

Key Topic Reviews

Version 1.0

Key Topic Reviews

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Reaching Highest Priority Patients

- 1. The risk-based screening tools and algorithms that are often used to determine PrEP eligibility don't work and stigmatize patients.
 - These papers demonstrate that commonly used risk-based algorithm and screening tools to determine PrEP eligibility (CDC guidelines, the HIRI-MSM, and the Gilead tool) did not accurately identify risk, especially among young Black men who have sex with men.
 - o <u>Lancki N, Almirol E, Alon L, McNulty M, Schneider JA. Preexposure prophylaxis guidelines have low sensitivity</u> for identifying seroconverters in a sample of young black MSM in Chicago. AIDS. 2018 Jan;32(3):383-92.
 - o Hoots BE, Finlayson T, Nerlander L, Paz-Bailey G, National HIV Behavioral Surveillance Study Group, Wortley P, Todd J, Sato K, Flynn C, German D, Fukuda D. Willingness to take, use of, and indications for pre-exposure prophylaxis among men who have sex with men—20 US cities, 2014. Clinical Infectious Diseases. 2016 Jun 9:63(5):672-7.
 - This paper applies risk criteria retrospectively to a cohort of Black women living with HIV in the Southeastern United States. The author concludes that standard risk assessment criteria would have failed to identify these women as patients who would have benefit from PrEP prior to their diagnosis
 - o <u>Tims-Cook Z. A Retrospective Assessment of Antecedent Pre-Exposure Prophylaxis Eligibility of HIV-Positive Women in the South. AIDS Patient Care STDS. 2019 Sep;33(9):384-387.</u>
 - This paper explains the ways in which HIV stigma is activated by risk assessments and screening, and may alienate patients. It also connects risk assessments to larger health programs and policies that reinforce or exacerbate stigma and can alienate patients.
 - o <u>Golub SA. PrEP Stigma: Implicit and Explicit Drivers of Disparity. Curr HIV/AIDS Rep. 2018 Apr;15(2):190-</u>197.
- 2. Anticipating stigma from healthcare providers or setting can deter patients from seeking out sexual health care, such as PrEP.
 - This paper demonstrates that perceptions of LGBTQ- and/or HIV-related stigma can act as barriers to PrEP awareness and uptake.
 - Cahill S, Taylor SW, Elsesser SA, Mena L, Hickson D, Mayer KH. Stigma, medical mistrust, and perceived racism may affect PrEP awareness and uptake in black compared to white gay and bisexual men in Jackson, Mississippi and Boston, Massachusetts. AIDS Care. 2017 Nov;29(11):1351-1358.

- This paper presents data regarding barriers to PrEP use for heterosexual cisgender women in the US, who reported that communicating about their sexuality or their potential need for PrEP with health care providers was a significant barrier. The women were concerned that disclosure of HIV risk behaviors to their providers would result in judgmental responses or harsh treatment.
 - o <u>Goparaju L, Praschan NC, Warren-Jeanpiere L, Experton LS, Young MA, Kassaye S. Stigma, Partners, Providers and Costs: Potential Barriers to PrEP Uptake among US Women. J AIDS Clin Res.</u> 2017;8(9):730.

3. Universal HIV/STI screening and PrEP education is more beneficial and cost effective than risk-based screening.

- This paper summarizes data on the failure of risk-based screening for sexually transmitted infections (STIs), and reviews the empirical evidence for the benefits and cost-effectiveness of opt-out screening strategies.
 - o <u>Hull S, Kelley S, Clarke JL. Sexually transmitted infections: compelling case for an improved screening strategy. Popul Health Manag. 2017;20(S1):S1–S11.</u>

4. Emphasizing benefits and self-efficacy —rather than risk and fear —is more successful in motivating patients toward prevention and care behavior.

- These papers provide evidence that "objective" risk is not associated with risk perception for most patients, and may not be an effective motivator for health behavior.
 - o <u>Biello KB, Edeza A, Montgomery MC, Almonte A, Chan PA. Risk perception and interest in HIV pre-exposure prophylaxis among men who have sex with men with rectal gonorrhea and chlamydia infection. Archives of sexual behavior. 2019 May;48(4):1185-90.</u>
 - o <u>Gallagher T, Link L, Ramos M, Bottger E, Aberg J, Daskalakis D. Self-perception of HIV risk and candidacy for pre-exposure prophylaxis among men who have sex with men testing for HIV at commercial sex venues in New York City. LGBT health. 2014 Sep 1;1(3):218-24.</u>
- This paper presents data from four studies that conclude that encouraging individuals to examine, compare, or focus on their personal risk actually increases reactance and optimistic bias (believing oneself to be at lower risk than others).
 - o <u>Weinstein ND, Klein WM. Resistance of personal risk perceptions to de-biasing interventions. Health psychology. 1995 Mar;14(2):132.</u>
- This paper reviews research on reactance and defensive response in health promotion, and provides evidence for the importance of self-affirmation (focusing on personal strengths and values) in reducing reactance and increasing effectiveness of health promotion messages.
 - o <u>Schüz N, Schüz B, Eid M. When risk communication backfires: Randomized controlled trial on self-affirmation and reactance to personalized risk feedback in high-risk individuals. Health Psychology.</u> 2013 May;32(5):561.
- This meta-analysis provides evidence that interventions that heighten risk appraisals (patients' risk perception and perceived severity of infection) are much more likely to be associated with health behavior change when they are combined with a focus on response efficacy (a belief that the behavior change will work to protect me from the illness) and self-efficacy (a belief that I can engage in the desired behavior).
 - o <u>Sheeran P, Harris PR, Epton T. Does heightening risk appraisals change people's intentions and behavior? A meta-analysis of experimental studies. Psychological bulletin. 2014 Mar;140(2):511.</u>

When we target individuals or groups, they feel targeted.

