PrEP updates and HIV prevention in primary care

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Overview

- Why PrEP guidance?
- PrEP guidance workgroup & process
- Key changes to the PrEP guidance
- Case studies and application of PrEP guidance



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Why PrEP Recommendations?

- PrEP is an <u>evidence-based, highly</u> <u>effective</u> biomedical addition to the suite of behavioural measures to prevent HIV transmission and infection
- Effectiveness of PrEP is <u>>96%</u> when taken correctly as prescribed
- Importance of <u>local</u> recommendations to guide the use of this powerful tool in Singapore



Preventing HIV is as easy as ABCD. Find out how you can protect yourself with these four simple steps.





Guidance Development Workgroup and Processes

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WORKGROUP

• Aim

 Provide guidance to prescribers and other practitioners on the optimal use of PrEP for the prevention of HIV infection in Singapore

Composition

- Directors of HIV clinical programmes and sexual health clinics (DSC)
- Private practitioners with interest and experience in HIV
- Community-based organisations who work with people from key populations at risk of HIV infection
- Sociobehavioural scientist with domain expertise in sexual health and public health





PROCESS

1) Review of select benchmark international guidelines and updates



- 2) Adaptation to Singapore context
 - ✓ Inclusion of guidance and experience from Singapore PrEP workgroup
- 3) Consultation & feedback
 - ✓ ID Chapter, College of Physicians, Singapore
 - ✓ NHIVP Community Advisory Board
 - ✓ MOH Communicable Diseases Group

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Key Changes to the Guidance

- Updates on special clinical scenarios for the use of HIV PrEP
- Clarifications on contraindications to the use of HIV PrEP
- Updates on the use of TAF/FTC as HIV PrEP
- Monitoring and evaluation of individuals taking PrEP
- Updates on the availability of intramuscular long acting cabotegravir as PrEP in Singapore





Case studies and application of PrEP guidance

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Mr A

- 30 year-old MSM[^], single
- 10 male sexual partners per month; engages in oral and anal sex; condom use inconsistent
- No chronic medical problems
- History of chlamydial infection 6 months ago
- Physical examination unremarkable
- HIV test one month ago was negative

^Men who have sex with men

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Mr B

- 19-year-old male
- 2 male sexual partners per month; engages in oral and anal sex; condom use consistent
- No chronic medical problems
- No prior sexually-transmitted infections
- HIV and STI testing one month ago was negative
- Asking for HIV PrEP



Are they both suitable for HIV PrEP use?

Who may be suitable for PrEP?

- 1. Anal or vaginal sex in **past 6 months** AND any of the following:
- a. HIV positive partner (especially if partner has an unknown or detectable viral load)

HIV viral suppression defined as plasma viral load <200 copies/mL for > 6 months

Additional Considerations

- b. Bacterial STI in past 6 months
- c. History of inconsistent or no condom use with sexual This may include individuals who has post exposure prophylaxis twice in the last 6 months, sex workers, etc.
- d. Engages in sexual activities under the influence of Or alcohol or other drugs

Or indicate that they may have such behaviour

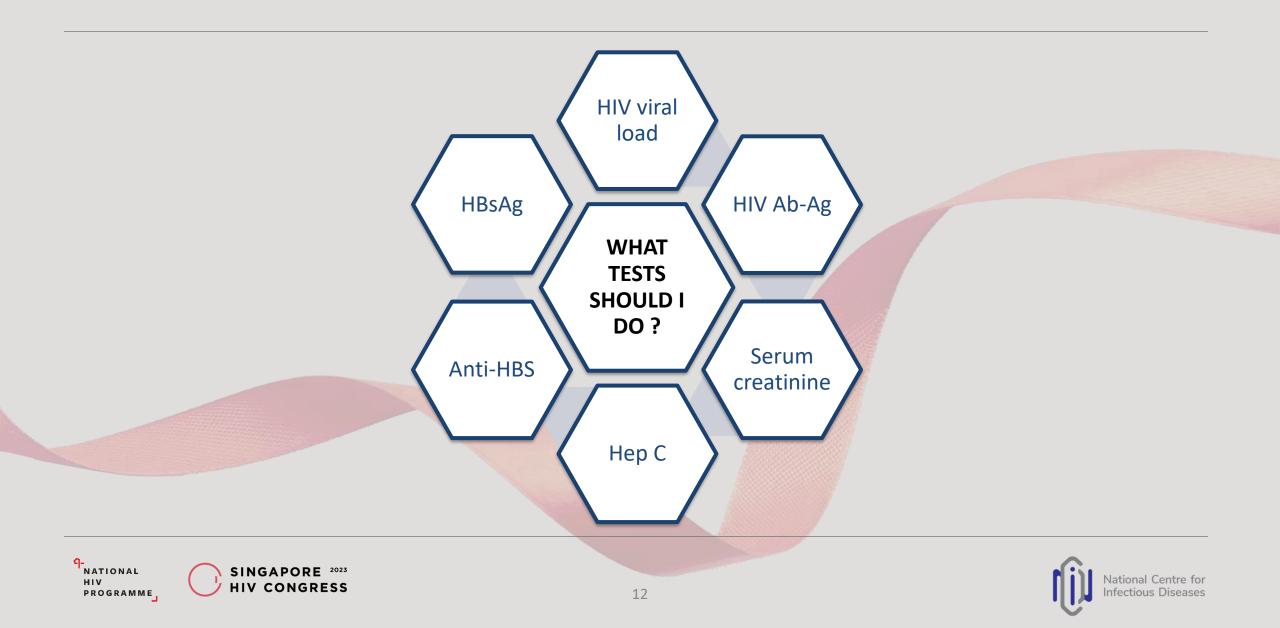
2. Any individual who request for PrEP <u>may be</u> offered it, even if no specific risk behaviors are identified

