The CQUIN Learning Network:

Differentiated Care for Patients at High Risk of HIV Disease Progression

Patients at High Risk: A Call to Action

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Why Focus on Patients at High Risk?

- The proportion of people starting ART in LMIC with CD4 < 200 is falling, but remains high (30-40%)
- Mortality amongst this population is high, particularly in the first 3-6 months on ART (8-26% in SSA)
- Systems and strategies for patients on ART but virally unsuppressed (patients with "unstable" HIV) lack a robust evidence base

Differentiated Care for Adults at High Risk of HIV Disease Progression

A Call to Action

HIV LEARNING NETWORK
The CQUIN Project for Differentiated Care

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How can we improve outcomes?

- Change the package of care (the “what”)
- Change the way we deliver care (the “how”)

Updated WHO Recommendations: Package of Interventions for Advanced HIV Disease (the "what")

14:45	**Welcome by co-chairs** Serge Eholie, University Félix Houphouët-Boigny, Cote D'Ivoire Meg Doherty, World Health Organization (WHO), Switzerland
14:50	**Keeping the sickest alive: Package of interventions for people with advanced HIV disease- the evidence and recommendation** Nathan Ford, World Health Organization, Switzerland
15:00	**Advanced disease care package in action: Experience from South Africa** Eric Goemaere, Médecins Sans Frontières (MSF), South Africa
15:10	**Rapid ART Initiation: Data from recent trials and the recommendation** Alexandra Calmy, Geneva University Hospital, Switzerland
15:20	**A viewpoint from civil society on rapid ART initiation** Maurine Murenga, International Community of Women Living with HIV (ICW), Kenya

World Health Organization

Key study characteristics	REALITY (enhanced OI prophylaxis package[1])	REMSTART (enhanced OI screening & adherence package[2])
Study countries	Kenya, Malawi, Uganda, Zimbabwe	Tanzania, Zambia
Sample size and design study	1805 individuals (open label)	1999 individuals (open label)
Eligibility criteria and population	CD4 < 100 (PLHIV ≥ 5 yrs old)	CD4 < 200 (PLHIV ≥ 18 yrs old)
Main outcome	Mortality reduction at 6 and 12 mo	Mortality reduction at 12 mo
Rapid ART initiation		✓
CrAg screening test		✓
Adherence support visits x 4 weeks		✓
CTX/isoniazid/B6 daily x 12 weeks	✓	
Fluconazole 100mg daily x 12 weeks	✓	
Azithromycin 500 mg daily x 5 days	✓	
Albendazole 400 mg x single dose	✓	
Costing analysis	✓	✓
Cost effectiveness analysis	✓	Slide courtesy of WHO

1 TB screening with GenXpert at baseline included in both arms of the study , re-screening at 6 weeks in intervention arm :TB cases only asssessed in interventiongroup

2 ART intensification (RAL) x 4 weeks and food supplementation x 12 weeks, not included a s part of the PICO question but assessed in th discounted.

World Health Organization

Potential Benefits and Harms

BENEFITS	HARMS
Reduced all-cause mortality	Potential for antimicrobial resistance: azithromycin
Reduced incident morbidity • New TB disease • New cryptococcal disease	Potential for antifungal resistance: fluconazole
Reduced (or unchanged) new hospitalisations	Potential increased absolute cost to health services
Simplified package consistent with public health approach	Simplified package may reduce attention to other important comorbidities/ co-infections
Promotes increased attention to advanced disease	

Slide courtesy of WHO

World Health Organization

WHO Recommendation: July 2017

A package of interventions including screening, treatment and/or prophylaxis for major opportunistic infections, rapid ART initiation and intensified adherence support interventions should be offered to everyone presenting with advanced HIV disease.

