	If yes, add 1 point If no, add 0 points	_____
Does your patient/client report 10 or more male sexual partners in the prior year?	If yes, add 3 points If no, add 0 points	_____
Sum total number of points		Total Points

Total Points	Estimated percentage of men with this score who will acquire HIV over 4 years
0	<5%
1-3	5%-9%
4-11	10%-14%
12+	> 14%

- How to use the chart**
1. Calculate your patient's/client's risk score.
 2. Match the risk score with the point range provided on the table to estimate 4-year HIV risk.
 3. Follow up with testing recommendations, referrals to services, and prevention intervention according to risk.



LONGITUDINAL HIV RISK (SMITH 2012)

- In 2012, Smith et al. published a study in *JAIDS* that sought to replicate this study using VAXGEN data.
- Smith and her colleagues found largely similar results for their risk index:
 - Age
 - Number of Sex Partners
 - Number of Occurrences of RAI
 - Number of Occurrences of IAI
 - HIV status of Partners
 - Methamphetamine Use
 - Nitrates Use

TABLE 4. HIRI-MSM—Administration and Scoring Format

HIRI-MSM Risk Index*			
1	How old are you today (yrs)?	<18 years	score 0
		18–28 years	score 8
		29–40 years	score 5
		41–48 years	score 2
2	How many men have you had sex with in the last 6 months?	≥49 years	score 0
		>10 male partners	score 7
		6–10 male partners	score 4
		0–5 male partners	score 0
3	In the last 6 months, how many times did you have receptive anal sex (you were the bottom) with a man?	1 or more times	score 10
		0 times	score 0
4	How many of your male sex partners were HIV positive?	>1 positive partner	score 8
		1 positive partner	score 4
		<1 positive partner	score 0
5	In the last 6 months, how many times did you have insertive anal sex (you were the top) with a man who was HIV positive?	5 or more times	score 6
		0 times	score 0
6	In the last 6 months, have you used methamphetamines such as crystal or speed?	Yes	score 5
		No	score 0
7	In the last 6 months, have you used poppers (amyl nitrate)?	Yes	score 3
		No	score 0
Add down entries in right column to calculate total score			Total score†



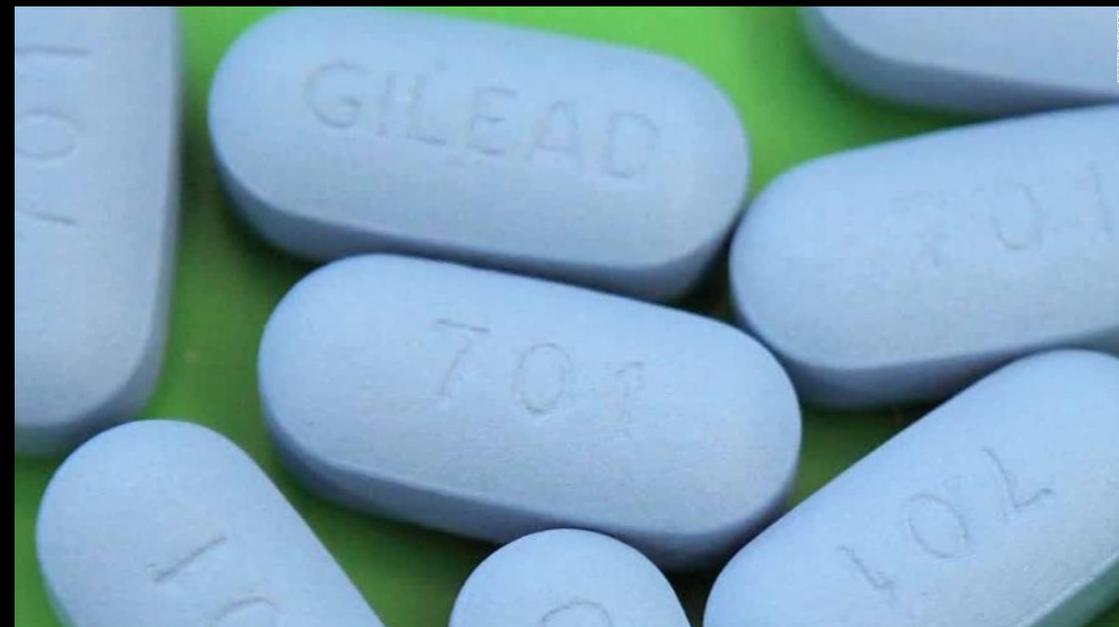
OTHER CONSIDERATIONS

- These studies had numerous strengths, but they also had limitations including:
 - Low proportion of individuals identifying with a racial or ethnic minority
 - Older datasets
 - Not based in theory
 - Did not consider biomedical interventions



