Clinical Guidelines for HIV Pre-Exposure Prophylaxis in The Bahamas:

2.1 HIV Pre-Exposure Prophylaxis: Who is Eligible for PrEP

HIV Pre-exposure Prophylaxis (PrEP) is recommended for use to reduce the risk of acquiring HIV infection in adults on The Bahamas.

- PrEP is recommended as an oral, daily fixed dose combination of tenofovir disproxil fumarate (TDF) and emtricitabine (FTC)
- PrEP is recommended as an HIV prevention option for people at substantial risk of HIV infection as part of a combination prevention approach
- PrEP should be offered as an HIV prevention option for:
 - HIV negative persons and
 - At substantial risk for HIV infection including:
 - Sexually active heterosexual men and women having vaginal or anal intercourse without condoms with more than one partner
 - Sexually active men who have sex with men (MSM) at substantial risk for HIV acquisition
 - Persons who exchange sex for money at substantial risk for HIV acquisition
 - Sexually active men and women with a sexual partner with one or more HIV risk factors
 - Sexually active men and women whose partners are known to have HIV infection (HIV sero-discordant couples) especially when the HIV sero-positive partner has not achieved virally suppression
 - A history of sexually transmitted infection (STI) by lab testing or self-report or syndromic STI treatment
 - Use of post-exposure prophylaxis (PEP) for sexual exposure
 - Other persons deemed by health care provider to be at substantial risk for HIV infection

The risks and benefits of PrEP for adolescents is recommended to be weighed in the context of laws and guidelines on providing health care decision making to those under the age of consent.

PrEP Is contraindicated in:

- HIV- positive individuals
- Individuals with an estimated creatinine clearance <60 mls/min
- Individuals with signs/symptoms of acute HIV infection/probable recent exposure to HIV
- Allergy or contraindication to any medicine in the PrEP regimen

2.2 Initiating PrEP: Baseline Evaluation and Management:

The first step to initiating PrEP is a thorough history including determining eligibility for PrEP.

Determining PrEP eligibility includes:

- Assessing client risk factors for PrEP. Individuals with a substantial ongoing risk for HIV may benefit from PrEP
- Commitment to taking meds daily and follow up
- Screening for HIV and the need for further assessment of early infection (viral load)
 - Acute and chronic HIV infection must be excluded by history and HIV testing immediately before PrEP is prescribed
- Baseline Hepatitis B screening and renal function
- Baseline STI screening
- Baseline Pregnancy testing and counselling

2.3 Prescribing PrEP

Prescribing PrEP involves the following key principles:

- Prescribe Tenofovir/Emtricitabine 300/200 mg one tablet once daily for three months
- Up to 90 days may be dispensed at a time
- Counsel the client on adherence and daily use should be emphasized
- Emphasize additional HIV prevention measures (critical minimum of seven days after commencing PrEP)

HIV infection should be assessed at a minimum of every three months for patients taking PrEP to prevent persons with incident HIV infection continuing to take PrEP as the 2 drug regimen for PrEP is inadequate for treatment of HIV infection.

Renal function should be assessed at baseline and monitored every 6 months at least.

Patients receiving PrEP should also be referred to HIV prevention/risk reduction services.

Patients receiving PrEP should be counseled and encouraged to use PrEP in combination with other effective HIV prevention options

Patients receiving PrEP should be counseled at baseline and during three months clinical follow up on high medication adherence for PrEP efficacy.

<u>Table 1. Recommended Investigations Prior to Starting PrEP:</u>

Investigation/Intervention	Rationale
HIV Test using National Diagnostic	To assess HIV infection status
Algorithm	If recent exposure (in the past 72 hours),
	consider PEP and re-test after 28 days. To
	complete a symptom checklist for possible
	acute HIV infection
Serum creatinine	To identify pre-existing renal disease
	(estimated creatinine clearance less than
	60 ml/min)
Hepatitis B surface antigen	If negative, consider vaccination against
	hepatitis B.
	If positive, further testing and assessment
	for hepatitis B treatment
Hepatitis C antibody	If positive referral for assessment and
	treatment for hepatitis C infection
Rapid plasma reagin (RPR)	To diagnose and treat syphilis infection
Other screening for sexually transmitted	To diagnose and treat STI (syndromic or
infection (STI)	diagnostic STI testing)
Pregnancy testing	To guide antenatal care, contraceptive
	counselling and PMTCT if relevant
Review vaccination history	Vaccination as per National guidelines
Counselling	-To assess whether the client is at
	substantial risk of HIV
	-To discuss prevention needs and provide
	condoms and lubricants
	-To discuss desire for PrEP and willingness
	to take PrEP
	-To develop a plan for effective PrEP use,
	sexual and reproductive health

-To assess fertility intentions and other
contraception or safer conception
counselling
-To assess intimate partner violence and
gender based violence
-To assess substance use and mental health
issues

Adapted from WHO Implementation Tool For Pre-ExposureProphylaxis (PrEP) of HIV Infection

2.4 PrEP Clinical Follow-up, Safety and Monitoring:

Individuals using PrEP should have followed up and monitored every three months as a minimum. The following should be offered during the follow up and monitoring visits:

Counselling:

- Risk-reduction counselling, adherence counselling and other preventive measures such as condom use should be offered and re-enforced
- STI counselling, review for symptoms
- HIV counselling, review for acute HIV sero-conversion symptoms
- Re-evaluate need for PrEP

Lab Monitoring:

- HIV testing to be repeated every 3 months
- STI screening to be repeated every 3 months
- Renal function at 3 months and every 3-6 months
- Repeat pregnancy testing for women of child bearing potential

Side Effects review:

- About 10% of users will have some short term, mild side-effects such as gastrointestinal symptoms including diarrhea, nausea, decreased appetite, abdominal cramping or flatulence
- Changes in renal function may occur

Review Behaviour Change and Risk Reduction Strategies

• Re-iterate comprehensive combination HIV prevention approaches

Table 2: Recommended PrEP Follow-Up Procedures

Intervention	Schedule Following PrEP Initiation
Confirmation of HIV-negative status	Every 3 months. Consider testing at 1
	month
Address side effects	Every visit
Brief adherence counselling	Every visit
Estimated creatinine clearance	Every 6 months
Hepatitis C antibody	Test every 12 months
Screen for STIs, condoms, contraception	Every visit

Counsel on PrEP use, adherence, STI	Every visit
prevention, mental health, intimate partner	
violence, substance use	

2.5 Duration of Pre-Exposure Prophylaxis

Persons should continue pre-exposure prophylaxis as long as the risk of HIV infection persists.

Notably for HIV un-infected persons who have a sexual partner who is HIV infected:

- Continue PrEP until the HIV-infected partner has achieved a stably suppressed viral load
- Certain HIV un-infected patients should continue PrEP even if their partner has been on ART
 - Including those HIV- uninfected patients who are having condom-less sex with other partners
 - Those who have concerns that their HIV-infected partner is not taking antiretroviral regimen as prescribed

2.6 Discontinuation of PrEP:

PrEP can be discontinued 28 days after last possible HIV exposure.

2.7 Managing HIV sero-conversion on PrEP:

HIV sero-conversion on PrEP may occur after receiving PrEP due to pre-existing HIV infection or due to no or inconsistent use of PrEP. Antiretroviral therapy can be offered as soon as possible after sero-conversion after confirming HIV test results and a fully suppressive antiretroviral therapy regimen should be initiated.

2.8 PrEP On Demand/Intermittent PrEP:

PrEP on demand is currently considered off label use as it relates to National Antiretroviral Treatment as Prevention guidelines. Persons may be eligible for PrEP on demand on an individual case basis.