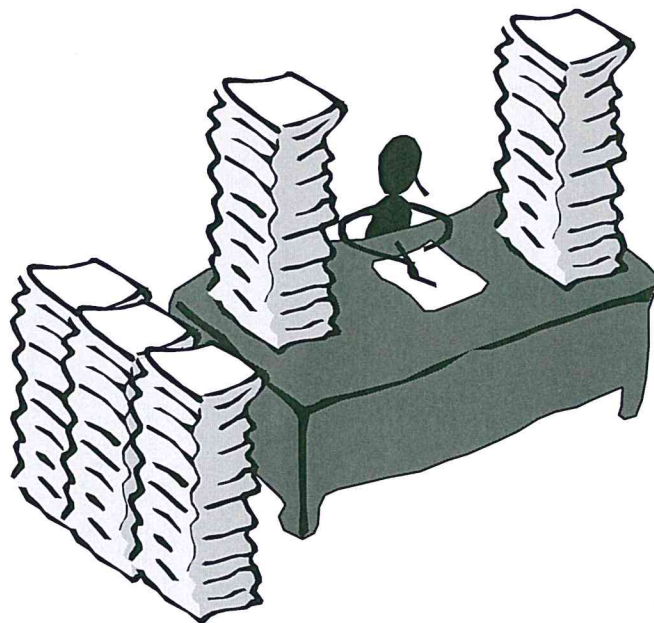


PREP IMPLEMENTATION

WORKSHEETS



Sarit A. Golub, PhD, MPH

WORKSHEET #1 – Priority Populations and Eligibility Criteria (see #1 on Program Template)

Consider the patient populations that are highest priority for your setting.

<i>PrEP priority at our setting...</i>	High	Medium	Low
Individuals in Magnetic (serodiscordant) relationships			
Gay Men and other MSM			
Cisgender Women			
Heterosexual Men			
Individuals of Trans Experience			
Young people (ages 18-24)			
Adolescents (under 18)			
Individuals who engage in transactional sex			
Injection Drug Users			
Other Substance Users (stimulants)			

A. What are the eligibility criteria for your PrEP program? (Some sample criteria are below; feel free to edit, delete, and add).

Eligibility Category	Criteria
1. HIV-status	1. HIV-negative
2. Age (e.g., 18 and over, 16 and over)	2.
3. Geographic Residence	3.
4. Patient Status (e.g., registered patient)	4.
5.	5.
6.	6.
7. At risk for HIV-infection	7. At least one from the list below

A1. How will you define the final eligibility criterion -- “at-risk for HIV infection”? (Sample criteria are taken from CDC guidance; feel free to edit, delete, and add).

- ☐ HIV+ sexual partner
- ☐ STI diagnosis in the past ____ months
- ☐ Reported condomless anal/vaginal sex in the past ____
- ☐ Reported needle sharing in the past ____
- ☐ More than ____ sex partners in the past ____
- ☐ Reported sex work or exchange
- ☐ In high-prevalence area or network
- ☐ History of PEP use in the past ____
- ☐ Self-reported concern about HIV infection*

*This criteria is designed to include patients who may be under-reporting relevant behaviors or who may be concerned about HIV exposure in the near future.

B. What are your exclusion criteria for PrEP? (There are specific contraindications for PrEP use, but settings may have additional exclusion criteria).

- ☐ Renal disease and/or abnormal renal function
- ☐
- ☐
- ☐

**Note: Provider perceptions of patients' future adherence are not reliable, and PrEP should not be withheld based solely on concerns about future non-adherence.*

C. What will happen to patients who don't meet risk criteria and/or who fit exclusion criteria? What alternative referral or treatment services will you offer?

Discussion Questions:

1. How straightforward are these choices? If not, what issues need to be discussed within your setting?
2. How controversial (or not controversial) will these PrEP populations be in your setting?
3. How will you handle patients who ask about PrEP but fall outside your priority populations?
4. How will you handle patients who ask about PrEP but are part of your exclusion criteria?