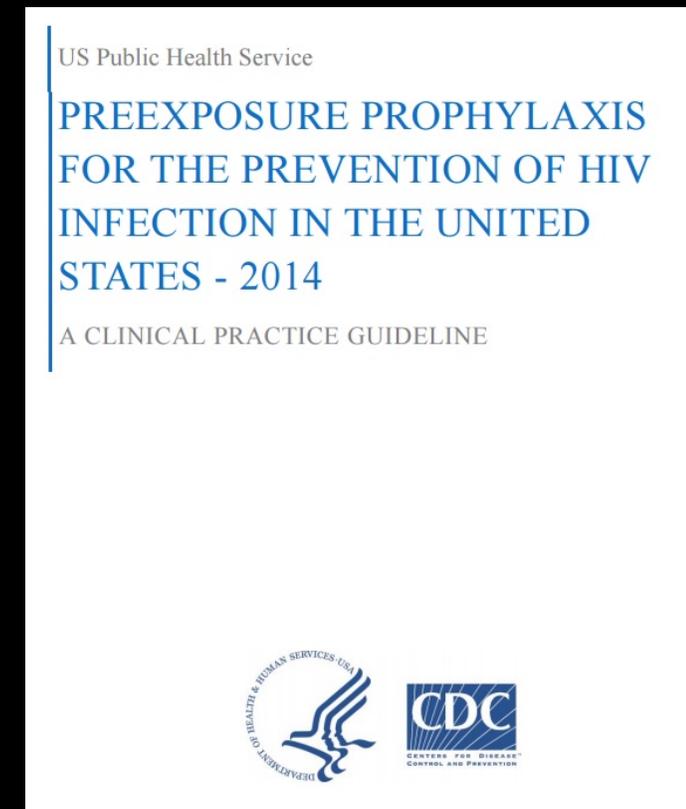
2012: A PREP ODYSSEY

- In 2012, pre-exposure prophylaxis (PrEP) was approved by the US Food and Drug Administration for use.
- PrEP is a daily anti-retroviral pill taken by HIV-negative individuals to prevent HIV.
- Mathematical models show that PrEP efficacy is over 99% effective if taken correctly.
- PrEP began to be offered on a wider basis in 2013 and at the Center beginning in 2014.



CURRENT CDC PREP GUIDELINES FOR MSM

- In 2014, the CDC released guidelines for PrEP use among MSM
- The guidelines stated that MSM are considered good PrEP candidates if they are sexually active, and met at least one of the following criteria
 - Any anal sex without condoms in the last 6 months
 - Diagnosed with at least one STI in the last 6 months
 - Ongoing relationship with an HIV-positive male partner



POTENTIAL GAPS IN THE GUIDELINES

- These guidelines may not be specific enough given
 - Other factors that are well-known predictors of HIV such as
 - Substance Use
 - Frequency of Sexual Exposure
 - Syndemic Factors that may be predictors of HIV including
 - Intimate Partner Violence



(REFORMULATED) STUDY OBJECTIVES

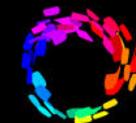
- Using survival analysis, we sought to create:
 - An HIV Risk Algorithm for Gay and Bisexual Men in Los Angeles based on HIV testing and behavioral risk assessment data
 - Select variables based on a priori knowledge and Syndemics Theory
 - Use this HIV Risk Algorithm to inform the provision of PrEP within our clinic population
 - Compare our algorithm with Current CDC guidelines



