SDC: COMPREHENSIVE CARE CLINIC ENROLMENT FORM: CREATES 2012- ERC#2477

Facility Name: | Date of visit:

Unique Patient Number: | Date of Birth: Age:

Unique Study Code:

Sex: ☐ Male ☐ Female Tel. Contact: Postal Address:

District: Location: Sub Location: Landmark:

Nearest Health facility: Treatment supporter:

Patient Point of referral

Entry Point: ☐PMTCT ☐VCT ☐TB/OPD ☐In-patient ☐CWC ☐HBCT ☐PITC ☐Other: _____

Transfer In: Date:_____ From: District:_____ Facility:_____ Date Started ART:_____

Date Confirmed HIV positive:_____ Date Enrolled in HIV Care _____

Is the Patient _____

Child, <5 years ☐ Child, 5 -12 years ☐ Child, 13 -17 years ☐ Adult, 18+ years ☐

Mode of HIV transmission

Perinatal ☐ Breastfeeding ☐ Not known ☐ Sexual ☐

Socio-demographic information

1. Marital Status: ☐ Married monogamous ☐ Married polygamous ☐ Divorced ☐ Separated ☐ Cohabiting ☐ Single ☐ Widowed.

If widowed, cause of death; ☐ Known HIV/AIDS ☐ Suspected HIV/AIDS ☐ Not HIV/AIDS related ☐ Unknown Cause

2. Highest Education Level: ☐ None ☐ Primary ☐ Secondary ☐ College/University

3. Occupation: _____

4. How many children do you currently have? _____

a) Children< 5 years old: _____

b) Children between 5 and 14 years: ____

5. Have you disclosed your status to anyone? ☐ Yes ☐ No

If Yes, to; ☐ Spouse ☐ Relative ☐ Friend ☐ Others

6. Are you sexually active? ☐ Yes ☐ No

If yes, Do you use condoms? ☐ Yes ☐ No

7. Is the patient or partner currently using any form of Family Planning? ☐ Yes (OnFP) ☐ No (NoFP)

If yes, which one? _____

8. Is the patient currently pregnant? ☐ Yes ☐ No ☐ N/A

If yes, (Gestation-wks) _____ EDD _____

9. PEER SUPPORT ACTIVITY

Aware of peer support programs (Y/N) _____

Actively involved ☐ Partly involved ☐ Never involved ☐

Year enrolled as applicable (e.g. Jan 2010)_____. If not in Support, do you want to enroll? (Y/N)_____

Activity interrupted since enrolment (Y/N)?: _____ Why (if 'Y'): _____. Rejoined? (Y/N):_____. Date:_____

10. HIV DISCLOSURE

Do you know your HIV status (Y/N) _____

Who else knows your HIV status?

☐ None ☐ Spouse (partner) only

☐ Spouse & others ☐ Others, but not spouse (partner)

Did you personally disclose your HIV status above? (Y/N) _____

Do you know your spouse's/partner's HIV status? (Y/N):_____. If yes, is he/she

☐ HIV positive ☐ HIV Negative

☐ Indeterminate ☐ Can't disclose

Is your spouse/partner ☐ Male ☐ Female

Medical History

11. Chief Complaints: □ Feeling well □ Having symptoms.

Specify;_____

_____

_____

_____

12. **Cryptococcus Treatment**: □ None □ Diflucan

13. **Multivitamin use**: □ No □ Yes

14. **PCP Prophylaxis** □ None □ Septrin □ Dapsone

15. Has the patient been hospitalized in the last 12 months?

□ Yes (Number of times._____) □ No

If yes, describe reason,

_____

_____

16a). Do you currently have any of the following symptoms?

□ Cough O days O weeks O months

□ Cough productive O white O purulent O bloody

□ Night sweats □ TB Suspect

□ Weight Loss

□ Fever

□Difficulty in breathing

16b). TB treatment: □ N/A

□ Currently on treatment _____(start date)

□ Treatment completed _____ (stop date)

If on treatment, mark regimen appropriately below:

□ Rifafour(RHZE) □ Ethizide(EH) □ Rifinah(RH)

□ Streptomicin(S) □ Ethambutol(E) □ Pyrazinamide.