Even well-meaning efforts to focus HIV prevention messaging or programs on certain patient
populations whose demographic characteristics match epidemiological trends in the epidemic
make people feel judged, pegged, or "marked" for HIV risk. This type of targeting risks
exacerbating stigma and alienating patients from healthcare programs. Assessment, education, and
services should be presented to patients as universal efforts to improve the sexual health of the
whole community.

Although risk-based screening tools to determine HIV testing or PrEP eligibility may be easier for providers, they are bad for patients.

• Clinics should consider protocols that universalize and normalize sexual health, including routine HIV/STI testing and PrEP education. Ask patients about their biggest sexual health concerns, rather than their "risk behaviors." Clinics or providers can adopt the GOALS Framework for Sexual History and Health as a model for brief, patient-centered sexual history conversations with universal screening and education goals.

"HIV risk" is not a motivator

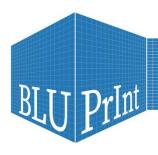
Patients who may have indications for PrEP often do not view themselves as "at risk" for HIV
infection. Focusing on objective risk factors does not motivate health behavior change and may
prove to be counter-productive and increase resistance to HIV prevention.

HIV prevention options and strategies should be presented in terms of their benefits – for empowerment, self-efficacy, and peace of mind.

• For example, explain to patients that they might want to use PrEP to increase control over their sexual health, reduce their anxiety about HIV, or increase sexual satisfaction and intimacy in sexual encounters.

BLUPrInt Tools

- PrEP Awareness & Engagement
- PrEP Decision-Making Counseling



Empowering Choice and Decision Making

- 1. Patients process information about new HIV prevention modalities by integrating information into their existing knowledge and understanding.
 - This paper demonstrates that LGBTQ young people of color have a sophisticated understanding of
 concepts such as immunology, antibodies, half-life, and extended release, but need focused
 education and support to apply this knowledge to understanding how biomedical prevention
 (especially emerging modalities) can work for them.
 - o <u>Golub SA, Meyers K, Enemchukwu C. Perspectives and Recommendations from LGBTQ Youth of Color regarding Engagement in Biomedical HIV Prevention. The Journal of adolescent health: official publication of the Society for Adolescent Medicine. 2020 Mar;66(3):281</u>
- 2. Patients want providers to acknowledge the wealth of knowledge and lived experience that they bring to conversations about their own health.
 - These papers present evidence that providers who prioritize learning about their patients' sexual identity and practices deliver more personalized and informed sexual health care. Engaging in open conversation about sex may help minimize stigma experienced by patients.
 - o <u>Maloney, K. M., Krakower, D. S., Ziobro, D., Rosenberger, J. G., Novak, D., & Mayer, K. H. (2017). Culturally competent sexual healthcare as a prerequisite for obtaining preexposure prophylaxis: findings from a qualitative study. LGBT health, 4(4), 310-314.</u>
 - o <u>Yang, C., Krishnan, N., Painter, J. E., & Latkin, C. (2019). The association between disclosure of same sex</u> <u>behavior to healthcare providers and PrEP awareness among BMSM in Baltimore. AIDS and Behavior, 23(7), 1888-1892.</u>
 - Calabrese, S. K., Magnus, M., Mayer, K. H., Krakower, D. S., Eldahan, A. I., Hawkins, L. A. G., . . . Betancourt, J. R. (2016). Putting PrEP into practice: lessons learned from early-adopting US providers' firsthand experiences providing HIV pre-exposure prophylaxis and associated care. PLoS One, 11(6), e0157324.
- 3. Using inclusive language with patients can be motivating and empowering.
 - These studies present preliminary findings that motivational interviewing (e.g. reflective
 questioning, person-centered and non-judgmental communication) may be an effective strategy
 utilized by clinicians to increase PrEP uptake.
 - Dale, S. K. (2020). Using Motivational Interviewing to Increase PrEP Uptake Among Black Women at Risk for HIV: an Open Pilot Trial of MI-PrEP. Journal of racial and ethnic health disparities, 7(5), 913-927.
 - Moitra, E., van den Berg, J. J., Sowemimo-Coker, G., Chau, S., Nunn, A., & Chan, P. A. (2019). Open pilot trial of a brief motivational interviewing-based HIV pre-exposure prophylaxis intervention for men who have sex with men: preliminary effects, and evidence of feasibility and acceptability. AIDS care.

