

8 Annexes

8.1 Patient record forms for the cohort data

Arba Minch Hospital Opportunistic Infection Clinic		Patient Record Form		P.O. Box 28 Tel. 251-6-81-11-43					
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				Arba Minch, Ethiopia					
BACKGROUND INFORMATION								Card No. _____	
Identification	Name			Reg. No		Date			
	Sex	Current Address	Region	Town Kebele No	Tel. POB		Contact person		
	Age (yrs)		Zone		Marital status				
			Woreda		Religion		No. Children		
Previous Occupation		Current Occupation			Monthly Income	Poor paper	Yes	No	
Education	Illiterate		Read only	Read and Write		Last grade completed			
Counseling	Pretest	Post test	Consent Paper	Yes	No	Test Result	Yes	No	
Date						Code			
Remarks									
Signature					Date		Place		



Name		Reg. No		Date				
MEDICAL HISTORY								
Past History	Disease							
	Year							
Main Presenting Complaint(s)								
Symptoms								
Duration								
History of Present Illness								
Coexisting medical	Diabetes		Hypertension		Pregnancy	TB	Others	
Conditions	Yes	No	Yes	No	Yes	No	Yes	No
Doctor's Signature						Date	Place	

Name		Reg. No		Date	
PHYSICAL FINDINGS					
General appearance (Mark "X")	Acutely Sick	Chronically sick	Acute on Chronic	Well Looking	
Vital Signs	BP (mmHg)	PR/minute	RR/minute		
	Weight (Kg)	Height (cm)	BMI (Kg/m ²)		
HEENT	Head/hair	Eyes	Ears	Nose	Tongue/throat
	Findings				
Glands					
Chest					
Cardiovascular system					
Abdomen					
Genitourinary System					
Musculo-skeletal system					
Integumentary System					
	Consciousness	Cranial nerves	Motor	Sensory	
Nervous system					
	Doctor's Signature		Date	Place	



Name		Reg. No	Date
LABORATORY INVESTIGATIONS			
Haematology	CD4	ESR	P-LCR
	MPV	PDW	RDW
	NEUT	MXD	LXM
	NEU%	LYM%	MxD%
	PLT	MCHC	MCH
		MCV	HCT
		Hgb	RB C
	WBC		
Chest X-ray	Description		Conclusion
			AFB
			+ -
Chemistry and Electrolytes	WIDAL	VDRL	Serology
	Weil felix		
Other investigations			
DIAGNOSIS AND TREATMENT			
Diagnosis (es)			
Treatment			
WHO STAGE	Evidences		Next visit

Doctor's Signature	Date	Place

FOLLOW-UP VISITS (1)	Name	Reg. No		
Examinations	Date of visit			
Subjective complaint(s)				
Objective finding(s)				
WBC (x10 ³ /micL)				
RBC (x10 ⁶ /micL)				
HGB (g/dl)				
HCT (%)				
MCV (fL)				
MCH (pg)				
MCHC (g/dL)				
PLT (x10 ³ /micL)				
LYM (%)				
MxD (%)				
NEUT (%)				
LYM (x10 ³ /micL)				
MxD(x10 ³ /micL)				
NEU (x10 ³ /micL)				
RDW (fL)				
MPV (fL)				
PDW (fL)				
FOLLOW-UP VISITS (2)	Name	Reg. No		
Examinations	Date of visit			

P-LCR (%)				
ESR (mm/hr)				
CD4				
Na				
K				
BUN				
Creatinine				
Amylase				
Bilirubin				
SGOT				
SGPT				
GGT				
ALP				
LD				
Cholesterol				
Amylase				
Sputum for AFB				
Chest X-ray				
New diagnosis				
Treatment				
Disease stage				
Doctor's sig.				
Next visit				

ART monitoring chart (Months 0, 3, and every three months thereafter)