INCLUSION CRITERIA

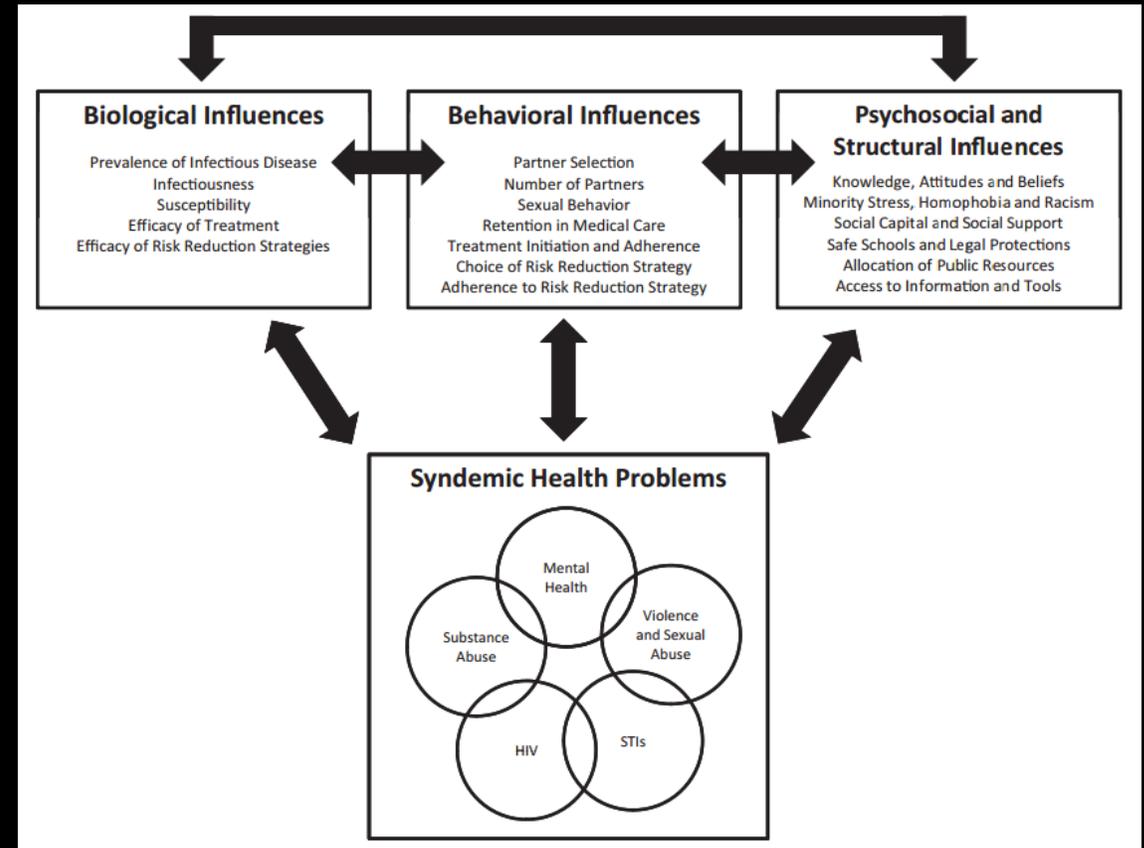
- Identified as MSM
- Tested HIV-negative at their baseline visit
- Reported sex with another man in the year prior to their baseline visit
- Tested for HIV on at least one occasion after their baseline visit during the analysis period
- Had a conclusive HIV result during their final testing visit

**Total Sample Size = 9,481 men who have sex with men between
January 2009 and June 2014**



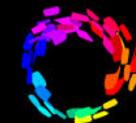
SYNDEMICS VARIABLE SELECTION

- Variables were chosen from the 82-item risk assessment to operationalize Syndemics Theory
- Biological Variables
 - STI History
 - STI Results
- Behavioral Variables
 - Types of Sex
 - Number of Partners
 - Substance Use
- Psychosocial Variables
 - Intimate Partner Violence
- Demographic Variables
 - Age Group
 - Race/Ethnicity



SURVIVAL ANALYSIS

- Bivariate Models
 - 28 different models
- Multivariable Models
 - Variables chosen to represent each Syndemics construct
 - Overlapping variables checked to ensure minimal multicollinearity
 - Built in one step, no forward selection or backward elimination
- Checking Assumptions for Survival Analysis
 - Proportional hazards assumption: Kolmogorov-type Supremum Test
 - Functional form assumption: Martingale residuals
 - Overall model adequacy (calibration): Grønnesby and Borgan test

