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Pre-exposure prophylaxis in the era of emerging methods for men who have sex with men in the USA: the HIV Prevention Cycle of Care model

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Abstract

Expanding on previous work, we present an HIV Prevention Cycle of Care model to facilitate understanding of the complexity of issues involved in pre-exposure prophylaxis implementation for gay, bisexual, and other men who have sex with men (MSM) in the USA, including individual, client–provider, and overarching issues such as health equity, stigma, and prevention nomenclature. The HIV prevention cycle of care applies to MSM who test negative for HIV. The Prevention Cycle of Care model includes seven steps: prevention knowledge, prevention self-awareness and preferences, prevention motivation, health-care access and cost, provider issues, adherence and persistence, and periodic reassessment and adjustment. HIV prevention is complex in an era of emerging multiple modalities, and more research is needed to successfully implement pre-exposure prophylaxis options over time and across diverse communities of MSM who are sexually active.

Introduction

Before approval and availability of daily oral pre-exposure prophylaxis (PrEP) in 2012,^{1,2} condoms were the only primary method available to prevent sexual transmission and acquisition of HIV in gay, bisexual, and other men who have sex with men (MSM). The historic transformation from only condom-based prevention to the availability of oral PrEP and now to the availability of multiple options for PrEP, including sexual event-driven (intermittent, 2–1–1) dosing³ and long-acting injectable PrEP,⁴ has been greatly welcomed. However, the introduction of PrEP has presented communication challenges for the field of

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HIV prevention.⁵ Lessons learned through the roll-out of daily oral PrEP by researchers, prevention practitioners, and health-care providers might be helpful to consider as we embark on implementation of event-driven and long-acting injectable PrEP. We present an HIV Prevention Cycle of Care model and discuss its implementation issues to consider an emerging, wider range of biomedical methods for MSM in the USA moving into the future, with an overview of what has been learned over the past decade through the implementation of daily oral PrEP.

Ongoing implementation of daily oral PrEP for MSM

Since the introduction of daily oral PrEP, its use in some MSM with behavioural indications remains relatively low, with some variability by urbanicity (35% of MSM in urban areas^{6,7} and 10% in rural areas⁸). The number of health-care providers who prescribe PrEP in the USA increased from 9600 in 2014 to 66 000 in 2019,⁹ yet most MSM who could have benefited from PrEP were not using it.¹⁰ Research has found that daily oral PrEP adherence in men tends to be good enough to be considered high-level protection,^{11,12} but the consistency of PrEP use over time (ie, PrEP persistence) is a challenge with 40–60% discontinuing use 6 months after initiation.^{11,13,14} Barriers for PrEP uptake vary and include: lack of PrEP knowledge, low HIV risk perception, use of other prevention methods, changing periods of personal risk, and HIV or PrEP-related stigma from family and friends.^{8,15–18} Other studies have found restricted knowledge among providers and poor client–provider communication regarding PrEP as barriers to access.¹⁵ Factors involved in preference between daily oral PrEP and condoms include issues such as sexual pleasure,¹⁹ convenience, protection, application privacy, and health side-effects.²⁰ In a study on intent to use existing and emerging prevention methods by MSM, two general methods were observed that suggest preference for more immediate control of prevention options near or during the risk event (eg, event-driven PrEP, sexual gels, or condoms) versus more distal prevention control away from risk events (eg, daily oral or injectable PrEP).²¹ Event-driven PrEP has been taken up more broadly outside of the USA,²² which might be because the initial efficacy and early implementation trials were done in Europe.³ However, there is high interest in event-driven PrEP in MSM from the USA,²³ and many aspects of a conceptual framework for a cycle of HIV prevention and care would also apply directly to event-driven PrEP.