WORKSHEET #2 – Strategies for Engaging and Identifying Priority Patients**Which strategies will you use to engage and identify priority patients?**

The next six pages include potential models and considerations for engaging and identifying patients using five basic strategies:

- A. **Passive Education.** In this strategy, PrEP posters, brochures, and other information are made available to patients, in order to increase awareness about PrEP.
- B. **General Education.** In this strategy, providers or other staff bring up PrEP with all patients they see. All patients are provided with a certain basic level of PrEP education.
- C. **Targeted Education via Screening.** In this strategy, only specific priority populations or patients who meet certain screening criteria are provided with PrEP education by staff. Screening can include a formal “tool” or can be based on information from a sexual history (see E). Other patients receive access to passive PrEP information (as in Section A, above).
- D. **Targeted Education via Visit-Type or Chart-Based Triggers.** In this strategy, PrEP education is linked to specific visit types (e.g., HIV testing visits, STI testing visits) or chart information (e.g., patient had an STI in the past year, patient was previously on PrEP).
- E. **Targeted Education via Sexual History Taking.** In this strategy, all patients (or certain patients) receive a sexual history, with PrEP education and counseling based on this sexual history conversation. Utilizing this strategy means deciding which providers will engage in a sexual history, with which types of patients, and what that sexual history will include.

Discussion Questions

1. Discuss the pros and cons of including specific strategies. Which values are most important to your setting?
2. Which strategies will best ensure that your priority populations will have access to PrEP?
3. What types of pushback are you likely to get for specific strategies (from other staff, administration, patients)?
4. What are the concrete steps that you will need to take to put this model in place?

Once you have decided on the strategies you will adopt, use the pages below to flesh out the logistics of the strategy for your setting. This process may cause you to go back and rethink your original decision – that’s OK! You can also combine aspects from multiple strategies to create an optimal model for your setting

WORKSHEET #2A – Passive Education

A. Passive Education. In this strategy, PrEP posters, brochures, and other information are made available to patients, in order to increase awareness about PrEP.

What type of passive educational materials do you want to make available for your patients?

What?	Where?				Target Date
	Waiting Room	Clinic Rooms	Bathroom	Other	
PrEP Posters					
PrEP Brochures					
PrEP Postcards					
PrEP Handouts or Referral Sheets					
Flyers specific to <u>your</u> PrEP Program					

Considerations for this strategy:

1. Which staff member(s) are responsible for getting these materials and keeping them stocked?
2. Which staff member(s) are responsible for making sure these materials are available in the setting?
3. What procedure needs to be in place to check on availability of these materials regularly?
4. Do you want to make a flyer that is specific to the services that your setting provides? If yes, who will be responsible for this?

WORKSHEET #2B – General Education

B. General Education. In this strategy, providers or other staff bring up PrEP with all patients they see. All patients are provided with a certain basic level of PrEP education.

Considerations for this strategy:

1. Which staff member(s) will provide general education for patients?
2. When will general education take place?
3. What information is included in general PrEP education? Will patients be given any written materials?
4. How will referrals be made for further PrEP counseling or screening, if indicated?
5. How will general PrEP education be documented?
6. What are the pros/cons of having general PrEP education be conducted by providers versus counselors? Perhaps *general* information can be given by counselors, and then more targeted information can be done by providers?
7. What are the concrete steps you will need to take to put this strategy into place?

WORKSHEET #2C – Targeted Education via Screening

C. Targeted Education. In this strategy, only specific priority populations or patients who meet certain screening criteria are provided with PrEP education by staff. Screening can include a formal “tool” or can be based on information from a sexual history (see E). Other patients receive access to passive PrEP information (as in Section A, above).

Considerations for this strategy:

1. Who is your “target” for PrEP education? How are they defined (e.g., priority populations, specific screening criteria, etc.)?
2. How will you identify patients who meet these target criteria? (e.g., screening tool, intake form...)
3. What information will be included in this targeted PrEP education? How will referrals be made for further PrEP screening or prescription, if indicated?
4. Who will provide the targeted education and at what point in the visit?
5. How will targeted PrEP education be documented?
6. What are the concrete steps you will need to take to put this strategy into place?