Name ----- Age ----- Sex ----- card no. ----- Reg. no ----- Rx. no ----
 Previous ART No Yes (Combination ----- Duration ----- Place -----
 Current Indication(s): Stage ----- TLC----- Wt-----
 Drug combination and dosage ----- Date started:----- Doctor's sig -----

Changes during the first month of treatment

Symptom	yes	no	Haematologic	Biochemical
Feeling well			WBC($\times 10^3$ micL)	SGOT
Gained wt()			RBC($\times 10^3$ micL)	SGPT
Diarrhea			Hgb(g/dl)	GGT
Fever			HCT(%)	ALP
Weight loss			MCV(fL)	Creatinine
Cough			MCH($\times 10^3$ micL)	BUN
Oral thrush			MCHC(g/dL)	Bilirubin(T)
Herpes zoster			PLT($\times 10^3$ micL)	Bilirubin(D)
TB at any site			LYM(%)	LD
CNS manifestations			MxD(%)	Amylase
Headache			NEUT(%)	Cholestrol
Itchy sensation			LYM($\times 10^3$ micL)	LD
Burning sensation			MxD($\times 10^3$ micL)	K
Jaundice			NEU($\times 10^3$ micL)	Na
			ESR	

Conclusions: Improved Same Worse Died

Adherence: As prescribed Less often More often Not at all

Recommendations: Continue with same drug Change drug

Next visit ----- Doctor's sign ----- Date -----

Monthly progress notes on ART

Name:----- Age ----- sex----- Reg.no -----

Date	Subjective Complaints	Objective Findings	Laboratory	Conclusions	Recommendations

ART Three-Monthly Review Checklist

Name	Age	Sex	Date ART started		Reg. No		ART	
Date								
Symptom/sign	Yes	No	Yes	No	Yes	No	Yes	No
Feeling well								
Gained wt()								
Diarrhea								
Fever								
Weight loss								
Cough								
Oral thrush								
Herpes zoster								
TB at any site								
CNS manifestations								
Headache								
Itchy sensation								
Burning sensation								
Jaundice								
CBC(attach result)								
Chemistry(attach)								
Summary notes								
General condition								
New adverse drug rxn and offending drug								
Adherence								
Plans								
Name and signature								
Date								

Key

General condition: Improved/Same/Worse/Died

Adherence: As prescribed Less often than prescribed More often than prescribed not at all

Additional Notes-----

8.2 Questionnaire

Questionnaire number

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Questionnaire on Acceptability of VCT among TB Patients

Arba Minch Hospital

Ethiopia

	Name	Date		
		dd	mm	YY
Interviewer 1				
Interviewer 2				
Supervisor				
Data entry				

Notes:

Section I: Socio-demographic information

- | | | | | |
|---|------------------------|------------------------------------------------------------------------------------------------|----------------------|----------------------|
| 1 | Age in years | | <input type="text"/> | <input type="text"/> |
| 2 | Gender | 0=Female | 1=Male | <input type="text"/> |
| 3 | Education | 0=No formal education
1= Primary education
2=Secondary education
3=Tertiary education | | <input type="text"/> |
| 4 | Marital status | 0=Married
1=Divorced
3=Separated
4=Never married | | <input type="text"/> |
| 5 | Address | 1=Urban
2=Rural
Specify _____ | | <input type="text"/> |
| 6 | Religion | 0=Orthodox
1=Protestant
2=Muslim
3=Other(Specify) _____ | | <input type="text"/> |
| 7 | Monthly income in Birr | 0=<200
2=500-100
4=Difficult to quantify
Actual value _____ | 1=200-500
3=>1000 | <input type="text"/> |
| 8 | Occupation | 0=Unemployed
1=Employed
Specify _____ | | <input type="text"/> |

Section II: History of TB treatment

- | | | | | |
|----|------------------------|--------------------------------------------------------------------------|--|----------------------|
| 9 | Have you ever had TB ? | 0=N0
1=Yes | | <input type="text"/> |
| 10 | If yes to Q9 when? | 0=Within the last 5 years
1=More than 5 years ago
2=Don't remember | | <input type="text"/> |

