

A PROGRAM OF THE FENWAY INSTITUTE



PrEP and Informatics

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Our Roots

Fenway Health

- Independent 501(c)(3) FQHC
- Founded 1971
- Mission: To enhance the wellbeing of the LGBTQIA+ community as well as people in our neighborhoods and beyond through access to the highest quality health care, education, research, and advocacy
- Integrated primary care model, including HIV and transgender health services

The Fenway Institute

Research, Education, Policy

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Today's Faculty

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Disclosures

No presenters for today's session have financial or other conflicts of interest to disclose.



Using Electronic Health Records to Identify Potential PrEP Candidates

Douglas Krakower, MD and Julia Marcus, PhD, MPH



DEPARTMENT OF POPULATION MEDICINE





FENWAY 🖽 HEALTH

Overview

- 1) Promise of EHRs to catalyze PrEP discussions
- 2) Development of EHR-based prediction models
- 3) Patient and provider perspectives
- 4) Implementation in diverse healthcare settings





PrEP works.



Volk et al., CID 2015; Marcus et al., JAIDS 2016; Marcus et al., CID 2017

Used least by those who could benefit most



Hess et al., Annals Epi 2017; Harris et al., MMWR 2019

Used least in regions that need it most



Need effective tools to assess HIV risk

Recommendation Summary				
Population	Recommendation	Grade (What's This?)		
Persons at high risk of HIV acquisition	The USPSTF recommends that clinicians offer preexposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition.	A		

"Research is needed to **develop and validate tools** that are highly accurate for identifying persons at high risk of HIV acquisition who would benefit from PrEP."

Limitations of existing HIV risk prediction tools

MSM Risk Index

1. How old are you today?	If <18 years, score 0. If 18-28 years, score 8. If 29-40 years, score 5. If 41-48 years, score 2. If 49 years or more, score 0.	
2. In the last 6 months, how many men have you had sex with?	If >10 male partners, score 7. If 6–10 male partners, score 4. If 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 without a condom?	If 1 or more times, score 10. If 0 times, score 0.	
4. In the last 6 months, how many of your male sex partners were HIV-positive?	If >1 positive partner, score 8 If 1 positive partner, score 4. If <1 positive partner, score 0.	
5. In the last 6 months, how many times did you have insertive anal sex (you were the top) without a condom with a man who was HIV- positive?	If 5 or more times, score 6. If 0 times, score 0.	
6. In the last 6 months, have you used methamphetamines such as crystal or speed?	If yes, score 6 If no, score 0.	
	Add down entries in right column to calculate total score.	TOTAL SCORE*

* If score is 10 or greater, evaluate for intensive HIV prevention services including PrEP. If score is below 10, provide indicated standard HIV prevention services.

Preexposure Prophylaxis for the Prevention of HIV Infection in the United States - 2014 Clinical Providers' Supplement Page 21 of 43

- Require providers to know a patient is in an HIV risk group (e.g., MSM)
- Difficult to use during busy clinical visits
- Not strongly predictive (Cstatistics 0.66-0.72)
- Underestimate HIV risk in Black MSM

Smith et al., JAIDS 2012; Lancki et al., AIDS 2018; Jones et al., STD 2017; Pyra et al., AJPH 2020

Envisioning EHR decision support for PrEP

PR	OMPT			Go To Patient PROMPT \rightarrow
A	.PM	Value	Actions	Catastrophic Hold
+	ASA		needs discussion - 15.9%, 60-69 Last: Due: CV Calc Discuss Rx	
+	CRC	 ✓ 	up to date fellowed by GI Last: 01/23/2015 Due: 01/27/2020 Colecton	y Holds ▼
+	D/T/Td	 	up to date Last: 10/02/2014 Due: 10/02/2024	
+	Flu	 ✓ 	up to date Last: 10/18/2017 Due: 10/01/2018	
+	Pneum	 	up to date Last: 02/29/2016 Due:	

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request timestamp: 09/21/2018 08:28:50 request url: prompt.kp.org program version: 2.34.1



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Develop and validate an HIV risk prediction model using EHR data to identify potential PrEP candidates in a large healthcare system



Study setting #1

- Kaiser Permanente
 Northern California
- Large integrated healthcare system
- 4.3 million members



HIV risk predictors retained in final model

Demographics

- Male
- Aged 50-59
- Aged ≥60
- Black
- Hispanic
- Asian
- Other race/ethnicity
- Lower SES categories as measured by neighborhood deprivation index (3 variables)
- Received care in 1 of 3 cities with higher HIV incidence (3 variables)
- Resided in 1 of 8 urban ZIP codes with higher HIV incidence (8 variables)

Social history

MSM

Sexually active

Laboratory tests and results

- Positive urine test for methadone, ever prior
- Positive urine test for cocaine, ever prior
- No. of HIV testing episodes, prior 2 years
- No. of HIV antibody or RNA tests, prior 2 years
- No. of tests for rectal GC/CT, ever prior
- No. of positive tests for rectal GC/CT, prior 2 years
- No. of positive tests for urethral CT, prior 2 years
- No. of positive tests for urethral GC, prior 2 years
- No. of syphilis tests, prior 2 years
- No. of positive syphilis tests, prior 2 years