Measuring condom and PrEP adherence and persistence is complex but necessary to be able to identify and address protection gaps. Researchers began to address the complexities of prevention, assessing PrEP and condom use across partners and windows of time to understand MSM risk for HIV infection.²⁴ Approaches such as prevention-effective adherence address dynamic risk for HIV infection and strategies for assessing the sufficiency of HIV protection.¹⁷ Yet, only a few studies have systematically assessed HIV protection and prevention persistence over time in the current era of condoms and daily oral PrEP.^{25,26}

Various efforts have been involved in implementing daily oral PrEP in MSM, and the lessons learned from that experience might be helpful in the roll-out of event-driven dosing and long-acting injectable PrEP. Dissemination of pertinent information to MSM and their care providers about the new prevention approach of daily oral PrEP has been broad and

not without challenges. HIV prevention messaging efforts to increase PrEP use have faced challenges in addressing low-risk perception, stigma associated with PrEP use, medical mistrust, concerns about side-effects, and provider concerns about risk compensation and other adverse events.²⁷ Social marketing campaigns with PrEP and sex positive messages have been disseminated widely.²⁸ Provider training and interventions to improve client–provider communication have been effective in increasing PrEP prescriptions and use.²⁹ Calls for incorporating PrEP into comprehensive sexual health approaches with more integration in primary sexual health and general practice care continue.^{27,30} Financial concerns for PrEP coverage have reduced, but despite the availability of financial assistance programmes some concerns remain.^{8,31,32} There have also been effective policy-level interventions, such as higher rates of PrEP use among MSM in the states with (vs without) Medicaid expansion.^{33,34} Other examples of policy-level approaches include legislation in California allowing pharmacists to provide PrEP without a prescription, a US Preventive Services Task Force Grade A recommendation for PrEP, and same-day PrEP implementation coverage.^{35,36} Expansion of technology-based interventions, such as websites and mobile apps, have effective reach to MSM for PrEP use.²⁵ Such interventions provide an opportunity for tailored prevention messaging and resources to guide and support PrEP access and use through risk self-assessments, provider and testing locators, appointment and medication reminders, and access to additional information about prevention options for a wide range of potential PrEP users.^{37,38}

One of the ongoing challenges for daily oral PrEP use is the racial, ethnic, and geographical disparities in access and persistence in MSM. Black and African American and Hispanic and Latino MSM have substantially lower rates of PrEP use compared with White MSM,^{14,39} particularly in the southern USA.^{39,40} Although state and local jurisdictional data on PrEP use by race are not broadly available, PrEP equity metrics, such as the PrEP to need ratio, will probably indicate even broader inequities by race in PrEP use relative to epidemic effect.⁴¹ Modelling studies have forecasted that racial and ethnic disparities would persist and even expand without enhancement of current PrEP implementation efforts,⁴² indicating a need for incorporating health equity metrics⁴¹ throughout any PrEP implementation approach.

Addressing prevention needs of MSM over time: the HIV prevention cycle of care

In 2015, Kelley and colleagues⁴³ proposed a generic continuum of PrEP care after the approval of daily oral PrEP for preventing HIV infection (figure 1A).⁴³ In 2018, an HIV serostatus neutral model was proposed for triaging HIV care at the point of HIV test result (figure 1B).⁴⁴ Due to the availability of increased PrEP options, we propose a model of the HIV cycle of care that considers the need for periodic reassessment of preferences for prevention modalities, in the context of identified individual, client–provider, and overarching issues (figure 2). Envisioned as a cyclical rather than linear model, similar models have suggested that focus on re-entry to PrEP care⁴⁵ and HIV care⁴⁶ are an important part of overall prevention and care. The original PrEP continuum of care model focused on the interactions of public health messages (eg, promoting awareness), processes

to increase salience and identify potential benefits of PrEP (willingness), access to health care, provider behaviours in prescribing PrEP, and adherence.⁴³ Additionally, since the publication of our original model, the inequitable uptake of PrEP by race and ethnicity has become apparent;^{8,47} therefore, we have added a layer to the model to capture the responsibility of providers and public health systems to examine how each of the steps in the PrEP cycle is addressed in ways that support equity. Implementing this model necessitates conceiving of the interaction between context, education, and campaigns. In other words, prevention messaging and materials need to be tailored for community contexts involving race, ethnicity, gender identity and expression, language, and geographical area. For example, are campaigns designed to promote awareness of PrEP responsive to the needs of diverse communities in need of PrEP? Are people with PrEP indications that are inequitably reached by PrEP clearly depicted in educational materials? Are physical materials and digital educational materials distributed in ways that align with populations so that they can reach groups inequitably served by PrEP? Although we articulate these concerns in the context of the USA, the principles are applicable globally (eg, the need to represent gay and bisexual men in PrEP scale-up in sub-Saharan Africa).⁴⁸

We endorse the public health principle that what is measured can change. Specifically, metrics of health equity must be measured and evaluated in public health jurisdictions. The PrEP to need ratio has been widely adopted to characterise the extent to which PrEP use in specific groups (eg, by region, sex, and age) is aligned with the effect of new HIV infections in that group. Of note, our ability to assess inequities in PrEP at a population level is restricted by the poor availability of population-based data on PrEP use by race and ethnicity in the USA.⁴⁹ We call for better methods to develop population-based data to measure PrEP use and PrEP to need ratios by race and ethnicity and to monitor this equity outcome over time.

