ACCESS CAMPAIGN
MEDECINS SANS FRONTIERES

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MSF Access Campaign

Outline

- HIV/AIDS – 20 Points to consider for HIV Programs
  - Treatment, Prevention, Cost & Rationale

Highlights:

- Opportunistic Infections
  - Cryptococcal Meningitis
- Service Delivery for Advanced Disease

20 Points for HIV Programs

TREATING & PREVENTING AIDS

Diagnostic and medicine checklist for the management of HIV and advanced HIV

Diagnostics	Medicines	
HIV Rapid Diagnostic Test (RDT)	PrEP: TDF/3TC or TDF/FTC	TPT children
Early infant diagnosis (EID) nucleic acid amplification test (NAAT)	1st Line ARVs Adults	Cotrimoxazole
Routine Viral Load (RVL)	1st Line ARVs Paeds	Fluconazole
CD4 count	2nd Line ARVs Adults	Flucytosine
Xpert MTB/RIF (Ultra) NAAT	2nd Line ARVs Paeds	Liposomal amphotericin B
TB LAM RDT	TB medicines	Regionally appropriate OI and cancer treatment (e.g. KS, CMV, penicilliosis)
CrAg RDT	TB prophylaxis therapy (TPT) adults	

Cryptococcal Meningitis

- *Why should CM be important for PEPFAR?*
  - In 2018, 223,000 cases of Crypto, with 181,000 deaths among PLHIV
  - 2nd leading cause of death for PLHIV → 15% of HIV-related deaths.
  - Most countries only have fluconazole available to treat people with Crypto Meningitis → 54% mortality at 10 weeks.
  - **Just starting people on ARVs is not going to eliminate opportunistic infections and advanced HIV…**

Cryptococcal Meningitis

- **Updated COP:** "*PEPFAR is committed to reducing mortality for PLHIV by providing appropriate diagnostics and treatment.*“

→ ***What’s the catch?***

- Crypto treatment per WHO guidelines, but not clear which regimen

Crypto Treatment

- Crypto treatment per WHO guidelines, but not clear which regimen…
- Preferred WHO 2018 Guideline Option:
  - **Amphotericin B + flucytosine x 1 week**

  ⇒**reduced mortality by 38% compared to previous 2 week regimen**

  ⇒**Safer – reduced anemia by 69%**

  ⇒**Preference is liposomal amphotericin B, which is better tolerated than the deoxycholate version**

Liposomal amphotericin B is preferred over amphotericin B deoxycholate, since liposomal amphotericin B has demonstrated equivalent efficacy and better safety compared with the conventional form of amphotericin B deoxycholate *(44,45)*. However, access to liposomal amphotericin B remains extremely limited in low- and middle-income countries because of its high cost.

Crypto Treatment

- Liposomal Ampho B → $16.25 USD per vial from Gilead for LMICs
- Flucytosine 500 mg tabs → $110 USD per bottle of 100 tabs

Cryptococcal Meningitis Treatment - Pricing for 50 kg patient					
Price	Amphotericin B Deoxycholate *(1mg/kg/day)*	Liposomal Amphotericin B *(3 mg/kg/day)*	5FC (100mg/kg/day)	Fluconazole	Total
Induction options					
ampho B + 5FC x1 week then fluconazole (1200mg) x 1 week	49€* *1 vial per day to have 50 mg dose	€ 277* *approx. 3 vials per day	€67* *10 tabs per day	€ 2.40	Conventional Ampho B based: **118€** Liposomal Ampho B based: **346€**

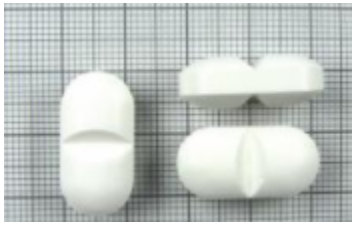
Prevention of Advanced HIV

- *Nov 2019 COP*: ”No PLHIV in PEPFAR programs should pay for cotrimoxazole’’.
- **Updated COP:**“No PLHIV in PEPFAR programs should pay for cotrimoxazole, TB preventive treatment, or fluconazole for secondary prophylaxis or pre-emptive treatment of cryptococcal meningitis.”