□ Rifater (RHZ) □ INH

17. History, including all illness related to HIV infection, Fill in appropriate 'o' next to each indicator condition

Primary HIV Infection		**WHO Stage 4**	
Unrecognised	**O**	***Conditions where a confirmatory diagnostic test is required in Italics***	
Acute Retroviral Syndrome	**O**	Oesophageal candidiasis	**O**
WHO Stage 1		Pneumocystis Carinii (jiroveci) pneumonia (PCP)	**O**
Asymptomatic	**O**	HIV wasting syndrome	**O**
Persistent Generalized Lymphadenopathy (PGL)	**O**	Reccurrent severe pneumonia (≥ 2 episodes within 1 year)	**O**
WHO Stage 2		Cryptococcal meningitis	**O**
Moderate weight loss (<10% of resumed or measured body weight)	**O**	Toxoplasmosis of the brain	**O**
Minor mucocutaneous manifestations (seborrheic dermatitis, prurigo, fungal infection, recurrent oral ulcerations)	**O**	Chronic oralabial, genital or ano-rectal herpes simplex infection for > 1 month	**O**
Herpes Zoster in preceding 2 years	**O**	Kaposi's sarcoma (KS)	**O**
Recurrent upper respiratory tract infections (bacterial sinusitis, bronchitis, otitis media, pharyngitis)	**O**	HIV Encephalopathy	**O**
WHO Stage 3		Extra pulmonary tuberculosis (EPTB) except TB Lymphadenopathy	**O**
Weight loss of >10% of presumed or measured body weight)	**O**	*Invasive cervical cancer*	**O**
Unexplained chronic diarrhea of > 1 month	**O**	*Chronic diarrhea > 1 month- cryptosporidiosis, isosporiasis*	**O**
Unexplained prolonged fever of > 1 month	**O**	*Lymphoma Cerebral or B cell Non-Hodgkins Lymphoma (NHL)*	**O**
Oral candidiasis (Thrush)	**O**	*Visceral Leishmaniasis*	**O**
Oral Hairy Leukoplakia (OHL)	**O**	*Cytomegalovirus (CMV) retinitis or disease of the organs*	**O**
Pulmonary Tuberculosis (PTB)	**O**		
Severe bacterial infections (pneumonia, pyomyositis, empyema, bone or joint infections)	**O**		
TB Lymphadenopathy	**O**		

18. ARV THERAPY

Has the patient; 18a. Ever taken any Antiretrovirals? □ Yes □ No 18.b. currently taking Antiretrovirals? □ Yes □ No

	Past Use			**Current Use**			
Medication	**PEP**	**PMTCT**	**Rx**	**PEP**	**PMTCT**	**Rx**	**Comments**
Lamivudine (3TC)	O	O	O	O	O	O	
Stavudine (d4T)	O	O	O	O	O	O	
Nevirapine (NVP)	O	O	O	O	O	O	
Efavirenz (EFV)	O	O	O	O	O	O	
Zidovudine (AZT)	O	O	O	O	O	O	
Didanosine (DDI)	O	O	O	O	O	O	
Abacavir (ABC)	O	O	O	O	O	O	
Nelfinavir (NFV)	O	O	O	O	O	O	
Kaletra/Alluvia	O	O	O	O	O	O	
Tenofovir (TDF)	O	O	O	O	O	O	
Other, Specify							

18c. ART ELIGIBILITY AND INTERRUPTIONS

Date Medically Eligible _____

Eligible through? ☐ WHO Clinical Stage_____ ☐ TLC _____ ☐ CD_4 (count/%) _____

COHORT: MONTH YEAR (e.g. Jan 2006)_____

Date Started on 1st Line Regimen: _____ Regimen: _____

At Start of ART:

Weight (Kgs)_____ Height for Children (Cms) _____ WHO Stage_____

Substitution of ARVs within 1st Line Regimen

Dates	Regimen	Reason(s)
_____	_____	_____
_____	_____	_____
_____	_____	_____

Switch to 2nd Line (indicate Substitute within 2nd Line with an asterisk '*')

Dates	Regimen	Reason(s)
_____	_____	_____
_____	_____	_____
_____	_____	_____

Transfer Out and Death

Dates	**Event (**Patient Transferred Out or died)	**Where?**
_____	_____	_____
_____	_____	_____