Medication use

- Medications for erectile dysfunction, ever prior
- No. of penicillin G benzathine injections with syphilis test within 90 days, prior 2 years

Diagnoses

- No. of anal wart diagnoses, ever prior
- Depression, ever prior
- Any psychiatric diagnosis, ever prior
- Transgender-related diagnosis, ever prior
- High-risk sexual behavior (homosexual), ever prior
- High-risk sexual behavior (unspecified), ever prior
- Exposure to HIV, ever prior
- HIV counseling, ever prior
- HIV education, ever prior

Cross-validated C-statistic in 2007-2014: 0.86 (95% CI: 0.85-0.87)

Discrimination

- C-statistic remained high in 2015-2017: 0.84 (95% CI: 0.80-0.89)
- Full model outperformed simpler models



Sensitivity of models among patients with high or very high risk scores (2.2%)

	Sens	itivity (% of HIV cases identified)
Model	Overall (n=83)	
Full model	39%	
MSM status and STI positivity, testing, and treatment	29%	
STI positivity, testing, and treatment	21%	
MSM status and STI positivity	25%	
MSM status	25%	
STI positivity	6%	

Marcus et al., *Lancet HIV* 2019

Study setting #2



Atrius Health, a large ambulatory practice in Boston 32 Sites, ~800,000 pts





- Age
- Race
- Sex
- Home language
- No. of Encounters per Year
- No. of Gonorrhea tests per year
- Positive Gonorrhea tests per year
- Rectal Gonorrhea tests per year
- Positive rectal Gonorrhea tests per year
- Pharyngeal Gonorrhea tests per year
- Positive pharyngeal Gonorrhea tests per year
- No. of Chlamydia tests per year
- Positive Chlamydia tests per year
- Rectal Chlamydia tests per year
- Positive rectal Chlamydia tests per year
- Pharyngeal Chlamydia tests per year
- Positive pharyngeal Chlamydia tests per year
- No. of syphilis tests per year
- Syphilis diagnosis per ESP
- LGV testing
- Anal cytology testing

- No. of HCV antibody tests
- No. of HCV RNA tests
- HCV antibody or RNA tests positive
- Acute Hepatitis C per ESP
- No. of HBV DNA tests per year
- HBSAg or HBV DNA positive
- Acute Hepatitis B per ESP
- No. of HIV ELISA tests per year
- No. of HIV Western Blots per year
- No. of HIV RNA tests per year
- HIV status per ESP
- HIV new diagnosis
- History of HIV meds
- HIV negative with HIV RNA tests
- Abnormal anal cytology
- Dx for Syphilis
- Dx for Anal syphilis
- Dx for Gonococcal infection of anus
- Dx for Gonococcal pharyngitis
- Dx for Chlamydia infection of anus
- Dx for Chlamydia pharyngitis
- Dx for LGV
- Dx for Chancroid
- Dx for Granuloma inguinale
- Dx for non-gonococcal urethritis

- Dx for HSV with complications
- Dx for Genital Herpes
- Dx for Anogenital warts
- Dx for Anorectal ulcers
- Dx for PID
- Dx for Contact / exposure to STD
- Dx for High risk sexual behavior
- Dx for HIV counseling
- Dx for HIV counseling
- Dx for Anorexia nervosa
- Dx for Bulimia nervosa
- Dx for Eating disorders
- Dx for Counseling for childhood sex abuse
- Dx for Alcohol dependence
- Dx for Opioid dependence
- Dx for Sedative, hypnotic, or anxiolytic dependence
- Dx for Cocaine dependence
- Dx for Amphetamine dependence
- Rx for bicillin
- Rx for azithromycin 1g
- Rx ceftriaxone 125mg or 250mg
- Rx for methadone
- Rx for Suboxone
- Rx for sildenafil or tadalafil or vardenafil



- No. of Gonorrhea tests per year
- Positive Gonorrhea tests per year
- Rectal Gonorrhea tests per year
- Positive rectal Gonorrhea tests per year
- Pharyngeal Gonorrhea tests per year
- Positive pharyngeal Gonorrhea tests per year
- No. of Chlamydia tests per year
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- Anal cytology testing

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- HCV antibody or RNA tests positive
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- Dx for Cocaine dependence
- Dx for Amphetamine dependence
- Rx for bicillin
- Rx for azithromycin 1g
- Rx ceftriaxone 125mg or 250mg
- Rx for methadone
- Rx for Suboxone
- Rx for sildenafil or tadalafil or vardenafil













9,515 (1.8%) of patients in the general population in 2016 had HIV risk scores above an inflection point

Atrius Health in 2016 537,257 patients 16 incident HIV infections C-statistic = 0.86



Very Low Risk

Low Risk



Krakower et al., Lancet HIV 2019

Would You Want a Computer to Judge Your Risk of H.I.V. Infection?

A new software algorithm decides which patients are most likely to become infected with the virus. But this is not like other risk calculators, some experts say.



July 30, 2019



What do providers think about the use of automated prediction models for PrEP?