Strong recommendation, moderate-quality evidence

Slide courtesy of WHO

World Health Organization

Table 1 Components of the package of care for people with advanced HIV disease

	Intervention	CD4 cell count	Adults	Adolescents	Children
Diagnosis	Sputum Xpert® MTB/RIF as the first test for TB diagnosis among symptomatic people	Any	Yes	Yes	Yes
	LF-LAM for TB diagnosis among people with symptoms and signs of TB	≤100 cells/mm³ Or at any CD4 count if seriously ill	Yes	Yes	Yes[a]
	Cryptococcal antigen screening	≤100 cells/mm³	Yes	Yes	No
Prophylaxis and pre-emptive treatment	Co-trimoxazole prophylaxis[b]	≤350 cells/mm³ or clinical stage 3 or 4 Any CD4 count in settings with high prevalence of malaria or severe bacterial infections	Yes	Yes	Yes For criteria, see Annex 1
	TB preventive treatment[b]	Any	Yes	Yes	Yes[c]
	Fluconazole pre-emptive therapy for cryptococcal antigen–positive people without evidence of meningitis	<100 cells/mm³	Yes	Yes	Not applicable (screening not advised)
ART initiation	Rapid ART initiation (as recommended in Chapter 3)	Any	Yes	Yes	Yes
	Defer initiation if clinical symptoms suggest TB or cryptococcal meningitis (see Chapter 3)	Any	Yes	Yes	Yes
Adapted adherence support	Tailored counselling to ensure optimal adherence to the advanced disease package, including home visits if feasible	<200 cells/mm³	Yes	Yes	Yes

Slide courtesy of WHO

World Health Organization

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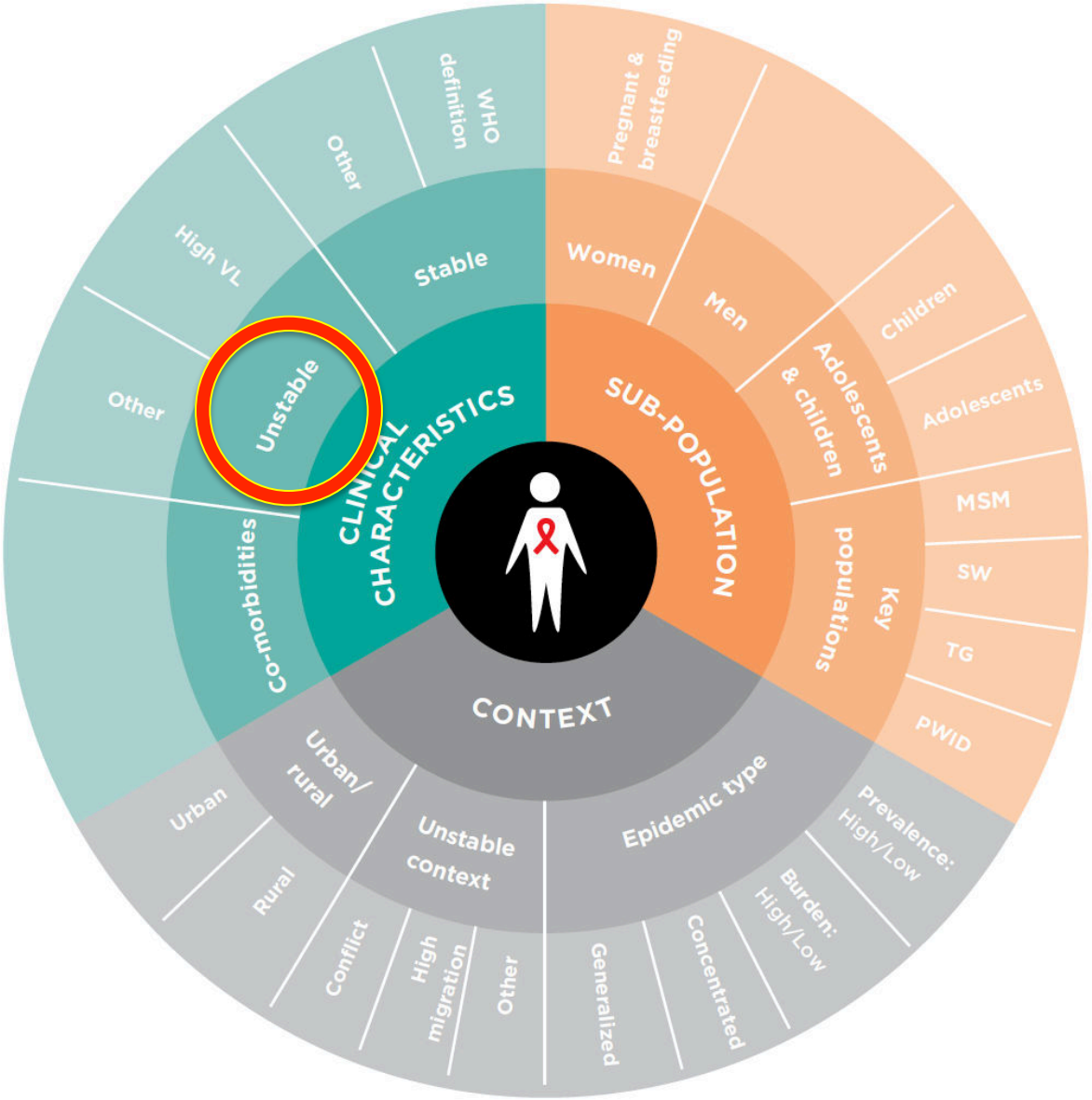
DSD is not just for stable patients