WORKSHEET #2D – Targeted Education via Visit-Type or Chart-Based Triggers

D. Visit-Type or Chart-Based Triggers. In this strategy, PrEP education is linked to specific visit types (e.g., HIV testing visits, STI testing visits) or chart information (e.g., patient had an STI in the past year, patient was previously on PrEP).

Sample Options for Visit-Type or Chart-Based Triggers

- ☐ Staff bring up PrEP with all patients during **certain types of visits** (e.g., HIV testing, STI testing, PEP, contraception).
- ☐ Patients who meet **certain criteria are flagged in EMR** (e.g. STI in past year; previous use of PEP)

Considerations for this strategy:

- 1a. If you chose to select patients based on **visit-type**, which types of visits should trigger a PrEP conversation?
- 1b. If you chose **EMR flags**, what patients should be flagged? How will the flagging process be done and how often?
1. How will staff be reminded of the visit-type or EMR trigger?
2. What information will be included in this targeted PrEP education? How will referrals be made for further PrEP screening or prescription, if indicated?
3. Who will provide the targeted education and at what point in the visit?
4. How will targeted PrEP education be documented?
5. What are the concrete steps you will need to take to put this strategy into place?

WORKSHEET #2E – Targeted Education via Sexual History Taking

E. Sexual History Taking. In this strategy, all patients (or certain patients) receive a sexual history, with PrEP education and counseling as indicated. Utilizing this strategy means deciding which providers will engage in a sexual history, with which types of patients, and what that sexual history will include. This strategy is similar to targeted education (see C, above), but is based on sexual history conversation, rather than a screening tool.

Sample Options for Sexual History-Taking

- ☐ Staff engage **all patients** in a sexual history, and discuss PrEP with those who meet PrEP program eligibility criteria (see Worksheet #1)
- ☐ Staff engage **priority populations** in a sexual history, and discuss PrEP those who meet PrEP program eligibility criteria (see Worksheet #1)
- ☐ Staff engage all (or priority) patients in a sexual history, then **refer** patients who meet PrEP program eligibility criteria to PrEP counseling.

Considerations for this strategy:

1. Which patients should be engaged in a sexual history?
2. How are these patients identified?
3. Which staff member(s) should conduct a sexual history with patients and at what point in the visit?
4. What should a sexual history entail? What happens if a sexual history suggests that PrEP is indicated? What education is provided if a sexual history suggests that PrEP is not indicated?
5. How/where will a sexual history be documented?
6. What are the concrete steps you will need to take to put this strategy into place?

WORKSHEET #3 – Components of PrEP Education

What educational components will you include for patients at each stage? If you want to provide patients with specific materials, put a “check” next to the ones you can order and circle those you’d need to adapt or develop.

Educational Components	A. General Education	B. Targeted Education	C. Prescription Visit	D. Follow-Up Visits
Basic PrEP Information				
What is PrEP?				
What is PEP?				
What's involved in using PrEP				
Pros and Cons of PrEP				
PrEP/PEP are provided here				
PrEP Decision-Making				
Side Effects				
Long-Term Safety				
Limitations of PrEP				
Benefits/Risks for Pregnancy				
PrEP and condom use				
Paying for PrEP				
PrEP Adherence Support				
How to use PrEP (5 steps)				
How PrEP Works				
Importance of adherence				
Adherence strategies				
What to do if you miss a pill				
How to manage side effects				
Stopping PrEP				
Symptoms of Seroconversion				
Discontinuing PrEP				
Patient Education Materials				
NYCDOH PrEP Brochure				
CDC PrEP Brochure				
PrEP Information Sheet				
NYCDOH Users Guide				
Adherence Handout				
Adherence Worksheet				

WORKSHEET #4 – Medical Eligibility and Prescription Visit

Identify your setting's standard of care for prescription visits.