Focus groups: 42 PCPs (Atrius, Fenway)

Anticipated benefits

- Identify candidates missed by busy clinicians
- Facilitate discussions about HIV risk
- Destigmatize and standardize risk assessment

Concerns

- Negative patient reactions
- Potential breaches in confidentiality
- Accuracy of model predictions

"I think I should probably be offering PrEP to more people than I am offering it to. So in that way, **it would improve my practice** and have me doing something that I would like to be doing."

- Attending, Atrius Health

What do patients think about the use of risk prediction tools for PrEP?

Interviews: 32 MSM (Fenway, BIDMC)

Themes

- Need for providers to contextualize information about risk
- Doubts about quantifying risk at a single point in time
- Belief that receiving a high risk score would prompt behavior change

"I would think [an HIV risk prediction score] actually could be helpful, in a way. I mean, obviously, I would take it with a grain of salt.... But I think it would help me understand where I am, you know how I've been doing. 'Ok, do I continue on the course that I'm on? Or do I need to readjust?"

- MSM participant

Implement in public health clinics in Alabama

- 1 of 7 hotspot states in Ending the Epidemic initiative
- Jefferson County diagnoses the most HIV cases in the state
- 3 primary care clinics and 1 STI clinic, with 17 years of EHR data



Harvard Center for AIDS Research Supplement (Krakower/Marcus): "EHRs to Scale Up PrEP in the South"

Pilot trial in network of community health centers

- 2.8 million patients
- 19% Black, 35% Latinx,
 65% below poverty line
- 155 clinics in HIV hotspot counties



ΟϹΗΙΝ

Trial at Kaiser Permanente San Francisco

- 121 PCPs serving 189,000 patients
- Refer to centralized PrEP program
- ~5000 pts on PrEP but substantial disparities



KP Delivery Science (Silverberg/Volk): "Leveraging EHR Data to Increase Uptake of HIV Preexposure Prophylaxis"

Conclusions

- We need to catalyze conversations about sexual health and PrEP in healthcare settings
- Rich EHR data can help providers identify patients likely to benefit from PrEP
- Next steps:
 - Optimize models (e.g., women, disseminability)
 - o Implement in EHRs
 - Evaluate impact on PrEP prescribing

Thank you! <u>dkrakowe@bidmc.harvard.edu</u> julia_marcus@harvardpilgrim.org

David Hicks Aadia Rana Susan Gruber Mike Klompas Ken Mayer Jonathan Volk Mike Silverberg Jonathan Todd Miguel Marino Stacey Alexeeff



- NIAID
 - K01 AI122853
 - R21 AI143386
 - P30 Al060354
- NIMH
 - K23 MH098795
 - R34 MH122291
- NIMHHD
 - R01 MD013565-02S1
- Kaiser Permanente
 - Community Benefit Research Program
 - Delivery Science Research Program



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Collecting and Extracting PrEP Data

Kenneth Levine, BCS

Collecting and Extracting PrEP Data

- Ways to collect data on PrEP usage for later review
- Using Forms
- PrEP is more than a service
 - Allows other important information about patient to be tracked
 - Gateway to improved care



Fulfilling Query Requests for PrEP users

- OPTION 1: Create a problem code called PrEP in Medical Record
 - For a PrEP patient
 - Create a PrEP problem at time of first Rx
 - Inactivate problem when patient goes off PrEP
 - Create a new PrEP problem each time they go back on PrEP
 - Queries can look for active PrEP in problem list
 - This places onus on provider accurately entering and removing the problem



Fulfilling Query Requests for PrEP users (conf.)

- OPTION 2: Identify PrEP Rx as being for PrEP
 - For a PrEP patient
 - Create a prep Rx in which the instructions state "for PrEP or some standard text.
 - Set up in custom med list so provider just chooses.
 - Inactivate Rx when patient goes off PrEP.
 - This places onus on provider accurately specifying that Rx is for PrEP, and ending Rx when patient stops.



Fulfilling Query Requests for PrEP users (cont.)

- OPTION 3: Use forms for PrEP data collection and tap this data for PrEP usage information
 - For a PrEP patient
 - Track not just their PrEP usage but where they are on the PrEP continuum, eg – considering, interested, initiating, follow up, termination.
 - Track other useful information like risk factors, sexual history, prior PrEP usage, prior nPEP usage, PrEP side effects, barriers to effectively taking PrEP, STI and acute HIV screening, counselling, plan follow ups.
 - Nursing staff involvement, can also track by telehealth
 - Richer opportunities for data mining
 - This places onus on providers to use these forms when indicated and to complete them as correctly.



Fulfilling Query Requests for PrEP users (cont.)