ART Treatment Interruptions

Dates	**Reason for Interruption**	**Date Restarted**
_____	_____	_____
_____	_____	_____
_____	_____	_____

ART Side effects or toxicity (specify with code, and indicate type and method of identification/diagnosis)

Codes for

ART substitute	**Switch to 2nd line regimen**	**ART side effects (*Grade where applicable*)**
1. Toxicity/side effects 2. Pregnancy 3. Risk of pregnancy 4. Due to new TB 5. New drug available 6. Drug out of stock 7. Other reasons (specify)	8. Clinical treatment failure 9. Immunologic failure 10. Virologic failure	**1.Peripheral neuropathy** **2. R**ash; **3. A**naemia **4. Pancreatitis; 5. J**aundice **6. FAT** redistribution **7. Hy**persensitivity **8. He**patotoxicity **9. CNS**: dizzy, anxiety, nightmare, depression

19. ADHERENCE DATA (personnel to count)

Dose/pills given at last visit

Date	Regimen	Counts
_____	_____	_____
_____	_____	_____
_____	_____	_____

Dose/pills in bottle at current visit

Date	Regimen	Counts
_____	_____	_____
_____	_____	_____
_____	_____	_____

Self reported medication/adherence (interviewer to ask patient at encounter)

Did you ever miss or skip your prescribed pill since the last refill (Y/N)? _____. If yes,

Dates skipped	**# Times skipped**	**Regimen & why skipped?**
_____	_____	_____
_____	_____	_____
_____	_____	_____

_____ _____ _____
_____ _____ _____
_____ _____ _____
_____ _____ _____

Did you combine your pill dose to cover for missed/skipped dose (Y/N)? _____. If yes,

Dates skipped	**# Regimen skipped**	**Doses combined (e.g 1, 2..)**
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Have you ever shared your ARV medications with someone? (Y/N)? _____. If yes,

With whom	**Why**	**Regimen shared**
_____	_____	_____
_____	_____	_____
_____	_____	_____

Do/have you receive (d) or refill (ed) your ARVs at a location other than this clinic? (Y/N)_ _____

Where	**Last refill**	**Regimen**
_____	_____	_____
_____	_____	_____
_____	_____	_____

Have you ever sold/discarded your ARV medications? (Y/N)? _____. If yes,

Regimen	**Date Sold/discarded**	**Why**
_____	_____	_____
_____	_____	_____
_____	_____	_____

(Reasons may include; money, beliefs, toxicity, intolerance. Personnel to redact as appropriate.)

Do you use/have a daily dose reminder for your ARV medication? (Y/N) _____. If yes,

Who/What	**Source**	**Use it daily?**
_____	_____	_____
_____	_____	_____

Do you use/have a refill reminder for your ARV medication? (Y/N) _____. For yes, specify if

Who (e.g family, peer support)	**Mode (e.g phone, call visit)**	**Days/hours before refill**
_____	_____	_____
_____	_____	_____

Codes for ART adherence.			**Codes for why poor adherence:**	
Adherence (circle)	**Actual dose counts missed last 30 days**	**% missed/skipped doses**	**1.** Toxicity/side effects **2**. Forgot; **3** Felt better **4** Too ill **5** Stigma, disclosure or privacy issues **6** Drug stock out—dispensing area **7** Patient lost/ran out of pills	**8** Delivery/travel problems 9 Inability to pay **10** Alcohol **11** Depression **12.** Share **13.** Other
Good	_____	<= 5%		
Fair	_____	6-15%		
Poor	_____	>15%		

20. OTHER DRUG AND SUBSTANCE USE

Do you Inject Drugs or use other (regulated) substances? (Y/N) _____. Date started_____(dd/mm/yyyy)

Drug/Substance	Mode (e.g. Inject, non-inject, smoke)	Regularity (e.g 1, 2../daily)	Source

Do you use these drugs as a replacement for your ARVs (Y/N)? _____. As a cure/management for your HIV? (Y/N):_____

Drug/Substance and date started	**Reason for use**
_____	_____
_____	_____
_____	_____

21. Drug Level study guide

Time of the day you take daily ARV dose (e.g Morning, midday, evening- as applicable): _

Regimen	Time of 1st dose	Time of 2nd dose	Time of 3rd dose	Any skipped?	Last dose/time skipped

Ever vomited after your ARV dose? (Y/N): _____. How often? Every time____, Often times_____, Occasionally____

Did you vomit after taking your last dose before this visit? (Y/N)_____. Study personnel to fill table below if patient answered yes

Regimen taken	Time of last dose	First episode after (min, hrs.)	# of times vomited	Re-dosed after episode

What other drugs or medications do you currently or regularly take?