Standard of Care for PrEP Prescription Visit		
	Required	Recommended
A. Medical Screening and Immunization		
4 th Generation Rapid Testing for HIV		
NAAT or Viral Load Testing		
Verification of creatinine clearance > 60/mL		
Screening for STIs (3 sites)		
Hepatitis B serology/immunization		
Pregnancy testing		
Hepatitis A immunization		
Hepatitis C screening		
HPV immunization		
Meninococcus immunization		
B. Adherence Support		
Rationale for daily dosing		
Assist in plan to integrate pill taking into routine		
Discuss side effects and their management		
Address disclosure and concealment		
Discuss considerations for stopping PrEP		
Provision of PrEP Users Guide Brochure		
Adherence Worksheet		
C. Referrals		
Engagement/referral for primary care		
Engagement/referral for contraceptive services		
Referrals for mental health and substance use		
D. Prescription		
30 day prescription with follow-up visit		
90 day prescription		
2-week Check-in		

Notes:

WORKSHEET #5 – Follow-Up Visits

Identify your setting's standard of care for follow-up visits.

Standard of Care for Follow-up Visits			
	Every 3 months	Every 6 months	Every 12 months
HIV testing			
Acute infection assessment			
Adherence assessment			
Side effect Assessment			
Assessment of STI symptoms			
STI testing			
Monitor eCrCl			
Pregnancy testing			
Urinalysis			
Hepatitis C testing			
Discussion of need/desire to continue PrEP			
STI risk reduction counseling			
Answer questions			

Notes:

Discussion Questions

1. What will be the biggest challenges for implementation in your setting?
2. What training needs to you have for implementation?

WORKSHEET #6 – Paying for PrEP**I. Identify your setting's capacity to provide PrEP care to uninsured patients.**

<i>Do you provide...</i>	Free	Copay (\$)	No
Primary care to uninsured patients			
HIV testing to uninsured patients			
STI testing to uninsured patients			
Other lab testing (e.g., metabolic panel) to uninsured patients			

II. Identify your setting's capacity to provide medication assistance for PrEP.

<i>Can you provide...</i>	No	Yes, in house By whom?	Through Referral Where?
ACA navigation services			
Information to patients about what their current insurance will cover			
Assistance with Gilead MAP application			
Management of Gilead MAP monthly follow-up			
Receipt and distribution of PrEP medication for MAP recipients			
Assistance getting Gilead co-pay card			

Notes:

III. Based on your answers to I and II (above), will your clinic need to have any PrEP exclusion criteria by insurance status?

IV. If you want to increase your capacity to cover uninsured patients, what would you need?

WORKSHEET #7 – Division of Labor Overview**What is your setting's ideal division of labor?**

What is your ideal PrEP "Model"?	
Will your site have designated "PrEP Providers" or a "PrEP Team"?	
To what extent should tasks be specialized and to what extent should staff be cross-trained on different components?	
Who will coordinate PrEP services in your setting?	
Who will be responsible for tracking or documentation?	
What level of provider will be responsible for prescription?	
What level of provider will be responsible for follow-up?	
Will there be training requirements for PrEP providers?	
To what extent should tasks be specialized and to what extent should staff be cross-trained on different components?	