- OPTION 4: Reality You may have some of options 1, 2, and 3 in place but still need to get creative when it comes to extracting the most accurate information on PrEP usage
 - No HIV in problem list
 - Rx for Descovy or Truvada if looking for first PrEP, should be first such Rx.
 - Rx instructions should not mention oPEP, nPEP or post exposure prophylaxis
 - Related document summary should only mention NPEP if PrEP is also mentioned, implying transition nPEP ro PrEP
 - Rx instructions should mention PrEP OR Rx should be written for more than 30 days
 - No concurrent ARV Rx (which might indicate nPEP regimen).
 - Take advantage of readily available information like age, race, ethnicity, SOGI data, insurance for useful analyses



PrEP Forms: More than Documenting PrEP Usage



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PrEP Forms: Intake

Ast Medical History		Assessment His	story Free med Courisein	ng FollowUp		
Instructurent restory I. Have you ever tested positive for HIV? Yes No Do you have a history of renal disease? Yes No Dont Know 3. Do you have a history of liver disease? Yes No Dont Know 3. Do you currently have Hepatitis B? Yes Yes No Corrent Medications (and medications) Ves No Interpretation (and medications) Yes No Dont Know (and medications) Add Medications (and Medications) Ves No (and Medications) <p< th=""><th>et Medic</th><th>al History</th><th></th><th></th><th></th><th></th></p<>	et Medic	al History				
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PrEP Intake Forms: Assessment

Intake Asse	essment History PreP Med C Physical	ounseling FollowUp Assessment
If yes to 2 or more, infection In the last month have you experienced any of the following:	refer to provider to assess for acute HIV Fever Fatigue Myalgia Rash Headache Sore Throat Cervial Adenopathy Arthalgias Night Sweats Diarrhea	Denies all Denies Fever Fatigue Myalgia Rash Headache Sore Throat Cervial Adenopathy Arthalgias Night Sweats Diarrhea
Assess for STI	Dysuria Discharge Anoretal Itching Anorectal Pain Rash Ulcers	

PrEP Intake Forms: History and Readiness

Intake	Assessment	History	PreP Med	Counseling	FollowUp		
ັ Sexual an	d Substance	Use Histo	ry				
1. How manys have you had in	exual partners n the last year?	(
2. What kind of	sex are you having	?					
Allow patients	s to answer, do no	ot prompt. (If p	atient request	s clarification:	receptive and/	or insertive ana	ıl, oral, vaginal, toys)
3. Are you in a	a sexual relationship	with someone v	/ho has HIV? 🔘	Yes		🔘 No	
4. Do y	you now or have you	ever engaged	in sex work? 🔘	Yes		🔘 No	
	5. Do you now or h	ave you ever us	ed IV drugs? 🔘	Yes		O No	
<u>Readines</u>	s for medicat	ion					
	1. What do you curre	ently know abou	t PreP?				
	2. Have you ever ta so when, why did y	ken PreP before rou stop?	? If				
	3. Do you know any	one on PreP?					
	4. Why are you inter	ested in going or	n PreP?				
	5. What, if any, barr	iers do you fors	ee?				
	6. How long do you on PreP?	ı anticipate being	1				

PrEP Intake Forms: PrEP Med

Intake	Assessment	History	PreP Med	Counseling	Follow	wUp	1	
Review	PreP Medicat	<u>tion</u>						
	1. Potential Side Eff	ects						
	Common:							
	diarrhea, d	lizziness, nause	a, headache, fatig	ue, abnormal dre	ams, slee	p proble	ems, rash, depressi	on
	Counsel:	If experience,	continue med, o	contact care tea	am withii	n 7 day	s	
	Cause for cond	cern:						
	lactic acid liver probl	dosis (weakness lems (jaundice, li	s, unusual pain, tro ight colored stools	ouble breathing, r , lack of appetite	iausea, vo , nausea, i	omiting, abdomi	fast heartbeat, feeli nal pain)	ng cold/dizzy/lightheaded),
	Counsel	: If experience	, stop medicatio	on, contact care	team for	r evalu	ation within 24 ho	urs
	2. Need for daily ad	herence (discus	s efficacy of and	resistance to me	dication)			
	Counsel:	Notify provide	er and need for H	HIV testing pric	or to rest	arting	PrEP if stopped fo	or seven or more days
	3. Time to protection	n						
	Approxin	mately 7 days a	fter starting PrE	EP in rectal tiss	ue			
	Approxin	nately 20 days	in cervicovagina	al tissue				
	4. Review risk rega	rding Hepatitis B	and acute HIV					
Baselin	e Testing							
DPH:								
	C	HIV Antibody					Syphilis	
	0	CT - Rectal Sv	vab and Urine				GC - Rect	al Throat swab and Urine
Quest:								
			Use the MED	: PrEP Visit (Sustom	List		
			Or	der Quest Labs	3			

PrEP Intake Forms:Counseling

N Intake	Assessment History PreP Med Counseling FollowUp	
	Assessment	
Assessment	Continues to be a good candidate for PrEP No apparent STI Risk for exposure to infection related to sexual behavior Symptoms concerning for an STI Concerned for contact to an STI Knowledge deficit related to medication use Knowledge deficit related to disease transmission Other	
	Counseling	
PrEP:	 Importance of regular exams every three months Reducing number of partners and knowing their status can reduce risk PrEP does not protect against other STIs Importance of good adherence to medications Call us if missing multiple doses Pt informed of adherence aids such as pill boxes and smart phone applications "Every dose Every Day" Tell provider if you get flu like symptoms while on PrEP Informed of Gilead Patient Assistance program if unable to afford PrEP Encouraged condom use 	
STD:	Importance of regular exams at least annually for sexually active adults If you are told you have come into contact with an STI please schedule a visit and refrain from sexual activity until treated Encouraged condom use	
As Applicable:	Patient informed of the Violence Recovery Program Patient informed of Team Case Manager for substance use resources.	
Patien	nt Instructions	Ŷ