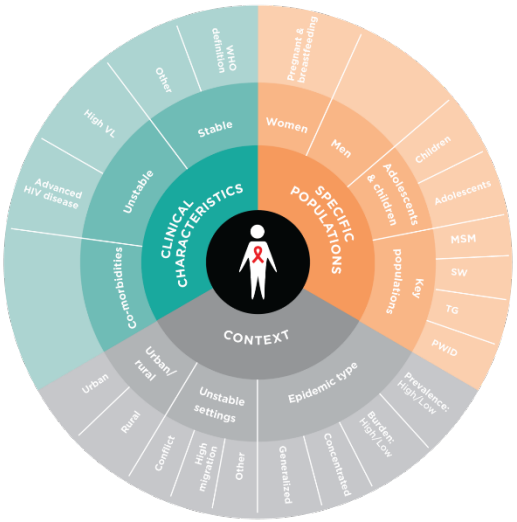
Prevention

- Cotrimox 800/160 mg – prevention of PCP and bacterial infections
- INH – prevention of TB
- Vit B6 – prevention of neuropathy from INH

- FDC – CTX/INH/B6, PQ approved - $2 per pak



Differentiated Service Delivery for advanced HIV disease: What do we expect from PEPFAR implementing partners?



The three elements and the four building blocks

1. Clinically unwell – admitted in IPD
2. Clinically unwell (Stage 3 and 4) – ambulatory - managed in OPD/PHC
3. Clinically well (Stage 1 and 2) – ambulatory, but CD4 <200 - managed in OPD/PHC

Components to consider when designing a differentiated service delivery model for advanced HIV disease

- Identifying advanced HIV disease
- Clinical package to screen, prevent and treat advanced HIV disease
    - Policy barriers to where tests placed and who can perform the test
- Rapid ART initiation and/or regimen switch
- Linkage to OPD/PHC ongoing care
- Post initiation/switch follow up

What does the PEPFAR COP say?

maximizing access these interventions. Use of DSD models that distinguish between those who are clinically unwell and admitted to hospital, those who are unwell but able to be managed in the outpatient department and those who are clinically well but have advanced disease may be particularly helpful and provide guidance for up-referral and allow resources to be deployed where they are most needed. See http://www.differentiatedcare.org/Resources/Resource-Library/DSD-for-advanced-HIV-disease-toolkit for more detail. Patients with advanced HIV

Decision-making process for determining the building blocks

The decision-making process to determine the building blocks for clients with advanced HIV disease – where tests are performed (OC, centralized), who performs tests (laboratory technician, lay worker) and who can initiate specific treatments (doctor, clinical officer, nurse) – may depend on the following factors:

- The urgency of the diagnosis – if the client is seriously unwell
- The complexity of the test being performed
- The throughput of each test – capacity to perform the volume of tests
- The ability to ensure quality control at multiple sites if only a few tests are being performed per site
- The availability and frequency of sample transport and result delivery mechanisms
- The policies in place for who can perform specific tests/procedures (for example, LP) and prescribe certain medications
- The technical knowledge and capacity of different levels of HR to manage complex cases

Identifying advanced HIV disease

	Identifying Clinical Signs and Symptoms	Performing CD4
WHEN	Each clinical visit At any time in between visits in community	At time of HIV diagnosis If identified with high viral load Presenting clinically unwell
WHERE	Facility Community	Facility Mobile clinic Community venue Home
WHO	All facility HCW (doctors , CO, Nurse) CHW , peers, CAG members and recipients of care	Lab technician Nurse Lay worker
WHAT	Identification of danger signs and symptoms *	CD4 (blood draw for centralised technology with sample transport or POC – choice dependant on strategic mix of testing)

Page 282- Use of CD4 to identify advanced disease

Viral load testing remains the primary method used to monitor the effect of therapy. CD4 testing is supported by PEPFAR in select settings (e.g., at referral facilities) to identify individuals with advanced HIV disease. It is not to be used for determining eligibility for ART or monitoring response to ART. Individuals ages 5 years and older who have persistent documented viremia despite ART may have a CD4 performed in order to identify those who would benefit from the recommended package for advanced disease.