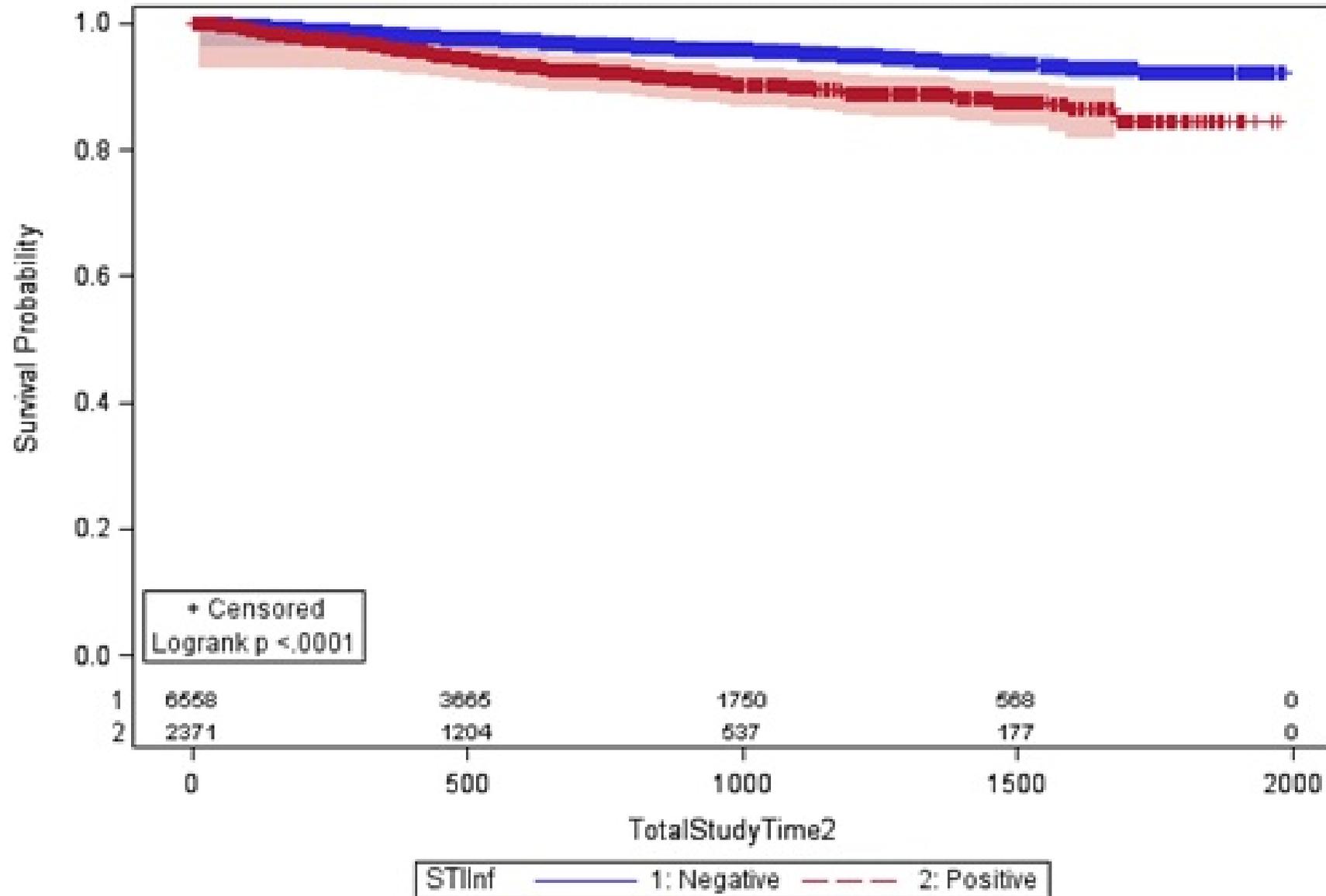


SURVIVAL ANALYSIS

```
☐ PROC PHREG DATA=ALGORITHM_2;
  CLASS ETHNICITY3 (PARAM=REF REF='White') AGEGRP2 (PARAM=REF REF='40+') HisSTI3 (PARAM=REF REF='0') LSEReceiveAnal3 (PARAM=REF REF='No')
  DomesticViol (PARAM=REF REF='0') RACE_PARTNER1 (PARAM=REF REF='Heterophilous') Ecstasy (PARAM=REF REF='0') Meth (PARAM=REF REF='0')
  Nitrates (PARAM=REF REF='0');
  MODEL TotalStudyTime2*HIVInf(0) = ETHNICITY3 AGEGRP2 HisSTI3 LSEReceiveAnal3 RACE_PARTNER1
  AgeDiff Partners3M DomesticViol Ecstasy Meth Nitrates / RISKLIMITS;
  WHERE FIRST_VISDATE=DATE2 AND HIVINF^=.;
  FORMAT AGEGRP2 AGEFMT.;
  TITLE 'Table 10 - Multivariable Survival Analysis (94% of Points Used), HIV Risk Algorithm Project.';
  RUN;
/*CHECKED - September 1st, 2016*/
```



Product-Limit Survival Estimates
 With Number of Subjects at Risk and 95% Hall-Wellner Bands



Bivariate
 Kaplan-
 Meier Plot

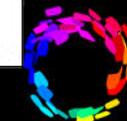
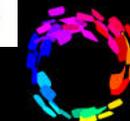


TABLE 5. Multivariable Survival Analyses of Demographic, Biological, Sexual Behavioral, and Substance Use Measured Constructs at Baseline by Final HIV Serostatus (n = 8898/n = 9481), January 2009 to June 2014*

	Estimate*	SE	P	HR (95% CI)
Race/ethnicity				<i>P</i> < 0.0001
Black	0.68	0.20	0.0009	1.97 (1.32–2.94)
Hispanic	0.52	0.12	<.0001	1.68 (1.32–2.14)
White	Reference	—	—	—
Other	0.27	0.22	0.22	1.31 (0.85–2.00)
Age group, y				<i>P</i> = 0.16
< 25	0.48	0.21	0.02	1.62 (1.07–2.45)
25–29	0.36	0.20	0.07	1.44 (0.97–2.13)