Steps of the new HIV prevention cycle

Prevention knowledge

As with condoms, awareness of PrEP as a protective measure is essential for MSM to pursue more information about the approach and to subsequently initiate use under care of a provider.^{43,50} This need for awareness is evident in recent studies of people with behavioural indications who were offered daily PrEP by a provider, but declined due to concerns of potential side-effects, an ongoing adherence regimen, or overall lack of information.⁵¹ Although some men continue to use condoms, the knowledge of PrEP required for an agreement for use is contextual: it varies by factors, such as perceived effectiveness and misconceptions about PrEP, social and sexual networks, sexual activity, recent unprotected (ie, without a condom or PrEP) anal sex, and access to health-care facilities.^{52–54} MSM who believe that PrEP has low efficacy, hold concerns about side-effects, and have misconceptions about PrEP might need more knowledge about PrEP to support initiation. Conversely, a lower degree of knowledge can be sufficient for MSM with high perceived HIV vulnerability and who have easy access to health-care facilities.^{50,55} Sources of knowledge might influence PrEP uptake. Information from peers in their social and sexual networks could act as drivers to initiate conversations about PrEP with a health-

care provider.^{50,52} Awareness of treatment as prevention is also crucial to allow MSM to make informed decisions on their personal need for PrEP depending on their circumstances and the circumstances of their partner or partners. Furthermore, socioeconomic status is associated with PrEP awareness, access, and uptake in MSM in the USA.^{56,57} Lower income, usually accompanied by an absence of adequate insurance coverage, could increase cost issues hindering PrEP uptake. There is a need to address the disparities based on socioeconomic status if MSM are to benefit from PrEP implementation efforts.

Prevention self-awareness and preferences

Creating self-awareness of the need for an effective personal HIV prevention strategy has been a central endeavour of HIV primary prevention since the beginning of the epidemic,⁵⁸ and continues to be as sequential generations of young men become sexually active. Basic awareness of the need for an effective HIV prevention plan based on partner type (monogamous primary or casual partners), number of partners, self and partner HIV testing frequency, HIV serostatus disclosure, and other HIV-related information is necessary to fully identify and implement a personal HIV prevention strategy that is appropriate for the individual's sexual context.^{59–61} The prevention strategy could include relying on the viral suppression of partners living with HIV (ie, treatment as prevention, sometimes referred to as HIV undetectable=untransmittable or U=U). As more PrEP options become available and used by MSM to prevent HIV infection and use of condoms reduces, the complexity of understanding how to identify and implement a sexual health plan expands and is complicated by concerns over other sexually transmitted infections that do not yet have an accepted parallel biomedical prevention option. In addition to general prevention self-awareness based on sexual context for correct and consistent condom use during anal sex as a prophylaxis method, self-awareness about successful adherence and persistence by PrEP method (eg, daily oral, event-driven, or long-acting injectable) and related gaps in protection for non-adherence or non-persistence are necessary for an individual to consider adjusting their behaviour for maximum HIV protection over time. MSM with behavioural indications have a choice of several HIV prevention methods, each with its own set of characteristics (table). MSM are not uniform in their product characteristic preferences,²¹ and providers should be knowledgeable about and discuss the pros and cons of each method given the user's personal context and needs. Over time, preferred product characteristics could change for a user, which might require transitioning from one product to another. An ongoing dialogue between the user and provider is necessary to facilitate maximum benefit of prevention product use over time as client context and needs might change. HIV prevention method choice is complex and based on discussions with a provider about personal contextual issues (panel), which vary in relative importance across users and over time. The five key areas of prevention method choice are personal aversion to prevention method form of administration (eg, needles and pills); preference for type of personal control over method use (eg, general or event-based control); preference for longevity of method protection after cessation of use (eg, days or less vs months or longer); partner-related factors (eg, primary partner and non-primary partner characteristics); and financial issues (eg, insurance coverage and relative cost of methods over time). These personal contextual issues are likely to change for an individual over time, and thus the preferred method might change as these circumstances fluctuate.