PrEP Forms: PHAST PrEP Check

Check-In Education/Referrals	
PrEP Side	Effect Check
	Denies all
Complains of Abdominal Pain Diarrhea Nausea Dark Urine Jaundice Muscle Pain Headache Weight Loss Lethargy Dizziness Depression Problems Sleeping Abnormal Dreams Rash	Denies Abdominal Pain Diarrhea Nausea Dark Urine Jaundice Muscle Pain Headache Weight Loss Lethargy Dizziness Depression Problems Sleeping Abnormal Dreams Rash
PrEP Bar	iers Check
Missed doses since last visit: Barriers to No barriers identified taking PrEP as described Cost Ability to pick up Side effects Storage Other	
Notes	

PrEP Forms: PHAST PrEP Check

 \mathbf{A}

Education and Referrals					
1. Education					
Education, Counseling and Discussion of	Risk Reduction P	ractio	es 🔘 Pro	ovided	
Condom Di	istribution and E	ducat	ion 🔘 Pro	ovided	
Recommended Regular R	outine HIV/STI So	reen	ing 🔘 Pro	ovided	
	Information abo	out nl	PEP 🔘 Pro	ovided	
	Information ab	out P	rEP 🔘 Pro	ovided	
Notify Partners and discuss	risk reduction p	ractio	es 🔘 Pro	ovided	
Discussed reporting requiements of infectious disease results to DP	H and required a	genc	ies 🔿 Pro	ovided	
2. Supported Referrals					
PrEP Initiation (start or restart PrEP)	Referred	0	Provided	0	Confirmed
PrEP Maintenance (PrEP labs, sending labs to PCP, etc.)	Referred	0	Provided	0	Confirmed
PrEP Adherence	Referred	C	Provided	C	Confirmed
(Every Dose, Every Day app for Truvada, Another mobile adherence app, Adherence Practice Review/Suggestions, PrEPAS, etc.)					
PrEP Financial Assistance (PrEPDAP, Gilead Copay Card, etc.) 🔿	Referred	\odot	Provided	0	Confirmed
nPEP 🔿	Referred	\odot	Provided	\odot	Confirmed
nPEP Financial Assistance 🔘	Referred	\bigcirc	Provided	\sim	Confirmed
Primary Care 🔘	Referred		\odot	Confirmed	
Hepatitis A/Hepatitis B Vaccine 🔘	Referred		\odot	Confirmed	
Transgender/Gender Affirming Care & Services 🔘	Referred	\bigcirc	Provided	\sim	Confirmed
Other Health Care Services (Optometry, Dental, Etc.) 🔿	Referred		\bigcirc	Confirmed	
Mental Health Services 🔿	Referred		\odot	Confirmed	
Health Insurance Assistance/Financial Services 🔿	Referred	\odot	Provided	\odot	Confirmed
Benefits Assistance/Case Management Services 🔿	Referred		\odot	Confirmed	
Transportation Services 🔘	Referred		\odot	Confirmed	
Employment Services 🔘	Referred		\odot	Confirmed	
Housing Support Services 🔘	Referred		\odot	Confirmed	
(Rental Assistance, Youth on Fire, Housing Search, etc.)					
Additional HIV/HCV/STI/TB Testing 〇	Referred	\odot	Provided	\odot	Confirmed
Substance Use Services 🔘	Referred	\odot	Provided	\sim	Confirmed
(Syringe Services Program, Drug/Alcohol Treatment, ATS, etc.)					
Medication Assisted Treatment Program	Referred	-	C	Confirmed	
Narcan Program/Overdose Education	Referred	C	Provided	0	Confirmed
Legal Services O	Referred		0	Confirmed	
Vein and Wound Care	Referred	~	0	Confirmed	
Other 🔿	Referred	C	Provided	\odot	Confirmed