30–39	0.27	0.19	0.15	1.32 (0.91–1.90)
40+	Reference	—	—	—
History of chlamydia, gonorrhea and/or syphilis				<i>P</i> < 0.0001
Never diagnosed	Reference	—	—	—
Diagnosed more than 1 year ago	0.19	0.16	0.23	1.21 (0.89–1.66)
Diagnosed less than 1 year ago	0.75	0.12	<.0001	2.13 (1.67–2.70)
Receptive anal sex at last sex				<i>P</i> < 0.0001
No	Reference	—	—	—
Yes with condom	0.35	0.14	0.01	1.42 (1.08–1.87)
Yes Without Condom	0.61	0.12	<.0001	1.84 (1.45–2.35)
Race/ethnicity of last sex partner				
Different race/ethnicity	Reference	—	—	—
Same race/ethnicity	0.45	0.13	0.0004	1.57 (1.23–2.02)
Age of last sex partner	0.005	0.01	0.51	1.01 (0.99–1.02)
No. sexual partners in the last 3 mo	0.01	0.00	0.003	1.01 (1.00–1.02)
Intimate partner violence				
Never	Reference	—	—	—
Ever, past year, or past 3 mo	0.31	0.16	0.05	1.36 (1.00–1.85)
Used ecstasy in the past 12 mo				
No	Reference	—	—	—
Yes	0.21	0.16	0.19	1.23 (0.90–1.67)
Used methamphetamine in the past 12 mo				
No	Reference	—	—	—
Yes	0.49	0.17	0.005	1.64 (1.17–2.30)
Used inhaled nitrates in the past 12 mo				
No	Reference	—	—	—
Yes	0.45	0.13	0.0006	1.57 (1.21–2.03)

Multivariable Survival Analysis Results



RISK SCORE CONSTRUCTION

- Continuous variables categorized
- Model re-run with all categorical predictors
- Coefficients added for everyone who had values for all predictors
- Sum was then exponentiated to create a risk score that compares that person's hazard of HIV infection to the hazard of a hypothetical person in the lowest risk group