WORKSHEET #8 – Responsible Staff

What staff member(s) will be responsible for what parts of the PrEP process?	RESPONSIBLE STAFF
PrEP Referral and Education	
<input type="checkbox"/> Tell patients about PrEP program	
<input type="checkbox"/> Identification of PrEP referral factors	
<input type="checkbox"/> Take PrEP-focused Sexual History	
<input type="checkbox"/> Provide PrEP Education	
<input type="checkbox"/> Discuss how patient will pay for PrEP	
PrEP Insurance navigation	
<input type="checkbox"/> Referral/assistance with ACA navigation	
<input type="checkbox"/> Assistance with Gilead MAP application	
<input type="checkbox"/> Monthly follow-up for Gilead MAP patients	
<input type="checkbox"/> Coordination of medication distribution for MAP patients	
<input type="checkbox"/> Assistance with Gilead Co-Pay card	
PrEP Eligibility/Screening	
<input type="checkbox"/> Rapid HIV test	
<input type="checkbox"/> Metabolic panel	
<input type="checkbox"/> STI screening	
<input type="checkbox"/> Pregnancy test	
<input type="checkbox"/> Hepatitis serology and immunization	
PrEP Prescription	
<input type="checkbox"/> Adherence education	
<input type="checkbox"/> Explanation of side effects and management	
<input type="checkbox"/> Assess adherence self-efficacy	
<input type="checkbox"/> Provide targeted adherence counseling	
<input type="checkbox"/> Write prescription for Truvada	
Follow-up	
<input type="checkbox"/> Follow-up on CrCL and STI results (3 days)	
<input type="checkbox"/> 2-week check in about adherence and side effects	
<input type="checkbox"/> HIV testing at follow-up visits	
<input type="checkbox"/> STI testing at follow-up visits	
<input type="checkbox"/> Adherence assessment at follow-up visits	
<input type="checkbox"/> Urinalysis and CrCL at follow-up visits	
<input type="checkbox"/> Counseling at follow-up visits	

Worksheet #9 -- Division of Labor Chart

1. Enter staff titles into the columns below.
2. Add program components not currently listed in the blank rows, or cross-out rows that will not be provided at your setting.
3. Make "X" in each row indicating who will be responsible for each task.

PrEP Program Division of Labor				
A. PrEP Awareness and Engagement				
Screening and Triage				
Sexual History				
Basic PrEP Awareness				
B. PrEP Education/Counseling				
C. Benefits Counseling/Navigation				
D. Medical screening				
Physical exam				
Screen for acute HIV				
Lab tests				
Immunizations (if indicated)				
E. Prescription				
F. Adherence counseling				
G. Interim follow-up calls				
H. Visit follow-up				
Physical exam				
Side effects review				
Lab tests				
Prescription				
Adherence Counseling				
Benefits troubleshooting				

DISCUSSION QUESTIONS – BY WHOM will each piece of the PrEP package be done?

1. What challenges do you anticipate in terms of PrEP division of labor?
 - a. Purview Paradox (NMJ?)
 - b. Time constraints
 - c. Resource constraints
 - d. Coordination constraints

2. Based on the division of labor on the chart above, what are your staffing needs for your PrEP program

Worksheet #10 – Time and Events

	Initial	Q3 Month	Q6 Month	Annual
A. PrEP Awareness and Engagement				
Screening and Triage				
Sexual History				
Basic PrEP Awareness				
B. PrEP Education/Counseling				
What PrEP is, how it works, how you take it, what it doesn't do, side effects				
Discussion of whether PrEP is the right choice for the patient at this time				
Patients' feelings about the impact of PrEP on their sex life and sexual health				
C. Benefits Counseling/Navigation				
Assessment of current insurance status				
Enrollment in MAP				
Enrollment in other insurance program				
Enrollment in Gilead Co-Pay card				
Maintenance of benefits assistance program				
D. PrEP Medical Screening				
Verification of HIV-negative Status				
Verification of creatinine clearance > 60/mL				
Screening for STIs				
Hepatitis B serology/immunization				
Pregnancy testing				
E. Prescription				
30 day prescription with follow-up visit				
90 day prescription				
F. Adherence Counseling/Support				
Instructions about adherence, missed doses and side effects				
Provision of PrEP Users Guide Brochure				
Targeted adherence counseling				
2-week check-in				
G. Additional Immunization/Screening				
Hepatitis A immunization				
Hepatitis C screening				
Vaccination for HPV				
Vaccination for meningococcus				
H. Referrals				
Engagement/referral for primary care				
Engagement/referral for contraceptive services				
Referrals for mental health and substance use				

WORKSHEET #11 – Planning for Next StepsPrEP Staffing**I. Identify a PrEP point-person or “champion.”**

Ideally, this should be a person with significant authority within your setting and someone who has knowledge and connections with staff in different areas. This person will be responsible for implementing your PrEP action plan and establishing a PrEP program in your setting.