- These papers provide specific strategies to improve providers' communication style, especially with LGBTQIA+ patients, including: positively framing sexual health messages, normalizing sexual behavior, avoiding stereotypical assumptions and better understanding their patients' personal lives.
 - o Schwartz, J., & Grimm, J. (2020). Communication Strategies for Discussing PrEP with Men Who Have Sex with Men. Journal of Homosexuality, 1-14.
 - o <u>Devarajan, S., Sales, J. M., Hunt, M., & Comeau, D. L. (2020). PrEP and sexual well-being: A qualitative study on PrEP, sexuality of MSM, and patient-provider relationships. AIDS care, 32(3), 386-393.</u>
 - o <u>Margolies, Liz LCSW; Brown, Carlton G. PhD, RN, AOCN, NEA-BC, FAAN Increasing cultural competence</u> with LGBTQ patients, Nursing: June 2019 Volume 49 Issue 6 p 34-40
- 4. Shared decision-making is a collaborative communication strategy used in person-centered healthcare to support patients in choosing an HIV prevention method based on their preferences, needs and values.
- These studies indicate that shared decision-making can be particularly useful when working with individuals with intersectional identities and/or those who belong to multiple groups that have historically been marginalized in health care.
 - o <u>Peek, Monica E., et al. "Development of a conceptual framework for understanding shared decision making among African-American LGBT patients and their clinicians." Journal of general internal medicine 31.6 (2016): 677-687.</u>
 - o <u>Moira C. McNulty, M. Ellen Acree, Jared Kerman, H. "Herukhuti" Sharif Williams & John A. Schneider</u> (2021) Shared decision making for HIV pre-exposure prophylaxis (PrEP) with black transgender women, Culture, Health & Sexuality.
 - O <u>Baig, A. A., Lopez, F. Y., DeMeester, R. H., Jia, J. L., Peek, M. E., & Vela, M. B. (2016). Addressing Barriers to Shared Decision Making Among Latino LGBTQ Patients and Healthcare Providers in Clinical Settings. LGBT health, 3(5), 335–341.</u>
- There is evidence that patient-led decision-making (a type of shared decision-making) may be particularly well-suited for HIV prevention decisions. This strategy is appropriate when there are several treatment or prevention options that are equally valid and the decision can be primarily made by the patient.
 - O Sewell, W.C., Solleveld, P., Seidman, D. et al. Patient-Led Decision-Making for HIV Preexposure Prophylaxis. Curr HIV/AIDS Rep 18, 48–56 (2021).
- Research suggests organizational and systems level characteristics (e.g. leadership, workflow, payment models and clinical practice protocols) are integral for the successful adoption of shared decision-making by providers.
 - o <u>Alsulamy, N., Andrew, L., Thokala, P., & Alessa, T. (2020). What influences the implementation of shared decision making: an umbrella review. Patient Education and Counseling.</u>
 - O Scholl, I., LaRussa, A., Hahlweg, P., Kobrin, S., & Elwyn, G. (2018). Organizational-and system-level characteristics that influence implementation of shared decision-making and strategies to address them—a scoping review. Implementation Science, 13(1), 1-22.

Patients who may benefit from PrEP are diverse in their demographics and sexual healthcare needs.

 Better understanding a patient's lived-experience, sexual practices and motivations for using PrEP can help a provider recommend an HIV prevention modality best suited for that patient's needs and lifestyle.

Inclusive and affirming language should be used when developing HIV prevention programs and policies.

• Gender-neutral terms, person-first language and the use of descriptive phrases over labels are small changes that help cultivate safe spaces where patients feel comfortable disclosing sensitive information around their sexual practices and health.

Shared decision-making is a strategy used to overcome implicit provider bias and inequitable health communication across diverse patient populations.

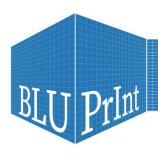
• Routinizing patient-provider collaborations promotes equity by enabling all patients to take ownership of their health and make an informed decision when considering the various HIV prevention modalities available.

The implementation of shared decision-making must be considered beyond interpersonal interactions.

• Integrating shared decision-making approaches into clinical interactions will require strategies to incentivize their use at the organization and systems level, for example reimbursements for time spent on shared decision-making.

BLUPrInt Tools

- PrEP Decision-Making Counseling
- PrEP Financial Navigation



Supporting Adherence and Persistence

- 1. Decreasing patient discomfort both physical and emotional can improve adherence and retention in care
- This paper demonstrates how patients' concern for long-term consequences of PrEP use can impact their medication adherence.
 - Holloway IW, Dougherty R, Gildner J, et al. Brief Report: PrEP Uptake, Adherence, and Discontinuation Among California YMSM Using Geosocial Networking Applications. J Acquir Immune Defic Syndr. 2017;74(1):15-20
- These papers present evidence on reasons for discontinuing PrEP and find that undesirable side effects are often primary or contributing factors.
 - <u>Whitfield THF, John SA, Rendina HJ, Grov C, Parsons JT. Why I Quit Pre-Exposure Prophylaxis (PrEP)? A Mixed-Method Study Exploring Reasons for PrEP Discontinuation and Potential Re-initiation Among Gay and Bisexual Men. AIDS Behav. 2018 Nov;22(11):3566-3575</u>
 - o <u>Chan PA, Mena L, Patel R, Oldenburg CE, Beauchamps L, Perez-Brumer AG, Parker S, Mayer KH, Mimiaga MJ, Nunn A. Retention in care outcomes for HIV pre-exposure prophylaxis implementation programmes among men who have sex with men in three US cities. J Int AIDS Soc. 2016 Jun 13;19(1):20903</u>
- This conference presentation describes the anxiety or stress that could accompany the unintended disclosure of PrEP use and potentially interfere with adherence.
 - O Goicochea P, Lama JR, McMahan V, et al. Social adverse events experienced by trans women and other men who have sex with men (MSM) participating in a HIV pre-exposure prophylaxis (PrEP) trial.