PrEP Forms: PHAST PrEP Check

3. Linkage to Care Referrals/Intervention

Partner Services (DIS) 🔿	Referred	0	Confirmed	
Medication Adherence Support 🔘	Referred	0	Confirmed	
(Peer Support Groups, Mobile Adherence Apps for ARVs, e	etc.)			
Every Dose, Every Day Mobile App for ARVs 🔘	Referred	O Provided	0	Confirmed
Healthy Relationships GLI 🔘	Referred	O Provided	\odot	Confirmed
Other HIP Behavioral Interventions for HIV+ persons	Referred	0	Confirmed	
ARTAS 🔿	Referred	O Provided	\odot	Confirmed
Hepatitis C Treatment 🔘	Referred	0	Confirmed	
Hepatitis C Treatment 〇 Gonorrhea/Chlamydia/Syphilis Treatment 〇	Referred Referred	O Provided	Confirmed	Confirmed
Hepatitis C Treatment Gonorrhea/Chlamydia/Syphilis Treatment <u>4. Other Interventions</u>	Referred Referred	C Provided	Confirmed 〇	Confirmed
Hepatitis C Treatment () Gonorrhea/Chlamydia/Syphilis Treatment () <u>4. Other Interventions</u> Couples HIV/STI Testing and Counseling ()	Referred Referred Referred	C Provided C Provided	Confirmed O	Confirmed Confirmed
Hepatitis C Treatment () Gonorrhea/Chlamydia/Syphilis Treatment () <u>4. Other Interventions</u> Couples HIV/STI Testing and Counseling () PCC (Personal Cognitive Counseling) ()	Referred Referred Referred Referred	C Provided C Provided C Provided	Confirmed O O	Confirmed Confirmed Confirmed
Hepatitis C Treatment () Gonorrhea/Chlamydia/Syphilis Treatment () <u>4. Other Interventions</u> Couples HIV/STI Testing and Counseling () PCC (Personal Cognitive Counseling) () Two-Session Risk Reduction Counseling ()	Referred Referred Referred Referred Referred	C Provided Provided Provided Provided	Confirmed C C C C	Confirmed Confirmed Confirmed Confirmed
Hepatitis C Treatment () Gonorrhea/Chlamydia/Syphilis Treatment () <u>4. Other Interventions</u> Couples HIV/STI Testing and Counseling () PCC (Personal Cognitive Counseling) () Two-Session Risk Reduction Counseling ()	Referred Referred Referred Referred Referred	C Provided Provided Provided Provided	Confirmed C C C C	Confirmed Confirmed Confirmed Confirmed

Summary

- Important to standardize PrEP data capture
- Benefits for keeping track of who is considering PrEP, on PrEP, discontinuing PrEP
- Track other vital information concurrently:
 - STDs
 - symptoms
 - sex practices
 - resources or referrals
- Improve patient care



HEALTH INFORMATION TECHNOLOGY,

Optimizing Health IT for PrEP

May 21, 2020

Jillian Maccini, MBA, PCMH CCE

Using health IT to support PrEP

- There are a number of best practices for PrEP that can be supported by configuring your EHR or health IT systems.
- These touch on a number of areas that are all important for creating a robust PrEP Program:
 - **Targeted Outreach/ Intervention-** What patients would most benefit from PrEP? What patients are at high or increased risk of acquiring HIV?
 - Standardized Documentation- Using structured data fields allows for reporting and tracking of treatment engagement as well as locating and closing gaps in patient care.
 - Routine F/U and Screening- PrEP treatment protocols call for quarterly patient visits as well as routine quarterly and bi-annually laboratory testing.
 - **Patient Education-** Patient education regarding acute HIV infection symptoms as well as the proper way to take PrEP medications and adherence strategies.
 - **Case Management/Care Coordination-** PrEP may not be covered by insurance, as such patients may need help navigating through government sponsored programs, or insurance authorization processes, to facilitate them receiving the medication.

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Best Practice: Patients should be regularly screened for Social Determinants of Health From the published literature:

- Access to education, effects of violence, and struggle to meet basic survival needs affect PrEP use and adherence.
 - Patients should be screened for
 challenges related to securing food,
 clothing or housing; getting health care;
 securing medications, paying rent; seeing
 a doctor, exposure to violence. When
 patients are facing barriers to social
 needs, they are often forced to prioritize
 those needs over engaging in
 preventative health services (like PrEP).

Source: Janet J. Myers et al., "Adherence to PrEP Among Young Men Who Have Sex With Men Participating in a Sexual Health Services Demonstration Project in Alameda County, California:," JAIDS Journal of Acquired Immune Deficiency Syndromes 81, no. 4 (August 2019): 406–13, https://doi.org/10.1097/QAI.000000000002051.

Related EHR Optimization

- Implement a Social Determinants of Health screener that is recorded in the EHR, and available for the care team to review prior to or during the visit.
 - Protocol for Responding to and Assessing Patients' Assets, <u>Risks, and Experiences (PRAPARE</u>) developed by NACHC
 - Templates available for many common EHRs
- Consider SDoH when creating care plan



Best Practice: Capture and consistently review insurance information in the EHR From the published literature:

- The EHR can be used to identify demographic risk factors, including health insurance status
- Insurance is a barrier for many young adults who are on their parents insurance and do not want their parents to be notified about PrEP.
- Not having insurance is also a barrier to accessing PrEP. Patients who do not have insurance can receive financial assistance through MAPs (Manufacturer Assistance Programs), but the requirements of enrollment for MAPS can delay initiation of PrEP.

Related EHR Optimization

- Create and maintain a process for registration staff to capture insurance in the EHR and confirm or update regularly. If the patient has insurance that requires it (such as managed care), registration staff should confirm the assigned primary care provider so referrals and prescriptions can be processed in a timely manner.
- Encourage care team to review and consider insurance coverage, as documented in the EHR, when creating a care plan that includes PrEP as those patients without insurance may have less continuity of care and access to labs, prescriptions, etc.
- Create and maintain a process for assisting patients who are uninsured, which may include referring to eligibility staff or case management, to get insurance coverage and continuity of coverage and care.