Prevention motivation

Even if the client has enough information to make a decision regarding PrEP use, motivation for accepting and adhering to a PrEP regimen is a crucial element of successful implementation. Research on motivation for PrEP use has found that monetary cost (or perceived cost), perceived HIV risk, issues with disclosing PrEP use to partners, and PrEP stigma were barriers to use.^{62–64} Providing information about financial assistance options and positive messaging normalising PrEP use could mitigate these concerns and increase motivation in MSM.^{43,65,66} Furthermore, providing information about the additional benefits of PrEP, such as less stress and less anxiety about HIV risk, peace of mind, and barrier-free sexual intimacy and pleasure, could motivate some MSM to take up PrEP.^{65,66}

Health-care access and cost

Out-of-pocket costs were a major barrier earlier in PrEP implementation.⁴³ This financial barrier has been somewhat reduced over the past decade due to an increased number of states expanding Medicare or Medicaid coverage, pharmaceutical company assistance programmes, and other initiatives.^{31,32} However, the number of people in the USA without medical insurance remains high and other cost barriers persist, such as the cost of monitoring laboratory and medical visits.^{15,18} Some of the financial barriers are expected to ease because PrEP received a Grade A recommendation from the US Preventive Services Task Force, which requires the private insurers to cover oral PrEP and associated services without copays,⁶⁷ with generic versions costing much less than brand name medications. Access to health care, including PrEP care, is a major concern for MSM in rural areas,⁸ in particular for MSM living in areas where PrEP is not easily accessible,^{39,68} and the Biden administration has clarified that insurers must cover all PrEP-related costs.⁶⁹ Implementation of unique interventions, such as PrEP delivery through non-traditional providers (pharmacists and nurses), telemedicine,⁷⁰ and home-based PrEP delivery options,⁷¹ could alleviate access barriers.⁶⁸ Disparities might still persist despite these innovations if equity is not centred as these interventions gain popularity.

Provider issues

Some health providers are well informed on HIV prevention methods and guidelines; however, others are not due to various reasons, such as provider bias, lack of training, and provider misconceptions about PrEP.^{15,72,73} This difference in provider knowledge of PrEP results in an access gap for many MSM having indications for PrEP. Furthermore, many providers are not comfortable or trained to discuss sexual behaviour and the life circumstances of clients,¹⁵ which is generally the context of determining behavioural indications for PrEP. More systematic provider communications and education about PrEP methods are needed broadly across the USA, and particularly outside of the large urban areas where PrEP provider infrastructure is often sound and well established.^{68,74} A crucial aspect of effective prevention product provision is an ongoing client–provider conversation about sexual behaviour and PrEP options, adherence monitoring over time, and changing PrEP methods when necessary on the basis of client needs and life circumstances.⁶⁵ To increase provider acceptance, PrEP guidelines published by the US Centers for Disease Control and Prevention in 2021⁷⁵ recommend discussing PrEP with all sexually active

adolescents and adults and prescribing PrEP to anyone who asks for it without eliciting a history of sexual or drug using behaviours.

Adherence and persistence

In addition to related provider issues, numerous client-related personal and contextual issues contribute to one's decision to use, not use, or discontinue PrEP. Recent studies have found that key reasons for discontinuing daily PrEP use are changes in sexual behaviours, relationships, and perceptions of PrEP need; side-effects; affordability; and problems with adherence to a daily pill regimen.^{16,18,50,65} Previous studies in the rollout of daily PrEP also found cost and stigma to be primary barriers.^{62,76} Stigma of taking PrEP has lessened as more MSM use PrEP,⁷⁷ and development of financial support options, such as Medicare, Medicaid, and drug company and federal assistance programmes, have eased drug-cost concerns.^{31,32} With emerging options of long-acting injectable and event-based oral PrEP, client concerns about daily adherence issues can be avoided;^{22,78} however, other issues, such as high cost and absence of equitable access of longer-acting products, could increase the disparities in PrEP use.^{79,80} Interventions to increase adherence are primarily focused on behaviour change by providing counselling and motivational interviewing, and addressing adherence problems and struggles to increase PrEP adherence. For example, Life-Step for PrEP, which consisted of four counselling sessions delivered by a nurse, resulted in improved adherence (84% vs 63% in the control group) at 6 months.¹² Interventions based on peer-navigation models with professional and peer navigators implemented by seven state health departments in the USA included components of providing appointment follow-up and prescription pick-ups to support adherence.⁸¹ Combined with home self-collection testing, technological innovations, such as sexual health mobile apps with medication reminders³⁸ and remote telemedicine visits with providers,⁸² can ease the ongoing burden of PrEP adherence and monitoring to facilitate successful prevention protection.