RISK SCORE RESULTS

TABLE 6. Sensitivity and Specificity for HIV Risk Algorithm Cutpoints (Range, 1–74) (n = 8898)

Cutpoint	All MSM			HIV Positives			HIV Negatives		
	% Greater Than or Equal to Cutpoint	n	No. HIV Infections per 100 Person-Years	Number Greater Than or Equal to Cutpoint*	Sensitivity % Greater Than or Equal to Cutpoint	n	Number Greater Than or Equal to Cutpoint*	1-Specificity % Greater Than or Equal to Cutpoint	
1	100.0%	0	0.00	362	100.0%	158	8,536	100.0%	
2	98.2%	13	0.53	362	100.0%	1306	8,378	98.1%	
3	83.4%	32	1.11	349	96.4%	1581	7,072	82.8%	
4	65.3%	47	2.04	317	87.6%	1240	5,491	64.3%	
5	50.8%	36	1.94	270	74.6%	1010	4,251	49.8%	
6	39.1%	22	1.75	234	64.6%	701	3,241	38.0%	
7	30.9%	18	1.97	212	58.6%	523	2,540	29.8%	
8	24.8%	29	3.25	194	53.6%	466	2,017	23.6%	
9	19.3%	22	3.98	165	45.6%	323	1,551	18.2%	
10	15.4%	19	4.28	143	39.5%	235	1,228	14.4%	
11	12.6%	14	4.61	124	34.3%	167	993	11.6%	
12	10.5%	22	9.52	110	30.4%	145	826	9.7%	
13	8.6%	14	7.23	88	24.3%	107	681	8.0%	
14	7.3%	10	5.03	74	20.4%	88	574	6.7%	
15	6.2%	9	6.80	64	17.7%	76	486	5.7%	



COMPARISON WITH OTHER MODELS

- The the CDC criteria would recommend PrEP for 69% of all MSM in this data set averting 86% of all infections provided positives were instead given PrEP and maintained appropriate adherence.
- In comparison, our model would recommend PrEP to 51% of all MSM in this dataset averting 76% of all infections given the same requirements.
- Our model had an AIC value of 6094, whereas the model that generated the CDC criteria had an AIC of 6162.
- Lower AIC values indicate better fit of the overall model, but our model was developed using our data providing a bias of unknown size in favor of our data.





LIMITATIONS

- Selection Bias
- Lack of additional Mental Health Predictors
- Self-Presentation / Social Desirability Bias
- Recall Bias
- Medication Adherence
- Repeated Measures



STRENGTHS

- Data from one of the largest LGBT services centers in the world
- Significant proportion of racial/ethnic minorities
- First predictive model based in theory
- First predictive model to incorporate a mental health component
- First predictive model to make significant comparisons for at-risk subgroups of MSM
- First model to serve as a predictive algorithm for PrEP



SO WHO CARES?

- CDC criteria are a good start to formulation of PrEP criteria, but our study provides more honed recommendations.
- At the Los Angeles LGBT Center, we find that this is greatly needed because even AFTER being educated about PrEP our clients have had the following distribution of responses when asked to evaluate their own PrEP candidacy

Table 7. Self-Perceived PrEP Candidacy Following PrEP Education at the Los Angeles LGBT Center (n = 11,086), August 2015 - September 2016.

Self-Perceived PrEP Candidacy	n	%
Yes, I am definitely an appropriate candidate for PrEP	2960	27%
Yes, I think I am an appropriate candidate for PrEP	1533	14%
I am not sure if I am an appropriate candidate for PrEP	2770	25%
No, I don't think I am an appropriate candidate for PrEP	2401	22%
No, I am definitely not appropriate candidate for PrEP	1422	13%
Total	11086	100%



THE RESULTS: ISPREPFORME.ORG

- Assessment is 11 questions and takes approximately 2 minutes to take
- Returns one of three values
 - Do Not Recommend PrEP
 - Recommend PrEP
 - Strongly Recommend PrEP
- Also provides a list of links at the bottom for individuals who want to get started on PrEP but may not be located in Los Angeles or California



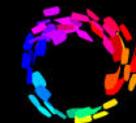


Legal Disclaimer (PLEASE READ): The information provided below is intended for your general knowledge only and is not a substitute for professional medical advice or treatment. You should not use this information to diagnose or treat a health problem or diseases without consulting with a qualified healthcare provider. Please consult your healthcare provider with any questions or concerns you may have regarding your health, including HIV.