 International AIDS Society. Rome 2011.
- This paper underscores the ways in which contextual cues in healthcare settings can signal
 safety for marginalized groups and contribute to a sense of trust between patients and
 providers; when these cues are present, they contribute to improved adherence to medical
 counseling.
 - o <u>Cipollina, R., & Sanchez, D.T. (2019). Reducing health care disparities through improving trust: An</u> <u>identity safety cues intervention for stigmatized groups. Translational Issues in Psychological Science, 5(4), 315-325.</u>

2. Taking time to explain *why* patients should follow care plans significantly increases the likelihood that they will do so.

- Applying lessons learned from other medications, these papers suggest that medication
 adherence is strongly associated with patients' understanding of drug information, especially at
 initiation.
 - o Rosenberg MJ, Waugh MS, Meehan TE. Use and misuse of oral contraceptives: risk indicators for poor pill taking and discontinuation. Contraception. May 1995;51(5):283-288.
 - o <u>Watson-Jones D, Weiss HA, Rusizoka M, et al. Effect of herpes simplex suppression on incidence of HIV among women in Tanzaniai. N Eng J Med. Apr 10 2008;358(15):1560-1571.</u>

3. Patients need information, tools, and strategies for integrating HIV prevention into their everyday lives.

- This paper finds that the best strategy for prescribing PrEP is one in which the provider contributes medical expertise, and the patient contributes expertise on their behavioral history, goals, and logistical ability to integrate PrEP into their daily life.
 - Calabrese SK, Magnus M, Mayer KH, Krakower DS, Eldahan AI, Gaston Hawkins LA, Hansen NB, Kershaw TS, Underhill K, Betancourt JR, Dovidio JF. Putting PrEP into Practice: Lessons Learned from Early-Adopting U.S. Providers' Firsthand Experiences Providing HIV Pre-Exposure Prophylaxis and Associated Care. PLoS One. 2016 Jun 15:11(6)e0157324.
- This paper demonstrates that integrating oral contraception pill-taking into a regular routine was the strongest single factor associated with adherence.
 - o <u>Rosenberg MJ, Waugh MS, Meehan TE. Use and misuse of oral contraceptives: risk indicators for poor pill</u> taking and discontinuation. Contraception. May 1995;51(5):283-288.
- This paper highlights the reasons that participants gave for adhering to PrEP medication and found that routine formation and use of tools was a facilitator of adherence.
 - o <u>Corneli A, Perry B, Agot K, Ahmed K, Malamatsho F, Van Damme L. Facilitators of adherence to the</u> study pill in the FEM-PrEP clinical trial. PLoS One. 2015 Apr 13;10(4):e0125458.

4. Self-efficacy is a critical predictor of PrEP adherence and persistence.

- This paper demonstrates the impact on self-efficacy for facilitating HIV treatment adherence that could be applied to PrEP implementation efforts.
 - o Bazzi AR, Draioni ML, Biancarelli DL, Harman JJ, Mimiaga MJ, Mayer KH, Biello KB. Systematic review of HIV treatment adherence research among people who inject drugs in the United States and Canada: evidence to inform pre-exposure prophylaxis (PrEP) adherence interventions. BMC Public Health. 2019 Jan 8;19(1):31.



- These papers emphasize the importance of self-efficacy in PrEP medication adherence on PrEP uptake and demonstrate that PrEP adherence self-efficacy may impact patients' decision-making around PrEP, including for young black men.
 - o <u>Golub SA, Fikslin RA, Goldberg MH, Peña SM, Radix A. Predictors of PrEP Uptake Among Patients with Equivalent Access. AIDS Behav. 2019 Jul;23(7):1917-1924.</u>
 - o <u>Serota DP, Rosenberg ES, Sullivan PS, Thorne AL, Rolle CM, Del Rio C, Cutro S, Luisi N, Siegler AJ, Sanchez TH, Kelley CF. Pre-exposure Prophylaxis Uptake and Discontinuation Among Young Black Men Who Have Sex With Men in Atlanta, Georgia: A Prospective Cohort Study. Clin Infect Dis. 2020 Jul 27;71(3):574-582.</u>
- This conference presentation highlights that the strongest predictor at each step of the PrEP cascade (i.e., acceptance of navigation and referral, PrEP initiation, and sustained PrEP use) was a personal PrEP efficacy scale that include measures on positive attitudes toward PrEP pills, self-efficacy for pill-taking, and confidence in PrEP's ability to work "for me."
 - o <u>Golub SA, Unger ZD, Allen AS, Enemchukwu CU, Borges CM, Pathela P, Hedberg T, Gandhi A, Edelstein ZR, Myers J. Optimizing PrEP Cascade Outcomes for Sexual Health Clinic Navigation. Conference on Retroviruses and Opportunistic Infections; 2020; Boston, Massachusetts.</u>