Periodic reassessment

Ongoing client-provider conversations are essential for successful prevention and protection of PrEP over time. This includes continuing discussion of the selected PrEP method and adjustments given the changing needs and life context of the client. Periodic reassessment of the most appropriate PrEP modality can maximise protection for MSM. Reassessment also includes HIV testing to confirm HIV-negative status and transition to the HIV treatment care cycle if the client tests HIV positive. Assessment and reassessment highlights that the new prevention cycle does not end at medication adherence and persistence, but requires a recurring and consistent evaluation of the individual's prevention needs, financial circumstances, and acceptance of new prevention technologies. Depending on the context of an individual engaged with prevention services, anything on the prevention spectrum from condoms to PrEP to viral suppression of primary partner might be appropriate personal strategies to prevent HIV.

Overarching issues for PrEP implementation

Overarching systemic and social obstacles continue to influence PrEP implementation, including issues of racial and ethnic health disparity and stigma associated with HIV

and sexual orientation and gender identification.^{47,55,83} PrEP nomenclature should be standardised for ease of reference and understanding various formulations of PrEP.

PrEP use is lower in Black and Hispanic MSM, compared with White MSM.⁸ Racially equal implementation of PrEP could actually widen the existing disparities;⁴² in turn, an equitable implementation, in which PrEP use is proportionate to epidemic effect,⁴¹ is needed to reduce the disparities. Given that many of the identified barriers to PrEP use (eg, absence of health insurance coverage,⁸⁴ stigma, and physical access to health-care facilities^{85,86}) might be more common in Black and Hispanic MSM, the potential to increase equitable PrEP use might be realised through structural means (eg, programmes to increase public coverage of PrEP and offer flexible options, such as telemedicine, for accessing PrEP could mitigate these inequities if these populations are centred in implementation). Interventions to reduce stigma are probably more challenging to implement broadly. However, a comprehensive approach to increasing equity should address all phases of a cascade of access, including improving accurate self-perception of HIV prevention need, increasing knowledge of PrEP, reducing structural barriers, and removing monetary barriers to PrEP access.

A meta-analysis, published in 2022, on stigma reduction interventions for MSM found only four interventions, none of which were associated with a significant intervention effect.⁸⁷ Societal efforts to address and improve these challenges are needed, such as interventions to reduce HIV-related and gay sexuality-related stigma, training providers to offer affirming and culturally competent care, and structural interventions to address discrimination and institutional racism. Implementing PrEP services in partnership with community members, community-based organisations, and local pharmacies could minimise some of the structural barriers.²⁵ For example, the One-Step PrEP clinic service implemented in Seattle, WA, USA, showed that 90% of MSM who were evaluated had initiated PrEP uptake and nearly all MSM had no out-of-pocket costs.⁸⁸ Findings from the US CDC's PrEP Implementation, Data-to-Care, and Evaluation evaluation showed successful expansion of PrEP services to MSM from minority racial and ethnic groups.⁸¹ Medicaid expansion could increase PrEP access to Black, Hispanic, and Latino MSM with lower PrEP to need ratio and living in states without Medicaid.^{33,34}