- Date (dd/mm/yy)
- 11 Date of diagnosis of current TB(dd/mm/yy)
(Check Clinic record)
- 12 Type of current TB (Check record)
0=Smear negative pulmonary
1=Smear positive pulmonary
2=Extrapulmonary
3=Disseminated
- 13 Current treatment category (Check record)
0=Category I
1=Category II
2=Category III
3=Category IV
4=Other(specify) _____
- 14 Phase of current treatment (Check record)
0=Intensive phase
1=Last day of intensive phase
2=Continuation phase
3=Last month of treatment
4=Last day of treatment

Section III: HIV-related awareness and risk

- 15 How do you rate your general knowledge about HIV/AIDS?
0=Poor
1=Good
2=Very good
- 16 How do you rate your risk of being HIV infected ?
0=Low
1=High

Section IV: Past history of HIV testing

- 17 Have you ever been counseled for HIV?
0=No
1=Yes
- 18 If yes to Q17, how was the outcome?
0=Refused the test
1=Negative
2=Positive
3=Don't know

4=Deferred

19 If Negative, where and where was the test done?

0=AMH (dd/mm/yy)

1=OSSA (dd/mm/yy)

2=other place (dd/mm/yy)

If Positive;

20 Are you taking Antiretroviral therapy?

0=No

1=Yes

21 Are you on co-trimoxazole prophylaxis?

0=No

1=Yes

22 Do you get any financial or material support?

0=No

1=Yes

Section V: Willingness to be tested (For Negative and Unknown Status)

23 Are you willing to be tested for HIV?

0=No

1=Yes

24 If yes to Q23, do you want to be counseled in this hospital?

0=No

1=Yes

(If Yes to Q24, refer to Room 101. If No, Conclude the interview)

Section IV: Counseling, testing and referral for services (To be filled in by counsellor)

25 Outcome of pre-test counseling

0=Refused

1=Accepted and blood drawn

26 If tested, test result

0=Negative

1=Positive

27 Did the patient return for results within 2 weeks of appointment date?

0=No

1=Yes

28 If Yes to Q27, did the patient want to be evaluated for ART?

0=No

- 1=Yes
29 Did the patient require referral to care and support organization?
0=No
1=Yes
- 30 Did the patient receive support within one week of referral?
0=No
1=Yes

8.3 Letters of Ethical Approval



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የኢትዮጵያ ሳይንስና ቴክኖሎጂ ኮሚሽን
The Federal Democratic Republic of Ethiopia
Ethiopian Science and Technology Commission

ቁጥር: RDHE/64-60/05
Ref No. 22 FEB 2005
ቀን: 22 FEB 2005
Date

The Regional Health Bureau, SNNPR
Awassa

Re: Simplified approaches to antiretroviral therapy in South Ethiopia

We have received the documents and clarifications on issues raised by the National Ethics Review Committee.

It is, therefore, my pleasure to inform you that the project is ethically approved for implementation.

Worth mentioning, however, your good office is kindly requested to strictly monitor and evaluate the ethical implementation of the project as stipulated in the project document.

Sincerely yours,



Yemane Teklai

YEMANE TEKLAJ (Dr.)
Head, Health Department

and secretary of NERC

c.c Dr. Degu Jerene PI
Awassa

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*Regional komité for
medisinsk forskningsetikk
Vest-Norge (REK Vest)*

Bergen, 17.12.04

To whom it may concern

Confirmation (REK Vest no. 200.04)

We hereby confirm that the research protocol *Simplified approaches to antiretroviral therapy in south Ethiopia: a model for resource-limited settings*, has been evaluated by The Regional Committee for Medical Research Ethics in Western Norway (REK Vest).

The protocol is now cleared.

Sincerely,

Arne Salbu
Secretary