Individuals at risk of acquiring HIV may feel uncomfortable reporting their sexual behaviours to healthcare workers due to concerns about stigma and discrimination

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Starting PrEP: Baseline Evaluations

What should be done at the first consultation?	Example	Additional Considerations
Baseline renal function testing	Serum creatinine	Estimated creatinine clearance can be calculated using the modified Cockcroft-Gault equation
	Urinalysis for proteinuria	Only for patients with pre-existing risk for renal impairment, e.g. diabetes, hypertension
Hepatitis B screening	Hepatitis B surface antigen (HBsAg) and antibody (anti-HBs)	Vaccination against hepatitis B should be offered to non-immune individuals. If patients test positive for hepatitis B, they should be considered for treatment and <u>not be</u> offered on-demand PrEP
Offer Hepatitis C screening	Hepatitis C antibody (anti-HCV)	Referral for hepatitis C treatment if positive
Offer STI screening and treatment	Syphilis screening	
	Other bacterial STIs (gonorrhoea, chlamydia, etc)	At relevant and appropriate sites based on sexual history or consider three-in-one testing as per site availability (urethral, rectal, pharyngeal, etc.)
Offer pregnancy screening	Urinary beta-HCG	Contraception should be discussed and provided for women who are on PrEP and who do not wish to become pregnant

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What options do they have?





PrEP Regimens

Methods	Suitable populations	Administration
Daily PrEP	All who have indications for	 All individuals: daily dosing of co-formulated TDF/FTC
	PrEP	- Cis-gender men who have sex with men and trans-gender women who have sex with men: these individuals can also use daily dosing of co-formulated TAF/FTC
		<u>Note:</u> - Needs to be taken for <u>7 days before</u> high levels of protection are achieved for both vaginal and rectal exposure to HIV
		- Alternative regimens such as taking PrEP four times a week is not recommended
		- TAF/FTC can be only be used in cis-gender men who have sex with men and trans- gender women who have sex with men as daily PrEP regimen
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PrEP Regimens

Methods	Suitable populations	Administration
On-Demand PrEP	Select populations only	- A double dose (two tablets) of co-formulated TDF/FTC to be taken 2-24 hours before potential sexual exposure, to be followed by single doses
		24 and 48 hours after the initial dose
	On-demand PrEP has only been investigated and is recommended in cis- gender men who have sex with men	- When potential exposure is sustained for more than a 24-hour period, 1 tablet per day should be taken until the last exposure followed by the 2 post exposure tablets
		Note:

-TAF/FTC **cannot** be used in on-demand PrEP regimen

*Note: WHO recommends that trans and gender diverse people assigned male at birth and are taking exogenous estradiol-based hormones should not be considered for on-demand PrEP