With multiple emerging PrEP modalities now approved by the US Food and Drug Administration and recommended by the US CDC, the discussion of PrEP has broadened beyond daily oral PrEP. As with PrEP messaging and marketing, the contexts for messaging and the diverse prevention needs are important to consider. For MSM, PrEP options present a unique opportunity because the per-act risk of transmission through anal intercourse is high;⁸⁹ strategies that tailor PrEP choices by identifying and taking the frequency of sex and knowledge of partner serostatus into account are especially important (NCT05072093). Long-acting injectable PrEP, sexual event-driven PrEP, and daily oral PrEP each have their own set of issues related to knowledge, motivation, uptake, adherence, and persistence over time; as a result HIV prevention cycle discussions will become more complex, referring to each of these prevention modalities and related implementation issues that are partly distinct from one another. It will become useful and necessary to clarify terminology across the various forms of PrEP for ease and clarity. Nomenclature understandably changes as new products become available and the contextual field of HIV prevention changes. As the

field adapted to daily oral PrEP by the need to clarify condomless anal sex rather than the previous term of unprotected anal sex,⁵ having multiple modalities of PrEP could benefit from naming adaptation for ease of reference and assessment of individual level risk (eg, I-PrEP for injectable, D-PrEP for daily oral, E-PrEP for event-level oral).⁵ Regardless of the selected naming, adapting and normalising simple terms for each PrEP modality will become a necessity for ease in research, programme, and clinic implementation.

The HIV Prevention Cycle of Care model is presented from the perspective of a person who is HIV negative with a provider in a health-care system. Due to adherence challenges and gaps in prevention coverage, some might eventually transition into an HIV treatment cycle. These models are consistent with the HIV status-neutral approach,⁴⁴ which depicts introduction into the HIV testing and care system of untested people, provides testing, and then triages people to either prevention or treatment care based on their HIV test result.

Conclusion and next steps

Our HIV Prevention Cycle of Care model is intended to better understand individual-level, interpersonal-level, and systemic-level issues involved in HIV prevention modality implementation over time based on the context for MSM in the USA. However, the model could be adapted to various communities and other countries. Although the model combines and expands on previous models, it is not meant to be exhaustive of every possible challenge to successfully implementing prevention or care programmes for individuals. The variety of PrEP modalities and need to improve PrEP equity call for additional research about preferences for and uptake, adherence, and persistence of PrEP. We need longitudinal research that documents trends and patterns in PrEP use in key populations. The PrEP to need ratio reshaped our discussion about PrEP equity by giving us a way to measure equity. Similarly, we must develop metrics that are clear and accessible to describe patterns of PrEP persistence, and to measure how successful we are in retaining people in all components of the contemporary PrEP cycle, including transitions from prevention to a treatment cycle when breakthrough infections occur.

More research is also needed to understand the optimal implementation strategies for offering a diverse set of PrEP alternatives to people who could benefit from the intervention and continuing to monitor and offer options for men that might change when personal prevention needs or relationship circumstances change. In an era when many MSM have not had an initial discussion with their health-care provider about PrEP, we should consider using more implementation methods to identify the most acceptable and scalable approaches for frequent updating of risk for HIV infection and PrEP eligibility status, including clinical decision tools to identify and support prevention care. Of note, mobile phone applications might offer good opportunities for providing up-to-date and tailored information on PrEP choices to MSM. A recently evaluated mobile phone app for MSM (M-cubed) was associated with a doubling of PrEP use 3 months after exposure to the app, and digital resources could also serve as points of information about PrEP options.³⁸ The new modalities of PrEP (injectable PrEP, event-driven PrEP, and pipelines for long-acting oral PrEP) also suggest that research on preferences, including methods such as discrete choice experiments, which can capture the contextual determinants of preference, should

be ongoing. Finally, studies assessing real-world evidence of PrEP preferences, uptake, adherence, persistence, and change of modalities over time and life circumstances in a community environment are needed to help provide a robust understanding of our successes in making the most of the opportunities for improving coverage and public health effect of PrEP. Finally, we must continue to adapt our mechanisms of PrEP offering and support new prevention products as they become available. Implants, long-acting oral medications, and coformulated products (eg, topical PrEP gels in sex lubricants) all hold promise to change the landscape of PrEP in the future.

We have arrived at a place for HIV prevention that was nearly unthinkable to the public a decade ago, with multiple modalities of delivering prophylaxis medication that can stop HIV infection before it is established. The call is to enhance our public health responses implementing these prophylactic options, and maximise opportunities to prevent HIV for MSM and others as their sexual and life circumstances change over time.