Best Practice: Implement a comprehensive sexual history template From the published literature:

- Provider initiated conversations with patients in which the provider asks about sexual-related behaviors and the patient's sexual orientation are linked with greater access to sexual health services, PrEP awareness, and greater willingness to take PrEP.
- Having standardized sexual history templates assists providers in doing risk assessments to identify which patients are at highest risk for HIV acquisition. The template should help the provider identify if the patient is in key populations or has key risk factors.

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Sources: Kevin F Kamis et al., Marisa Felsher et al. Full references in notes.

Related EHR Optimization

- Create and/or implement a standard sexual history template in the EHR to assist in identifying patients who may be in need of PrEP.
 - Sample guidance for what to include in that template is available from the LGBT Education Center: <u>Taking Routine Histories of Sexual Health: A System-Wide Approach for Health</u> <u>Centers</u>
 - Implement other screening questions from the literature, such as:
 - In the past 3 months, how many people did you have sex with?
 - In the last 6 months, including today, has a health care provider told you that you had an STD?
 - Have you ever had sex with someone who is HIV-positive?
 - Have you ever had sex with an anonymous person?
 - Have you ever paid money for sex?
 - Have you ever sold sex for drugs or money?
 - Over the past 3 months when you had sex, how often did you use a condom?

"Standardized documentation, specifically using structured data fields, allows for reporting and tracking of treatment engagement as well as locating and closing gaps in patient care." "Community Health Center at Buffalo, Inc

Hea	lth	Risk	Assess	ment
i cu		1 (ISI)	103033	in the fire

Assessment

Cancel

Select an Assessment Sexual Health Assessment	Logs 🚽 📑 🕞 🕤
How do you identify yourself?	$\overline{\mathbf{m}}$
What gender were you assigned at birth?	$\overline{\mathbf{m}}$
What are your pronouns?	<u><u></u></u>
Have you been on PrEP before?	<u></u>
Have you had sex in the last 6 months?	
Do you have sex with	
Do you know the HIV status of your partners?	
Do you use any drugs?	
Do you use any alcohol?	
Do you have sex for drugs?	
Do you have sex for money?	
Do you have housing?	
Are you employed?	
Have you been incarcerated?	
Do you have medical insurance?	
* Assessment completed by	$\overline{\mathbf{m}}$

Sample from Health Center using eClinicalWorks:

Health Risk Assessment> Sexual Health Assessment



Further EHR Optimization

Use clinical decision support tools such as Best Practice Alerts or Clinical Rules Engine to prompt providers to consider PrEP and order appropriate labs and tests needed for PrEP, or to automate this process.

- Based on responses on the assessment, providers can be alerted to order labs or follow the clinic's defined clinical pathway for PrEP.
- Creating order sets can assist with this as well, practices may want to create order sets that include HIV testing along with bacterial STI testing (gonorrhea, syphilis, chlamydia) or other STI testing.
- Similarly, consider creating an order set for PrEP Initial testing and labs.

Automating screening alerts, orders, and follow-up facilitates provider decision making, allows proper patient care or follow-up with less effort, and allows the system to automate orders for needed services based on structured data responses entered by the clinician.

Order Se	ts	pre		×				
Order Set	PrEP	Initial	T	New	Сору	Update	Delete	1
								_

🤱 Labs

Add

F	Description	Lab Company
	OraQuick	
	Pregnancy Test, Urine	
	HIV Ab Screen 4th Generation wRfx (use this for sliding fee) [Labc	LabcorpOG
	HIV-RNA, real time PCR(viral load) [Labcorp]	LabcorpOG
	Comp. Metabolic Panel -14 Labcorp	LabcorpOG
	Hep A Ab, Total [Labcorp]	LabcorpOG,Quest
	HBV Prevaccination (Profile X)	LabcorpOG
	Hep C (HCV) Antibody With Reflex for HCV Antibody Verification	LabcorpOG
	RPR, Rfx Qn RPR/Confirm TP	LabcorpOG
	Ct, Ng, Trich vag by NAA	LabcorpOG
	Chlamydia/GC [PHARYNGEAL], NAA [Labcorp]	LabcorpOG
	Chlamydia/GC [RECTAL], NAA [Labcorp]	LabcorpOG