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PrEP Regimens

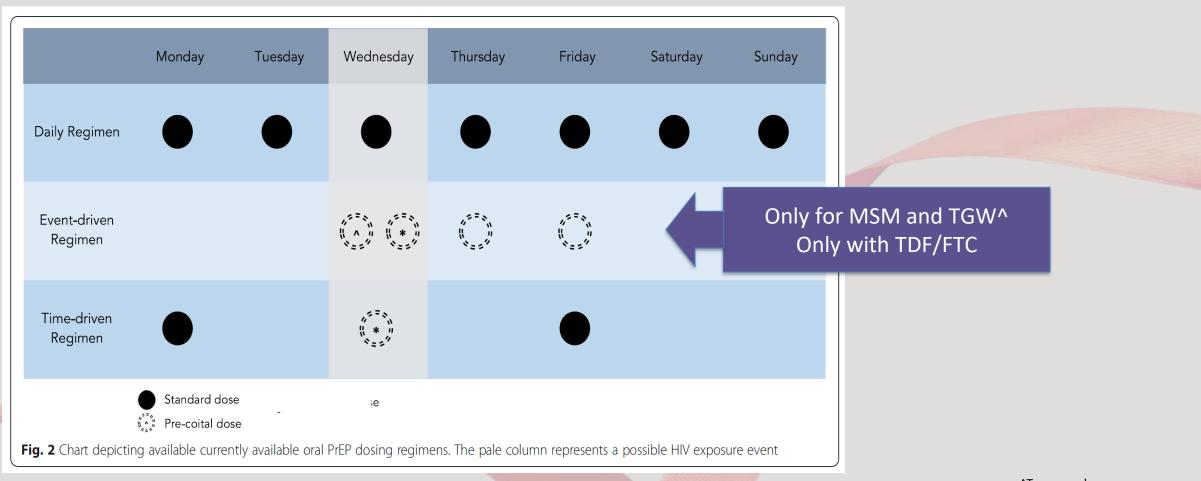
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^Trans-gender women



How would you counsel him?





Starting PrEP: Counselling

What should be done at the first consultation?	Example	Additional Considerations
Counselling	Types of PrEP- daily PrEP and on-demand PrEP	Key Message: On-demand PrEP should only be used for cisgender men who have sex with men due to the lack of data on the effectiveness of on-demand PrEP among heterosexual men and women, people who inject drugs, and transgender persons. Individuals other than MSM should <u>not</u> use on-demand PrEP. MSM who chose to be
		on daily PrEP should be advised on how to switch to on-demand PrEP should they wish to do so.
	Efficacy of PrEP	Key Message: PrEP is highly effective if taken as prescribed as part of an overall HIV prevention strategy (including the use of condoms)
	Adherence counselling	Key Message: It is important to take PrEP every day (for daily PrEP) and according to the schedule (for on-demand PrEP) for it to be effective.
	Engagement in care	Key Message: It is important to return for visits to get tested for HIV and assess for medication side effects, as well as to obtain a new prescription so that PrEP is not interrupted.
	Sexual health counselling	Key Message: PrEP does not prevent other STIs, and regular testing and treatment for other STIs is needed to maintain sexual health. PrEP also does not prevent pregnancy, and contraception should be used to prevent pregnancy if needed.

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- 35 year-old MSM who was treated for secondary syphilis
- He had 1-2 new sexual encounters per month, mostly casual male partners
- He had an unprotected receptive anal sex 1 day ago
- Latest HIV test was negative (3 months ago)
- He was eager to start PrEP



How would you manage his recent high risk exposure and his PrEP request?

Start post-exposure prophylaxis (PEP) with tenofovir-emtricitabine+ dolutegravir, then continue PrEP alone after 28 days

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Starting PrEP: Ensuring that the patient is HIV-negative

What should be done at the first consultation?	Example	Additional Considerations
Ensure that the patient is HIV-negative	Using a 4 th generation HIV test (either routine HIV EIA (enzyme-linked immunoassay) within the past 4 weeks OR rapid point-of-care finger-prick blood test on the day of consultation if there is no concern of recent exposure	Lab-based HIV 4th General EIA test is preferred
	If recent high-risk exposure (within the past 72 hours), consider PEP and re-test after 28 days	Consider Post Exposure Prophylaxis
	If high-risk exposure after 72 hours but within the past 28 days, repeat HIV testing after 4 weeks	
	If the patient is keen to initiate PrEP immediately, consider HIV RNA (viral load) testing	





Contraindications to use of PrEP

Contraindications to use of PrEP

Known HIV infection

Clinical syndrome suggestive of acute HIV infection/HIV seroconversion (please refer to special clinical scenarios section D.)

Known impairment of renal function (estimated creatinine clearance <60 ml/min for individuals considering TDF/FTC and estimated creatinine clearance < 30ml/min for individuals eligible for TAF/FTC)

Allergy or other known contraindication to any of the drugs in the PrEP regimen





Mr C, Follow up

- After completion of his PEP for 28 days without issue, he then continued daily PrEP alone after.
- At his 3-month follow-up, his HIV test is negative, and his creatinine is stable.
- He has heard that "on-demand" PrEP and he is keen to switch now.