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Panel: Personal contextual issues related to HIV prevention method choice**Aversion to prevention method administration**

- Aversion to injection needles, particularly administered in the glute
- Aversion to oral medication dosing, particularly on a daily basis
- Aversion to condoms as a penile barrier during sex, physically or emotionally
- General aversion to any internalised medication, whether oral or injected

Prevention control preference

- Prefer user control near or during the sex event (event-based control)
- Prefer user control more generally and unrelated to sex event (general control)

Preference for prevention method protection longevity after cessation of use

- Prefer methods with short duration that have a short tail of protection after internalisation (eg, days or less)
- Prefer methods with long duration that have a long tail of protection after internalisation (eg, weeks or months)

Partner-related issues**Primary partner**

- Yes or no
- Partner's HIV status
- Agreed-upon and confirmed monogamous relationship

Non-primary partners

- Yes or no
- Frequency and duration of sexual partnering
- Anal sex with any partner

Financial issues

- User has insurance coverage or access to other cost coverage (eg, established grant programmes)
- Relative cost of prevention method implementation for user
- Consider relative costs of required health-care monitoring for each method over a period of time (eg, one year)

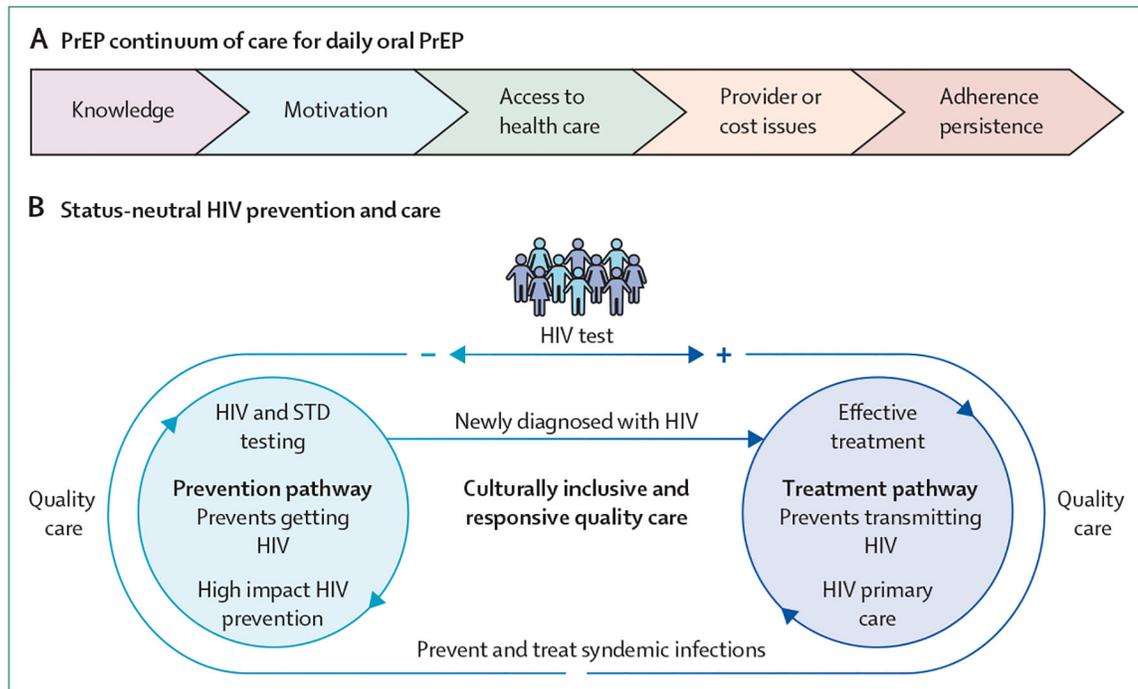


Figure 1: The PrEP continuum of care model⁴³ (A) and the HIV serostatus-neutral model⁴⁴(B)
 The HIV serostatus-neutral model was reproduced with permission from the US Centers of Disease Control and Prevention. PrEP=pre-exposure prophylaxis. STD=sexually transmitted disease.