Yes to triggered CD4- those with high VL

Patients initiating care in geographic regions or populations where the suspected or documented prevalence of patients presenting or re-presenting with advanced disease is >15% either overall or in specific age or risk group may also have a CD4 at initiation of therapy. Finally, if surveillance or public health investigation indicates disproportionately high morbidity or mortality among PLHIV in specific SNUs or populations, or for sites meeting the above criteria of >15% of the population presenting with advanced HIV disease, CD4 testing may be warranted. OU teams should budget for CD4 testing support at high volume facilities implem advanced disease treatment models.

Combination of CD4 technologies:

Centralised
PIMA
Visitec Lateral Flow

Baseline CD4 if geographical/ population prevalence of > 15%

Follow up after initiation/switch

	Clinical review	Tracing
WHEN	Weeks 1, 2, 3, 4, 6, 8, 12 if IPD or Stage 3 or 4 Weeks 2, 4, 8, 12 if clinically well CD4 <200	Prioritize tracing of clients with advanced HIV disease Trigger tracing on same day as missed appointment
WHERE	Facility Remote telephone consultation Community visit	From facility by phone Physical tracing at home (if no response to telephone call)
WHO	Doctor, clinical officer, nurse Community visit CHW/lay worker Peer (e.g., CAG member)	Nurse, CHW, peer
WHAT	Assessment of treated disease, symptoms, side-effects; new OIs; IRIS; ART adherence; consider early VL if client is initiated after discontinuation	By phone SMS or call Physical tracing

Example 1: Clinically unwell – admitted to IPD

	Identifying HIV advanced disease		Clinical package to screen, prevent and treat advanced disease						Rapid ART		Linkage to outpatient/PHC	Post-initiation follow up	
	Identifying symptoms and signs	**CD4**	**Xpert MTB/Rif**	**LAM**	**CRAG**	**Fluconazole pre-emptive**	**Crypto Rx regimen**	**TPT**	**Initiation**	**Switch**		**Clinical review**	**Tracing**
WHEN	Any time In community At PHC visit At entry to hospital	At entry to hospital	At entry to hospital	At entry to hospital	At entry to hospital	Where indicated, day 1	Where indicated, ASAP at rapid assess-ment unit	Where indicated, day 1	Within 7 days or as clinically indicated	Rapid switch as clinically indicated	Linked to post-discharge clinic, then to PHC	Week 2, 4 if stable Every 2 months	Same day as no show
WHERE	In emergency room	District laboratory	Sent to laboratory for urgent processing	Sent to laboratory for urgent processing	Sent to laboratory for urgent processing	Initiated on ward Continued at PHC	Initiated on ward Continued at PHC	Initiated on ward Continued at PHC	Initiated on ward Continued at PHC	Switched on ward Continued at PHC	Done from ward	Post-discharge clinic at hospital for 6 months; then PHC	By phone If not contact-ed, home visit
WHO	Doctor/CO	Lab technician	Laboratory technician	Laboratory technician	Laboratory technician	Doctor, CO, nurse	Doctor, CO	Doctor, CO, nurse	Doctor, CO, nurse	Doctor, CO, nurse	Doctor or nurse	Doctor/CO	CHW
WHAT	History and examination	PIMA CD4									Call made to PHC; referral letter sent		

Resources

- http://www.differentiatedservicedelivery.org/Resources/Resource-Library/DSD-for-advanced-HIV-disease-toolkit
- https://samumsf.org/en/news/advanced-hiv-disease-toolkit
- WHO IATT Formulary – Pediatric ARVs: https://www.who.int/hiv/pub/paediatric/optimal-paediatric-arv-formulary/en/
- ARV Procurement Working Group (APWG): https://www.arvprocurementworkinggroup.org/?l=en
- Stopping Senseless Deaths: https://msfaccess.org/stopping-senseless-deaths
- 20 Points for HIV Programs

Thanks! Merci!

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