5. Logistical and structural barriers can hinder adherence and persistence on PrEP.

- These papers are a few of the many that document the logistical and structural challenges that have presented barriers to PrEP access, adherence, and persistence, such as the high price of medication, inadequate insurance coverage, location of PrEP access points, and lack of flexible clinic hours.
 - o <u>Golub SA, Gamarel KE, Rendina HJ, Surace A, Lelutiu-Weinberger CL. From efficacy to effectiveness:</u> <u>facilitators and barriers to PrEP acceptability and motivations for adherence among MSM and transgender</u> women in New York City. AIDS Patient Care STDS. 2013 Apr;27(4):248-54.
 - o Arnold T, Brinkley-Rubinstein L, Chan PA, Perez-Brumer A, Bologna ES, Beauchamps L, Johnson K, Mena L, Nunn A. Social, structural, behavioral and clinical factors influencing retention in Pre-Exposure Prophylaxis (PrEP) care in Mississippi. PLoS One. 2017 Feb 21;12(2):e0172354.
 - o Whitfield THF, John SA, Rendina HJ, Grov C, Parsons JT. Why I Quit Pre-Exposure Prophylaxis (PrEP)? A Mixed-Method Study Exploring Reasons for PrEP Discontinuation and Potential Re-initiation Among Gay and Bisexual Men. AIDS Behav. 2018 Nov;22(11):3566-3575.
- These papers demonstrate that structural and logistical barriers significantly impact communities
 that have been prioritized for HIV prevention, such as Black and Latino/a MSM and transgender
 women and people living in the Southern U.S.
 - o <u>Nieto O, Brooks RA, Landrian A, Cabral A, Fehrenbacher AE. PrEP discontinuation among Latino/a and Black MSM and transgender women: A need for PrEP support services. PLoS One. 2020 Nov 5;15(11):e241340</u>
 - Sullivan PS, Mena L, Elopre L, Siegler AJ. Implementation Strategies to Increase PrEP Uptake in the South. Curr HIV/AIDS Rep. 2019 Aug;15(4):259-269.

Patients appreciate understanding how PrEP works and why adherence matters.

• Giving PrEP users a clear message about the scientific evidence behind adherence to PrEP is critical, whether patients are following a daily regimen or an event-driven/ 2-1-1 dosing strategy.

Embrace positive messaging.

• In contrast to focusing on risk, data suggest the importance of messaging and counseling that enhances self-efficacy beliefs around PrEP use. Providers can help build patients' confidence in seeing PrEP as an HIV prevention strategy that will work for them.

Context matters.

• Sustained adherence to PrEP regimens will be possible only to the extent that patients are able to incorporate PrEP into their everyday lives. Providers can support patients in building routines that will integrate PrEP into their daily life and developing strategies for when that routine is disrupted.

Side effects aren't a side issue for patients.

• Uncomfortable side effects, such as nausea and diarrhea, can dissuade patients from initiating, adhering to, and persisting on PrEP. It is critical that patients are informed of potential side effects, strategies to minimized side effects, and are supported in stopping PrEP if they do experience intolerable side effects. At PrEP initiation, providers can help patients think through which side effects they are and are not willing to tolerate and develop specific action plans if intolerable side effects occur.

Disclosure happens.

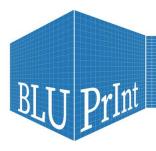
• Planned or unplanned disclosure of one's PrEP use happens, and providers can help decrease patient discomfort (and therefore enhance adherence and persistence) by facilitating strategies to address disclosure. Patients may want assistance considering to whom and in what contexts they would disclose their PrEP use and how they would respond to an accidental disclosure.

New PrEP modalities may be a game-changer.

• As more PrEP modalities become available (i.e., long-acting injectables, vaginal rings, etc.), barriers to adherence and persistence will need to be integrated into decision-making counseling. Providers should help patients consider the different side effect profiles, disclosure concerns, and contexts that may affect HIV prevention method selection. Additionally, novel modalities will introduce new challenges to adherence and persistence that will require new support strategies. For example, medication adherence strategies may need to expand to support study visit adherence; planning responses to disclosure may need to include responses to a partner feeling the vaginal ring.

BLUPrINT Tools

- PrEP Adherence & Sustainment Support
- PrEP Financial Navigation



Enhancing Patient-Provider Interactions

What We Know

1. Provider communication is a behavioral skill that can be learned

- This paper synthesizes the evidence that provider communication skills (i.e., open-ended questions, active listening, accessible language, and demonstrating interest in the patient) are associated with patient satisfaction of care and improved health outcomes.
 - o <u>Meyers K, Price D, Golub S. Behavioral and social science research to support accelerated and equitable implementation of long-acting preexposure prophylaxis. Curr Opin HIV AIDS. 2020 Jan;15(1):66-7.</u>
- This paper demonstrates that patient provider communication skills can be taught and can increase both patient satisfaction and the physician experience, including improved self-efficacy and reduced burnout.
 - o <u>Boissy A, Windover AK, Bokar D, Karafa M, Neuendorf K, Frankel RM, Merlino J, Rothberg MB.</u>
 <u>Communication Skills Training for Physicians Improves Patient Satisfaction. J Gen Intern. Med. 2016</u>
 Jul;31(7):755-61

2. Improving provider communication skills and use of inclusive language can reduce stigma

- This paper points to the ways in which young, Black MSM feel targeted and marginalized by current PrEP messaging, suggesting that broad, inclusive language in PrEP messaging would be equally relevant to patients and be less stigmatizing.
 - o <u>Rogers BG, Whiteley L, Haubrick KK, Mena LA, Brown LK. Intervention Messaging About Pre-Exposure</u> <u>Prophylaxis Use Among Young, Black Sexual Minority Men. AIDS Patient Care STDS. 2019 Nov;33(11):473-481.</u>
- This paper summarizes aspects of PrEP care that can exacerbate and perpetuate PrEP stigma and highlights the ways in which language around PrEP candidacy (i.e., for patients "at very high risk" of HIV infection) can fuel stigma.
 - o <u>Golub SA. PrEP Stigma: Implicit and Explicit Drivers of Disparity. Curr HIV/AIDS Rep. 2018 Apr;15(2):190-</u>197
- This paper qualitative explores how patient-provider communication impacts PrEP decision-making for women, finding that the decision to use PrEP is facilitated by trusting their provider, provider support, and receiving a specific and tailored recommendation for PrEP use by their provider.
 - D Jackson GY, Darlington CK, Van Tieu H, Brawner BM, Flores DD, Bannon JA, Davis A, Frye V, Chittamuru D, Gugerty P, Koblin BA, Teitelman AM. Women's view on communication with health care providers about pre-exposure prophylaxis (PrEP) for HIV prevention. Cult Health Sex. 2021 Feb 4:1-16