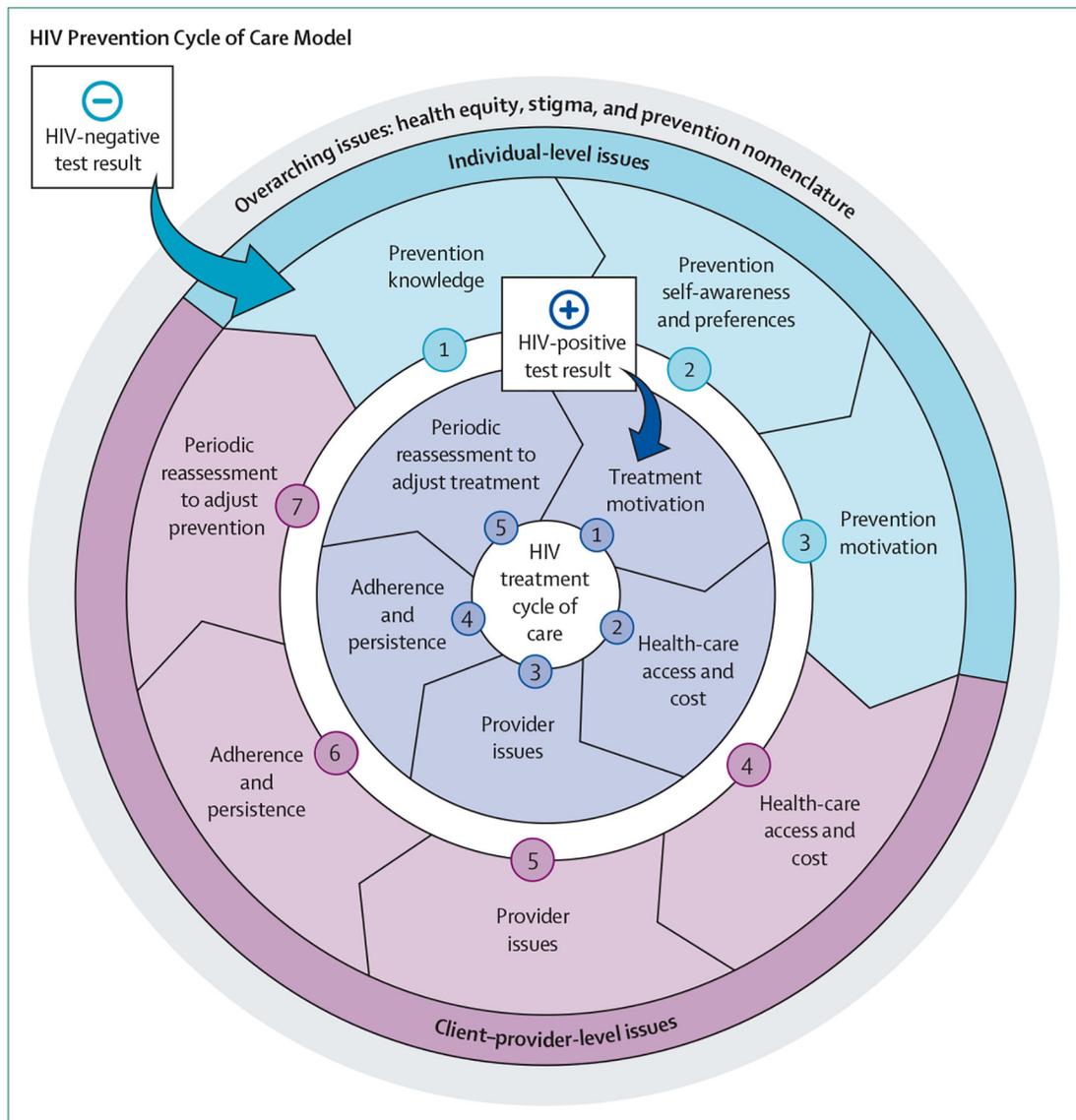


Figure 2:
The HIV Prevention Cycle of Care model

Table:

Characteristics of currently available HIV prevention methods for men who have sex with men

	Condom	Daily PrEP	Event PrEP	Injectable PrEP
Highest levels of protection shown	No	Yes	Yes	Yes
Requires prescription and monitoring by provider	No	Yes	Yes	Yes
Available over the counter as needed	Yes	No	No	No
Covered by insurance for minimal user cost	No	Yes	Yes	Yes
Used only near or at time of risk event	Yes	No	Yes	No
Used outside or away from risk event	No	Yes	No	Yes
Self-administered and controlled	Yes	Yes	Yes	No
Provider-administered via a needle	No	No	No	Yes
Administered only six times per year for protection	No	No	No	Yes
Requires coordinated lead-in and tapering off	No	No	No	Yes
Requires daily dosing and adherence	No	Yes	No	No
Requires support of and coordination with partner	Yes	No	No	No

PrEP=pre-exposure prophylaxis.

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