Programmatic Challenges

Challenge	Illustrative Barriers/Challenges
Identification of high-risk patients	Delayed ART eligibility assessment
	Delayed identification of failing regimens
	Delayed linkage from testing to treatment
ART initiation and management	Delayed switch to 2nd/3rd line regimens
	Lack of standard operating protocols (SOPs) for high risk patients
Prevention and management of acute co-morbid conditions(s)	Insufficient or absent OI screening/prophylaxis
	Weak linkages for up-referral to more specialized site/providers
	Discontinuity between inpatient, outpatient, and community-based services
	Siloed HIV and NCD services
Management of chronic co-morbid condition(s)	Lack of strong home care systems
	Need for specialized adherence support

Illustrative Programmatic Challenges

- How can we swiftly identify P@HR and “flag” them for rapid and prioritized services?
- How can we provide services that are both intensified and patient-centered?

The SIPOC Model from Kenya

("Severely Immunosuppressed Package of Care")

ROOM	SERVICES
RECORDS ROOM	▪ Filing of CD4 results from laboratory ▪ Identify and flag files with CD4 less than 100cells/mm³ or CD4 less than 15% using the checkered SIPOC sticker ▪ Insert SIPOC patient assessement form in patient file
CLINICAL ROOM	Clinical assessment including: ▪ TB screening at each clinical visit ▪ Clinical examination including temperature with special attention to detecting Opportunistic Infections (OI)
LABORATORY/ RADIOLOGY	Investigations: ▪ Haemoglobin ▪ Xpert MTB/Rif assay testing ▪ Cryptococcal antigen (CrAg) screening ▪ Hepatitis B screening ▪ Stool for parasites and AFB in anyone with diarrhea Other investigations to consider ▪ Chest X-ray in patients with presumptive TB ▪ Liver Function Test (LFT) ▪ Mid-Stream Urine in clients with urinary symptoms ▪ Fine Needle Aspirate (FNA) or biopsy in patients with focal lymphadenopathy
CLINICIAN/ NUTRITIONIST/ COUNSELLOR	**Clinical Management:** ▪ Cotrimoxazole Preventive Therapy ▪ Initiation of ART as per national guidelines ▪ IPT after 3 months ▪ Fortnightly clinical visits after ART (Assess for IRIS) **Nutritional Assessment:** ▪ Nutritional assessment, counseling and supplementation ▪ Grade nutrition and manage accordingly **Psychosocial support:** ▪ Adherence counseling at each clinic visit ▪ Clinical visits scheduled fortnightly for one month then monthly thereafter ▪ Linkage to peer educator with weekly phone call to assess progress

DSDM for P@HR

SERVICE FREQUENCY	SERVICE INTENSITY
- Weekly or biweekly visits?	- Enhanced prophylaxis? - Enhanced counseling?
SERVICE LOCATION	**SERVICE PROVIDERS**
- Specialty clinics? - Intermediate care facilities? - Housing near facility (like maternity waiting homes)? - Home-based care?	- NIMART “plus”? - Super-mentors in Kenya - Oversight committees

Thank You