Starting PrEP: 3 – 6 monthly reviews

Consider repeat HIV testing at 4 weeks via use of 4 th generation HIV test	Especially if there are concerns about adherence to PrEP in the first 4 weeks or if there was a high-risk exposure 3 days or more prior to PrEP initiation
via use of 4 th generation HIV test	there was a high-risk exposure 3 days or
	more prior to PrEP initiation
	Check for adherence to PrEP
	Confirm that daily OR on-demand regimen
	are being taken appropriately
	Check for side-effects



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Starting PrEP: 3 – 6 monthly reviews

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What should be done after PrEP is started?	Tests/agenda to be done	Additional Considerations	
Review 3-6 monthly thereafter	3 rd /4 th generation HIV test (either routine HIV EIA OR rapid POCT finger-prick blood test) <mark>3 monthly</mark>		
	Serum Creatinine	For individuals with co-morbidities or 50 years and	
	All individuals should get a repeat creatinine <mark>1-3 months</mark> after starting PrEP.	above with routine creatinine monitoring done in oth settings, PrEP providers can consider using these	
	In individuals younger than 50 years old without any co-morbidities, <mark>nil</mark>	results in their clinic review instead of obtaining a	
	<mark>further creatinine monitoring</mark> is required if the repeat creatinine test is normal.	separate serum creatinine if appropriate.	
	Individuals with kidney-related co-morbidities or age 50 years and above should have a repeat serum creatinine check at least once every 12 months.		
	STI screening and treatment	Syphilis, gonorrhoea and chlamydia screening <mark>3 – 6</mark> monthly	
		The frequency of screening depends on patient- reported sexual risk behaviour	
	Anti-HCV	Especially for PrEP services provided to men who have	
	12 monthly, consider 3 monthly with very high-risk behaviour	sex with men and people who use drugs.	
	Urinary beta-HCG		
	3 monthly		

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nfectious Diseases

While on PrEP: Important Considerations

What should be done after PrEP is started?	Tests/agenda to be done	Additional Considerations
sess if the modality of PrEP is still propriate cisgender MSM should be	Cisgender MSM patients who wish to switch from daily to on-demand PrEP (or vice versa) should be advised on how to do so.	
	assessed at each visit.	On-demand PrEP should only be used for cisgender men who have sex with men due to the lack of data on the effectiveness of on-demand PrEP among heterosexual men and women, people who inject drugs, and transgender persons.
		All other individuals should be advised that on-demand PrEP cannot be used in their situation.



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Mr C, Follow up

- During his 3-month follow-up, he told you that he is having an exclusive relationship • with his current partner.
- His HIV test is negative.
- He is keen to stop his PrEP now.



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Stopping PrEP: Important Considerations

What should be done after PrEP is started?	Tests/agenda to be done	Additional Considerations
Assess if PrEP is still needed	The need for continued PrEP should be assessed 12 monthly	Patients should continue taking daily PrEP for 7 days after the last sexual exposure, putting them at risk of HIV infection before discontinuing PrEP.
		Only cis-gender MSM can safely stop PrEP after taking a dose 24 and 48 hours after the last at- risk exposure, regardless of the PrEP modality used.
Linkage to care for patients who seroconvert	All patients who test positive for HIV should be referred for treatment at a HIV care centre on an urgent basis	HIV-infected patients can be started on HIV treatment without interruption.
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Stopping PrEP: What to Do

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What should be done if PrEP is discontinued?	Tests/agenda to be done	Additional Considerations
Assess HIV status	HIV testing	
Hepatitis B testing and treatment considerations	Consider repeat HBsAg testing on planning to discontinue PrEP unless there is documented immunity	Patients who are HBsAg-positive and stop PrEP should have their liver function and hepatitis B viral load monitored after cessation of PrEP as there is a risk of
Counselling	Advice on re-initiation of PrEP	reactivation of infection Patients should be counselled that they should consider
		re-initiation of PrEP if the risk of HIV infection should become present again, e.g.
		 Entering a period of engaging in unprotected sex Leaving a long-term relationship Starting a serodiscordant relationship with a partner who is yet to be virally suppressed or with a partner of unknown HIV status
		Other risk factors for HIV acquisition



LONG ACTING IM CABOTEGRAVIR

- In recent years, long-acting injectable cabotegravir (LA-CAB) has also been found to be effective as an alternative form of PrEP in heterosexual women, cisgender men who have sex with men and transgender women who have sex with men.
- As of the writing of this recommendation, LA-CAB has so far been approved for use as PrEP in the United States of America, Australia and Zimbabwe.
- However, it is currently not licensed for use as PrEP in Singapore. Hence, this recommendation will not cover the use of LA-CAB as PrEP





Who is suitable for PrEP?



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