Drug/medication	Date started	Regularity (e.g 1, 2../daily)	Source	Reason for medication

Do you Smoke Cigarette? (Y/N):_____. Did you smoke Cigar before your last ARV dose? (Y/N):_____

Do you drink Alcohol? (Y/N):_____. Did you drink alcohol before your last ARV dose? (Y/N):_____

FOR WOMEN ONLY. Personnel to fill table below with appropriate regimen as applicable

Pregnant? (Y/N):_____			Breastfeeding? (Y/N):_____			Other ARVs		
ARVs for PMTCT	Dose	Date started	ARVs for PMTCT	Dose	Date started	Regimen	Dose	Date started

22. General Exam (Extract from Clinic records after interview):

Systemic Exam: _____

_____

_____

23. Indicate most advanced WHO staging indicator. WHO Stage: □ 1 □ 2 □ 3 □ 4 Karnofsky score_____%

24. Labs ordered today: □ FHG □ ALT □ Creatinine □ VDRL □ Urinalysis □ CD4 □ Pregnancy Test
□ Sputum for AFB □ CXR □ Malaria Smear □Viral Load □ Other: (specify)_____

25. **Results:**

Test	Result	Date	Test	Result	Date
WBC /mm3			Hb g/dl		
TLC /mm3			VDRL		
CD4/CD4%			Creatinine mmol/L		
ALT			Viral load, copies/ml		
CXR-					

PLAN

26. **ARV's** dispensed today □ Yes □ No (If yes indicate regimen) _____

27. **Prophylaxis**: □ None □ Cotrimoxazole □ Dapsone □ Fluconazole □ INH □ multivitamin

28. **TB treatment;** □ None □ Start □ Continue Regimen □ Change Regimen □ Stop
If start/change, indicate regimen appropriately: □ Rifater (RHZ) □ Rifafour (RHZE) □ Ethizide (EH) □ Rifinah (RH)
□ Streptomicin _____mgs □ Ethambutol □ Rifampicin □ Pyrazinamide □ Other, specify _____

29. Other Meds; 1) _____ **3)** _____
2) _____ **4)** _____

30. Referral/Hospitalized. □ None □ TB/DOT prog □ FP services □ In-patient care □ Nutritional support
□ Adherence counseling □ Social support services □ ANC/PMTCT □ Other (specify) _____

31. **Next appointment. Weeks** _____/52 **Months** _____/12 **Date** _____/_____/ _____
Completed by. _____ **Provider initials.**_____

Adapted from MOH, to incorporate study specific information

Supplementary digital contents (SDC)

SDC-table 5: Comparison of various datasets among the six (6) study sites

	Community Peer Support Activity, %N | VL2			Total
	Active	Occasional	None	
Homa-Bay, n=102	16.7 | 2.13	19.5 | 3.08	20.9 | 3.12	18.7 | 2.7
Kisumu, n=112	23.9 | 1.93	18.6 | 3.12	17 | 2.93	20.5 | 2.43
Kitengela, n=79	12 | 1.74	11.5 | 1.87	19.8 | 3.23	14.5 | 2.44
Kiambu, n=72	12.7 | 1.67	15.9 | 2.56	12.1 | 3.26	13.2 | 2.38
Malindi, n=120	22.7 | 1.76	25.7 | 2.29	18.7 | 3.2	22 | 2.3
Naivasha, n=61	12 | 1.96	8.8 | 1.59	11.5 | 2.97	11.2 | 2.25
Total, N	251 | 1.87	113 | 2.53	182 | 3.12	546 | 2.43
χ^2 p value (comparing proportion of patients across CPS and study site)				0.269