3. Addressing provider bias (both current and historical) can build trust

- This paper demonstrates how a patient's race/ethnicity can impact their trust in their provider and, as a result, their willingness to consider PrEP use
 - o <u>Braksmaier A, Fedor TM, Chen SR, Corales R, Holt S, Valenti W, McMahon JM. Willingness to Take PrEP</u> for HIV Prevention: the Combined Effects of Race/Ethnicity and Provider Trust. AIDS Educ Prev. 2018 Feb;30(1):1-12.

4. Tailored counseling, including a shared decision-making approach, can center patients' needs to increase PrEP acceptability

- This paper draws parallels between contraceptive counseling and HIVI prevention counseling and summarizes research to support the development of tools that support patient-centered communication, address provider bias, and adopt a shared decision-making approach to PrEP use
 - o <u>Meyers K, Price D, Golub S. Behavioral and social science research to support accelerated and equitable</u> implementation of long-acting preexposure prophylaxis. Curr Opin HIV AIDS. 2020 Jan;15(1):66-72
- This review of decision aids in a variety of screening or treatment circumstances demonstrates
 that patients who use decision aids feel more knowledgeable and informed, are clearer about
 their values, play a more active role in decision-making and have more accurate risk
 perceptions.
 - o <u>Stacey D, Légaré F, Lewis K, Barry MJ, Bennett CL, Eden KB, Holmes-Royner M, Llewellyn-Thomas H, Lyddiatt A, Thomson R, Trevena L. Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev. 2017 Apr 12;4(4):CD001431.</u>



Patients-provider communication can harm or heal.

• Provider communication skills can be learned and harnessed to improve patient satisfaction and health outcomes. Using inclusive language and discussions that demonstrate that a provider is listening and cares can build trust, reduce stigma, and increase patients' receptivity to care.

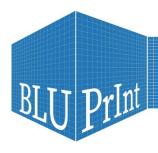
Shared decision-making is key in an expanding PrEP landscape.

• A shared decision-making approach in which the provider offers clinical expertise and the patient contributes expertise on their behavioral history and health-seeking goals offers a roadmap for helping patients navigate multiple HIV prevention modalities. Lessons from contraception and other fields in which health decisions are preference-sensitive should be harnessed to improve PrEP access

BLUPrInt Tools

- PrEP Awareness & Engagement
- PrEP Decision-Making Counseling





Minimizing Structural Barriers and Stigma

- 1. Overcoming logistical and financial barriers to PrEP is critical for expanding equitable access.
 - This paper describes key barriers to PrEP initiation and continuation at a community-based clinic, including: number of doctor visits required, long wait times, distance to clinic, insurance issues, and cost of medication.
 - O <u>Hojilla, J., Vlahov, D., Crouch, PC. et al. HIV Pre-exposure Prophylaxis (PrEP) Uptake and Retention</u>
 <u>Among Men Who Have Sex with Men in a Community-Based Sexual Health Clinic. AIDS Behav 22, 1096–1099 (2018).</u>
 - This paper presents evidence for structural and financial factors driving disparities in PrEP retention in a study with young, majority Black MSM in Mississippi.
 - o <u>Arnold T, Brinkley-Rubinstein L, Chan PA, Perez-Brumer A, Bologna ES, Beauchamps L, et al. (2017)</u> Social, structural, behavioral and clinical factors influencing retention in Pre-Exposure Prophylaxis (PrEP) care in Mississippi. PLoS ONE 12(2): e0172354.
 - This paper describes the interaction between syndemic factors (e.g., intimate partner violence, substance use, poverty) and structural factors (e.g., poor access to social services, transport and childcare) as barriers to PrEP adoption for Black women.
 - o <u>Liesl A. Nydegger, Julia Dickson-Gomez & Thant Ko Ko (2021) Structural and syndemic barriers to PrEP adoption among Black women at high risk for HIV: a qualitative exploration, Culture, Health & Sexuality, 23:5, 659 673.</u>
- 2. Structural barriers can impede PrEP access and exacerbate clients' alienation from the healthcare system
 - This paper provides evidence that when given free, low threshold access to PrEP, patients are more likely to accept and maintain a PrEP prescription.
 - o <u>Golub, S.A., Fikslin, R.A., Goldberg, M.H. et al. Predictors of PrEP Uptake Among Patients with Equivalent Access. AIDS Behav 23, 1917–1924 (2019).</u>
 - This paper reviews the evidence that the way PrEP provision systems are organized make many women in the U.S. feel like biomedical HIV prevention is not "for them."
 - O Goparaju, L., Praschan, N. C., Warren-Jeanpiere, L., Experton, L. S., Young, M. A., & Kassaye, S. (2017). Stigma, Partners, Providers and Costs: Potential Barriers to PrEP Uptake among US Women. Journal of AIDS & clinical research, 8(9), 730.