Example of 'PrEP Initial' order set that providers can use to

order all appropriate labs/ tests for initiation of PrEP



Table 1: Suggested	Step-by-Step	Checklist for	Providers	Initiating PrEP

§ indicates detailed info available in Table 3

Risks for sexual transmission Any condomless sex in prior 6 months	Risks for parenteral transmission	
 Any STI diagnosed in prior 6 months Not in a monogamous relationship with a partner confirmed to be HIV-uninfected Having sex with HIV+ partner(s) Commercial sex work 	 Shared injection equipment needles & "works" for illicit/recreational drugs consider anabolic steroids, body fillers, etc. Known HIV+ injecting partner(s) Having sex with injecting partner(s) 	UNC has a very clear
Within 30 days BEFORE starting PrEP, check hepatitis B	status and renal function	
Hepatitis B surface antigen (sAg) REQUIRED Hepatitis B surface antibody (sAb) RECOMMENDED	 CAUTION if active hepatitis B (sAg+) Truvada treats HBV; use may cause "flare" ⁵ 	checklist that can help
Serum creatinine REQUIRED Estimated creatinine clearance REQUIRED Urinalysis (to establish baseline) RECOMMENDED	eCrCl must be ≥ 60 mL/min by Cockcroft-Gault Truvada dose reduction is <u>not</u> permitted for PrEP Descovy is NOT YET approved for use as PrEP 	determine what needs to
	· Descovy is not tet approved for use as the	be in order sets, or what
Within 7 days BEFORE starting PrEP, test for HIV infection	on	
Order ONE of these REQUIRED – UNC's suggested order of preference ↓ Automated, lab-based antigen/antibody combination assay (4th or "5th" generation)	 Must be confirmed as HIV-uninfected before PrEP Rapid 4th gen (Determine HIV-1/2 Ag/Ab Combo) has had poor performance for detection of p24 antigen, 	appropriate prompts for
 Automated, lab-based IgM/IgG-sensitive antibody assay (3rd generation) HIV RNA ("viral load"), quantitative 	 missing many early infections \$ If high-risk exposures, consider RNA and 4th gen Do NOT rely on oral fluid testing; sensitivity is lower with 	next steps might be.
Point-of-care (rapid) test with fingerstick blood	oral fluid than with blood	https://www.med.unc.edu/
Any of these symptoms in prior month?	Cannot have recent symptoms of acute HIV	
G Fatigue	starting PrEP	nchivtraining/files/2019/09
 Pharyngitis Cervical adenopathy 	ordering quantitative HIV RNA	/PrEPchecklist.pdf
If not already done in the prior 3-6 months RECOMMENDED Serum RPR for syphilis		
 Nucleic acid amplification tests (NAATs) for gonorrh Control of the second second	nea and chlamydia	
Nucleic acid amplification test for <i>Trichomonas vag</i> Hepatitis C antibody [§]	inalis (or wet prep), as appropriate	
	partner confirmed to be HIV-uninfected Having sex with HIV+ partner(s) Commercial sex work Within 30 days BEFORE starting PrEP, check hepatitis B Hepatitis B surface antigen (sAg) REQUIRED Hepatitis B surface antibody (sAb) RECOMMENDED Serum creatinine REQUIRED Estimated creatinine clearance REQUIRED Urinalysis (to establish baseline) RECOMMENDED Within 7 days BEFORE starting PrEP, test for HIV infection Order ONE of these REQUIRED - UNC's suggested order of preference Automated, lab-based antigen/antibody combination assay (4th or "5th" generation) Automated, lab-based IgM/IgG-sensitive antibody assay (3rd generation) HIV RNA ("viral load"), quantitative Point-of-care (rapid) test with fingerstick blood Any of these symptoms in prior month? Fever Fatigue Skin rash Pharyngitis Cervical adenopathy If not already done in the prior 3-6 months RECOMMENDED Serum RPR for syphillis Nucleic acid amplification tests (NAATs) for gonorff Cervix or vaginal swab for women, urine for men – Nucleic acid amplification test for Trichomonas vag Hepatitis C antibody \$	partner confirmed to be HIV-uninfected Innown HIV+ injecting partner(s) Having sex with HIV+ partner(s) Having sex with injecting partner(s) Within 30 days BEFORE starting PrEP, check hepatitis B status and renal function Hepatitis B surface antibedy (sAb) recommence Bestimated creatinine clearance recoursed Serum creatinine recommence Urinalysis (to establish baseline) recommence Automated, lab-based antigen/antibody combination assay (4th or "5th" generation) Automated, lab-based antigen/antibody combination assay (3rd generation) HVR NA Critral load"), quantitative Point-of-care (rapid) test with fingerstick blood Any of these symptoms in prior month? Fear Fatigue Skin rash Pharyngitis Cervical adenopathy

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Best Practice: Utilize mechanisms for patient and provider reminders to improve adherence



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From published literature:

- Forgetting to take PrEP is often cited by patients as a perceived barrier to adherence. Patients are typically **more likely to forget to take PrEP due to a change in a routine, such as sleeping somewhere else, or when they are under the influence of substances**, both of which are times when they may need to take PrEP the most.
- **Text message reminders**, as well as regular reminders from health care partners and peers, promote PrEP adherence.
- Providers should continuously remind their patients of the importance of adherence in order to maximize prevention benefits

Sources: Maxwell, Gafos, and Shahmanesh, Pre-Exposure Prophylaxis Use and Medication Adherence Among Men Who Have Sex With Men. Full references in notes.

Reminders to Promote Adherence

Patients

- Patient centered care plans that include goals for taking PrEP, integrating PrEP into daily routine.
- Electronic patient engagement
 - Texting for PrEP reminders
 - Reminders for follow up appointments and testing
 - Remote patient monitoring

Providers

- Use reporting or huddle tools to plan for follow-up or for upcoming visits:
 - Identifying patients who may be at risk of acquiring HIV
 - PrEP Treatment
 - Initial follow up to assess adherence and side effects
 - Due for a 3 month visit
 - Due for check of creatinine and eCrCl
 - Timely PrEP Prescription refills









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