	Adherence, % N | VL2			Total
	Good	Fair	Poor	
Homa-Bay, n=102	16.7 | 2.08	15.6 | 2.57	27.1 | 3.77	18.7 | 2.7
Kisumu, n=112	22.5 | 2.08	20.5 | 2.5	15.3 | 3.7	20.5 | 2.43
Kitengela, n=79	12.4 | 1.88	15.6 | 2.3	18.6 | 3.54	14.5 | 2.44
Kiambu, n=72	13.7 | 1.98	14.8 | 2.55	10.2 | 3.5	13.2 | 2.38
Malindi, n=120	23.5 | 1.84	23 | 2.5	16.9 | 3.63	22 | 2.3
Naivasha, n=61	11.1 | 1.67	10.7 | 2.64	11.9 | 3.29	11.2 | 2.25
Total, N	306 | 1.94	122 | 2.5	118 | 3.61	546 | 2.43
Anova p= 0.204†				

	Number of missing VL1 by sex and age group					Virologic response, N | %	
	Males	Females	18-35	36-45	>45years	Failure	Responders
Homa-Bay	3	4	1	1	5	40 | 44.4	50 | 55.6
Kisumu	1	0	1	0	0	27 | 30.3	62 | 69.7
Kitengela	9	10	6	11	2	19 | 32.8	39 | 67.2
Kiambu	4	13	4	10	3	20 | 36.4	35 | 63.6
Malindi	10	18	6*	15	7	30 | 33.3	60 | 66.7
Naivasha	8	16	7	7	10	14 | 38.9	22 | 61.1
[§]Total	35	61	25*	44	27	150 | 35.9	268 | 64.1

Distribution across the 6 study sites, of patients and of viral load (VL2) in each peer support and adherence categories (top and middle). Adherence levels were comparable among the sites (χ^2 p= p=0.205). †Anova compares VL2 between study sites. Bottom: [§]Ninety-six of the 514 patients under 'Sex' and 'Age group' columns and 418 (514 less 96) under virologic response column. Virologic failure rates not significantly different between sites (p=0.453). *Includes 1

patient aged 12-17 years.

SDC-table 6: Reasons for Adherence behavior or pattern and relationship with adherence outcome

	Adherence outcome, N | %			Total
Reasons	Good	Fair	Poor	
Health & longevity	213 | 74.2	28 | 24.6	7 | 6.2	248 | 48.2
Out of drugs	35 | 12.2	33 | 28.9	14 | 12.4	82 | 16
Feeling not sick	20 | 7	27 | 23.7	13 | 11.5	60 | 11.7
Felt bad, hopeless, inconvenienced	19 | 6.6	26 | 22.8	79 | 69.9	124 | 24.1
Total	287	114	113	514
Chi-Square p value				<0.001

Patients were asked why they took their ART pills the way they did. Varied answers were collated and grouped into four adherence variables (reasons) and compared with adherence outcomes. Chi square test compares the adherence variables in rows between column cells of adherence outcomes. The relationships are significant.

SDC table #7, Viral load before regimen switch and treatment failure definition under cross-sectional and longitudinal strategies.

		VL before regimen switch (log RNA copies)			
		<40 copies	40-999 copies	>=1000 copies	Total
Switched					
Yes (N=43)	VL | %N	1.59 | 16.3	2.65 | 18.6	3.93 | 65.1	3.31 | 100
No (N=379)	VL | %N	1.59 | 21.4	2.76 | 11.3	3.96 | 67.3	3.32 | 100
Total	VL | %N	1.59 | 20.9	2.75 | 12.1	3.96 | 67.1	3.32 | 100
Anova, p-value					0.969
Chi-Square p value					0.334

	Virologic failure definition under CSVL			Virologic failure definition under LMVL
	6 months	12 months	24 months	
Treatment response				
Undefined	3 | 0.7	31 | 7.4	82 | 19.6	N/A
Failure	147 | 35.2	138 | 33	113 | 27	150 | 35.9
Responders	268 | 64.1	249 | 59.6	223 | 53.3	268 | 64.1

Analysis of variance compares viral load (VL) before time of switch between patients switching and patients not switching regimen. Chi square test compares the proportion of patients switching or not switching regimen between VL categories. Data is based on 418/546 patients who initiated first-line regimen in the AZT, D4T and TDF arms and having 2 complete VL readings. CSVL**,** cross-sectional single VL; LMVL, longitudinal multiple VL