3. Clinic-level protocols and policies can either exacerbate stigma or mitigate against it.

- This paper reviews the ways in which HIV stigma manifests in health care settings and provides specific recommendation for reducing stigma at the environmental and policy levels.
 - o <u>Nyblade L, Stangl A, Weiss E, Ashburn K. Combating HIV stigma in health care settings: what works?</u> Journal of the international AIDS Society. 2009;12(1):1-7.
- This paper explains how practice norms -- such as discussing or offering PrEP only in response to direct patient requests – favor more privileged groups. Protocols and policies that allow for a high-level of provider discretion in PrEP prescription may limit access and exacerbate inequity.
 - o <u>Calabrese, S. K., Tekeste, M., Mayer, K. H., Magnus, M., Krakower, D. S., Kershaw, T. S., . . . Hansen, N. B.</u> (2019). Considering Stigma in the Provision of HIV Pre-Exposure Prophylaxis: Reflections from <u>Current Prescribers. AIDS patient care and STDs, 33(2), 79-88.</u>
- This paper examines the ways in which complicated protocols for PrEP provision (e.g., requiring multiple follow-up visits prior to full PrEP prescription) can send the message to priority populations that their sexual health does not matter. Improving the ease of these systems makes patients feel that their sexual health actually matters to their providers.
 - o <u>Cipollina, R., & Sanchez, D.T. (2019). Reducing health care disparities through improving trust: An</u> identity safety cues intervention for stigmatized groups. Translational Issues in Psychological <u>Science, 5(4), 315-325</u>.

4. Implementation strategies that include navigation and financial management/support can reduce burdens on patients.

- This paper provides evidence that PrEP navigation systems that facilitate both financial and logistical aspects of PrEP access (e.g., medication assistance, visit co-pays, appointment scheduling and reminders) increase PrEP uptake and retention across a variety of different patient populations.
 - o <u>Doblecki-Lewis, S., Butts, S., Botero, V., Klose, K., Cardenas, G., & Feaster, D. (2019). A randomized study of passive versus active PrEP patient navigation for a heterogeneous population at risk for HIV in South Florida. Journal of the International Association of Providers of AIDS Care (JIAPAC), 18, 2325958219848848.</u>

Stigma is perpetuated at the structural level within clinics.

• PrEP protocols that are burdensome to clients can send the message that PrEP and sexual healthcare in general is "not for them," since it is so hard to access.

Cultural competency trainings may impact individual biases of providers, but don't necessarily address structural factors in clinical settings that can perpetuate stigma and disparities in access.

• While it is of paramount importance that providers and staff are trained to examine their implicit biases and how these biases can impact their decision making, changing clinical protocols to reduce burden on patients can serve as a structural intervention to reduce stigma.

Clinics that prioritize low threshold, easy-access systems of PrEP delivery and that invest in financial and logistical patient navigation and support are able to reduce disparities in PrEP access.

Patients who feel like their healthcare providers genuinely care about their sexual health and are
invested in helping them access health care services are more likely to engage in care. Clinics can help
foster this experience for patients by easing the logistical burden of PrEP initiation and retention and
creating systems for direct communication when questions or concerns arise.

The introduction of more than one PrEP modality offers an opportunity to reimagine PrEP provision.

 Health system and providers should capitalize on lessons learned from oral PrEP as they introduce new forms of PrEP, with particular attention to creating systems of care that minimize burden on clients.

BLUPrInt Tools

- Planning Roadmap
- <u>Visit Flow and Staffing Models</u>
- PrEP Awareness & Engagement
- PrEP Financial Navigation





Monitoring & Evaluating Programs

- 1. Health centers can monitor and evaluate (M&E) their programs to assess progress toward programmatic goals, identify challenges, and facilitate program adaptation to improve service delivery and reach the desired outcomes.
 - This module developed by the World Health Organization (WHO) provides information on how to monitor and evaluate the performance of PrEP programs, and how health providers can use actionable data for decision-making and quality improvement.
 - World Health Organization. WHO Implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection: module 5: monitoring and evaluation. World Health Organization; 2018.
 - BLUPrInt has developed a set of <u>Quality Assurance Metrics</u> that can be integrated into PrEP program evaluation.
- 2. A logic framework is a useful tool that health centers can use to map out available resources and identify the objectives of a program and how they will be measured. The tool can help program implementers articulate what the inputs, outcome, and impact of the program are, and specify indicators for M&E activities.
 - This presentation discuss how implementation science can be harnessed in the Ending the HIV Epidemic (EHE) initiative to inform tools, models and frameworks. When programs use a logic framework that specifies intervention components, articulates mechanisms of action, and details strategies and outcomes at the provider, program, and system levels.
 - Golub SA. Bridging the Gap: Implementation Science as an Implementation Strategy for EHE. PSMG: Innovations in Ending the HIV Epidemic Series; November 2020.
 - This paper describes the Implementation Research Logic Model, a tool designed for implementation scientists and practitioners to enhance the rigor and transparency of describing the often-complex processes of improving the adoption of evidence-based interventions in healthcare delivery systems.
 - Smith JD, Li DH, Rafferty MR. The Implementation Research Logic Model: a method for planning, executing, reporting, and synthesizing implementation projects. Implementation Science. 2020 Dec;15(1):1-2.