II. Identify a PrEP Coordinator.

This position is more administrative. Ideally, this would be a point-person for PrEP questions and calls for the setting. This person would work with providers to ensure that the PrEP protocol is being implemented and to facilitate its implementation. This person could do any of the following activities (as indicated by your protocol):

- Track & follow-up on patient labs (CrCL, STI testing)
- Coordinate Gilead MAP Applications and Monthly Follow-up
- Coordinate and distribute medications to MAP patients
- Conduct adherence check-ins at 2-weeks
- Staff a PrEP warmline for patients
- Ensure that PrEP patients come back for 3-month visits

Policies and Procedures

III. Based on what you've done today, how much "work" do you feel is left in each component of the protocol? What are the major decisions or negotiations that you face?

Component	How much work is left?				Decisions/Negotiations
	Almost None	Some	Quite a bit	All of it	
PrEP Eligibility and Referral					
PrEP Education					
PrEP Screening					
PrEP Prescription Visit					
PrEP Follow-up Visits					
Interim follow-up					
Timing of PrEP Components					
Division of Labor					

Materials and Resources**IV. What materials do you need and how can you get them?**

	I can make this	I can get this from:	Help!
<input type="checkbox"/> DOH PrEP Brochure			
<input type="checkbox"/> DOH PEP Brochure			
<input type="checkbox"/> DOH PrEP/PEP Posters			
<input type="checkbox"/> PrEP Basic Patient Education			
<input type="checkbox"/> DOH PrEP Users Guide			
<input type="checkbox"/> FAQs about PrEP for Front Desk Staff			
<input type="checkbox"/> FAQs about Side Effects			
<input type="checkbox"/> Provider Checklists – PrEP Education			
<input type="checkbox"/> Provider Checklists – Screening			
<input type="checkbox"/> Provider Checklists – Prescription Visit			
<input type="checkbox"/> Provider Checklists – Follow-Up			
<input type="checkbox"/> Information about MAP			
<input type="checkbox"/> Information about the Co-Pay card			

Identifying Training Needs

V. Identify your staff training needs by checking the boxes below. Which can you do in-house? Which do you need to identify resources for? Count the number of training needs and rank them in order of priority. Have you looked at the NYC Biomedical HIV Prevention Checklist?

Training Area	Availability	Rank
<input type="checkbox"/> PrEP Basics		
<input type="checkbox"/> FAQ from patients		
<input type="checkbox"/> PrEP-focused sexual history taking		
<input type="checkbox"/> How to help patients decide whether or not to take PrEP		
<input type="checkbox"/> PrEP adherence counseling		
<input type="checkbox"/> PrEP insurance coverage		
<input type="checkbox"/> Clinical guidelines for PrEP prescription and follow-up		
<input type="checkbox"/> Clinical update on PrEP prescription		
<input type="checkbox"/> Protocol Training		
<input type="checkbox"/> Documentation Training		

Communication And Feedback

VI. What mechanisms might you use for communication about implementation, QA and follow-up?

VII. How will you ensure that protocols are followed and feedback about protocol adherence is provided to staff?

WORKSHEET #12: Action Plan

Identify at least three goals for the development of your PrEP program when you get back to your setting. The goals should be "SMART":

Specific: What do you want to accomplish and who will be involved in accomplishing it?

Measureable: How will you measure whether/when this goal was accomplished?

Achievable: Make sure this goal is appropriate for the current stage of your setting. Do you need to achieve a different goal before this one?

Relevant: How will this goal move you toward meeting your ultimate objective of PrEP implementation? How does this goal rank in importance?

Timely: By what date (month/year) will you achieve this goal?

***If there are action steps that need to be achieved on the way to this goal, you can identify those too. Make sure that each action step is "SMART" as well.*

Goal #1:

Goal #2

Goal #3

(Add more!)

Use the table on the next page to specify your goals/action steps

IMPLEMENTATION WORKSHEETS

Goal/Action Step	Measurement of Success	Target Date	Responsible Staff
1.			
1a.			
1b.			
2.			
2a.			
2b.			
3.			
3a.			
3b.			