PrEP is 90% Effective in Preventing HIV

Pre-exposure prophylaxis, also known as PrEP, is a pill that HIV-negative people can take once a day to prevent HIV infection. Previous studies have shown that PrEP is more than 90% effective if taken every day as directed. The Los Angeles LGBT Center believes that "If you're a sexually active gay/bi man or a transgender woman who is HIV negative, PrEP is for you. PrEP is safe and highly effective at preventing HIV transmission, though not other sexually transmitted diseases. Together, we can help end HIV transmission in the U.S. through the use of PrEP. Whether you're insured or not, the Los Angeles LGBT Center can help."

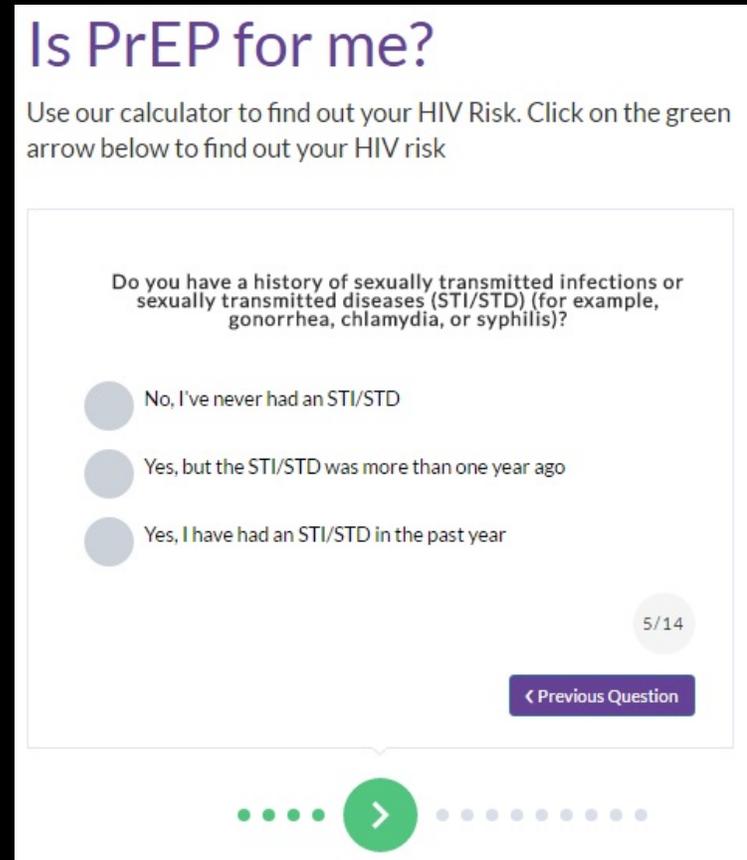
Although PrEP education is provided as part of our standard



LOS ANGELES LGBT CENTER

PLANNED ROLL-OUT

- Planned for deployment on World AIDS Day to coincide with our new PrEP promotion campaign
- Posters will appear in the waiting room with the QR code to allow people to take the assessment while they are waiting.
- Provided they are recommended PrEP, they will have an opportunity to speak with their counselor about getting linked to PrEP services.



Is PrEP for me?

Use our calculator to find out your HIV Risk. Click on the green arrow below to find out your HIV risk

Do you have a history of sexually transmitted infections or sexually transmitted diseases (STI/STD) (for example, gonorrhea, chlamydia, or syphilis)?

- No, I've never had an STI/STD
- Yes, but the STI/STD was more than one year ago
- Yes, I have had an STI/STD in the past year

5/14

[← Previous Question](#)

Progress indicator: 5 dots, with the 5th dot highlighted in green and containing a right-pointing arrow.



ACKNOWLEDGEMENTS

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- My dissertation committee
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 - Dustin Kerrone
 - The counseling and treatment staff
 - The Web Developers at Black Brick Software





QUESTIONS OR COMMENTS?

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