- 3. Health centers can use the PrEP cascade to quantify steps and identify gaps in service delivery. Mapping real-world programmatic / clinical data onto the PrEP cascade can help implementers monitor program performance and inform strategies to improve service delivery.
 - This paper presents evidence about how the PrEP cascade can be used to guide the planning, implementation, and monitoring performance of real-world PrEP programs. Using routine programmatic data to populate the PrEP cascade, the authors identified missed opportunities in PrEP implementation, and employed interventions to increase effective and equitable delivery of PrEP services.
 - Were D, Musau A, Mutegi J, Ongwen P, Manguro G, Kamau M, Marwa T, Gwaro H, Mukui I, Plotkin M, Reed J. Using a HIV prevention cascade for identifying missed opportunities in PrEP delivery in Kenya: results from a programmatic surveillance study. Journal of the International AIDS Society. 2020 Jun;23:e25537.
- 4. A good M&E plan should be data-driven and minimize the data collection and reporting burden. Extracting data from the electronic medical record (EMR) is a good start but may prove challenging for capturing process metrics.
 - This paper presents the minimum reporting variables (n=4) needed for ongoing monitoring of PrEP programs and inter-country comparison. It utilizes routine surveillance items to monitor key stages in PrEP delivery and to inform strategies to improve program performance.
 - Saunders J, Gill ON, Delpech V, Estcourt C. Minimum dataset for monitoring national human immunodeficiency virus pre-exposure prophylaxis (HIV PrEP) programmes: a five-nation consensus, 2019. Eurosurveillance. 2021 Jun 10:26(23):2001595.
 - These papers demonstrate how EMR data can be useful for the monitoring and evaluation of HIV treatment and prevention programs, while also noting the need to refine existing EMR system to allow the collection of additional M&E metrics (e.g., process indicators).
 - Reidy WJ, Rabkin M, Syowai M, Schaaf A, El-Sadr WM. Patient-level and program-level monitoring and evaluation of differentiated service delivery for HIV: a pragmatic and parsimonious approach is needed. AIDS (London, England). 2018 Jan 28;32(3):399.
 - Nash D, Elul B, Rabkin M, Tun M, Saito S, Becker M, Nuwagaba-Biribonwoha H. Strategies for more effective monitoring and evaluation systems in HIV programmatic scale-up in resource-limited settings: implications for health systems strengthening. JAIDS Journal of Acquired Immune Deficiency Syndromes. 2009 Nov 1;52:S58-62.

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- 5. Significant disparities exist in PrEP awareness, uptake, and HIV incidence in the U.S. M&E metrics measuring disparities are needed to ensure equity.
 - These papers present evidence of the racial and ethnic disparities in PrEP awareness and uptake in the U.S.
 - Nosyk B, Krebs E, Zang X, Piske M, Enns B, Min JE, Behrends CN, Del Rio C, Feaster DJ, Golden M, Marshall BD. "Ending the Epidemic" Will Not Happen Without Addressing Racial/Ethnic Disparities in the United States Human Immunodeficiency Virus Epidemic. Clinical Infectious Diseases. 2020 Dec 1;71(11):2968-71.
 - Kanny D, Jeffries IV WL, Chapin-Bardales J, Denning P, Cha S, Finlayson T, Weinert C, Abrego M, Al-Tayyib A, Anderson B, Barak N. Racial/ethnic disparities in HIV preexposure prophylaxis among men who have sex with men—23 urban areas, 2017. Morbidity and Mortality Weekly Report. 2019 Sep 20:68(37):801.
 - o Elopre L, Kudroff K, Westfall AO, Overton ET, Mugavero MJ. The right people, right places, and right practices: Disparities in PrEP access among African American men, women and MSM in the Deep South. Journal of acquired immune deficiency syndromes (1999). 2017 Jan 1;74(1):56.
 - This paper highlights the importance of including disparities metrics as part of the monitoring system in the "End the HIV Epidemic" (EtHE) plan and discusses how the health disparities can be addressed via the EtHE plan.
 - o <u>Nash D. Designing and disseminating metrics to support jurisdictional efforts to end the public health</u> threat posed by HIV epidemics. American journal of public health. 2020 Jan;110(1):53-7

6. Using unified metrics for M&E facilitates consistency and comparability across programs.

- While universal PrEP M&E metrics do not yet exist in the U.S. context, the CDC is working on data protocols that provide a set of unified performance measures for STD clinics that are implementing PrEP.
- This conference presentation shows how the PrEP retention outcomes varied depending on the
 definition of the measure. It demonstrates how the generalizability and the sharing of best
 practices is challenged by a lack of consistent and standardized set of measures.
 - Jason Zucker. Moving From Uptake to Engagement: Understanding Persistence in Comprehensive HIV
 Prevention Care. IAPAC 2020.

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M&E is an iterative process and should be integrated into the planning and implementation of a PrEP program.

Clinics should consider creating logic framework for their PrEP programs and develop M&E strategies that work for their service delivery models, clinic flow, and local context.

Routine monitoring of PrEP programs is essential to assess program performance and inform strategies to improve service delivery.

Outcome measures as well as process measures (e.g., percentage of patients who were discussed PrEP, percentage of patients who had their sexual history taken) should be included in routine monitoring. Clinics should review their EHR system to understand whether modifications are needed to improve routine capturing of M&E metrics.

There is an urgent need for standardized PrEP M&E metrics.

The lack of common and systematic metrics for evaluating PrEP programs in the U.S. has greatly restricted the comparability of PrEP programs. Policy makers and public health agencies should work with health centers to develop a set of metrics that are useful for developing programs and conducting M&E to improve programs.

Disaggregation of M&E data by race/ethnicity, sociodemographic factors, sexual and gender minority status, and geography is critical.

Only through such disaggregation can programs to understand disparities in program implementation and actively identify remedies to address them.

BLUPrInt Tools

- **Quality Assurance Metrics**
- PrEP Patient Tracker
- Planning Roadmap

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