**S1 Table. CONSORT checklist for cluster randomised trials**

| PAPER SECTION  and topic | Item | Descriptor | Reported on Page No. |
| --- | --- | --- | --- |
| ***TITLE & ABSTRACT*** | | | |
|  | 1a\* | Identification as a randomised trial in the title | Title |
| 1b | How participants were allocated to interventions (e.g., “random allocation”, “randomised”, or “randomly assigned”), *specifying that allocation was based on clusters* | Abstract |
| ***INTRODUCTION*** | | | |
| Background & Objectives | 2a | Scientific background and explanation of rationale, *including the rationale for using a cluster design.* | Introduction, Study design,  Naikoba et al. [9] |
| 2b | Specific objectives or hypotheses, *Whether objectives pertain to the cluster level, the individual participant level or both* | Introduction |
| ***METHODS*** | | | |
| Trial Design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio | Study design |
| 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | Not applicable |
| Participants | 4a | Eligibility criteria for participants *and clusters* and the settings and locations where the data were collected. | Participants and eligibility, Miceli et al.[16], Naikoba et al.[9] |
| 4b | Settings and locations where the data were collected | Participants and eligibility,  Naikoba et al.[9] |
| Interventions | 5 | Precise details of the interventions intended for each group, *whether they pertain to the individual level, the cluster level or both,* and how and when they were actually administered. | Interventions, Miceli et al.[16], Naikoba et al.[9] |
| Outcomes | 6a | Report clearly defined primary and secondary outcome measures, *whether they pertain to the individual level, the cluster level or both*, and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors). | Outcome definitions, Data collection |
| 6b | Any changes to trial outcomes after the trial commenced, with reasons | Outcome definitions |
| Sample size | 7a | How *total* sample size was determined *(including method of calculation, number of clusters, cluster size, a coefficient of intracluster correlation (ICC or k), and an indication of its uncertainty*) and, when applicable, explanation of any interim analyses and stopping rules. | Sample size, Naikoba et al.[6] |
| 7b | When applicable, explanation of any interim analyses and stopping guidelines | Not applicable |
| **RANDOMIZATION** | | | |
| Sequence generation | 8a | Method used to generate the random allocation sequence, | Randomization,  Naikoba et al. [9], Weaver et. al.[12] |
| 8b | Type of randomisation; details of any restriction (such as blocking and block size) Details of stratification or matching if used | Randomization,  Naikoba et al. [9], Weaver et. al. [12] |
| Allocation concealment | 9\* | Method used to implement the random allocation sequence, *specifying that allocation was based on clusters rather than individuals and* clarifying whether the sequence was concealed until interventions were assigned. | Randomization,  Naikoba et al. [9] |
| Implemen-tation | 10a | Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups. | Randomization,  Naikoba et al. [9] |
| 10b | Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling) | Participants and eligibility |
| 10c | From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation | Ethical considerations |
| Blinding | 11a | Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. | Randomization |
| 11b | If relevant, description of the similarity of interventions | Not applicable |
| Statistical methods | 12a | Statistical methods used to compare groups for primary outcome(s) *indicating how clustering was taken into account*; methods for additional analyses, such as subgroup analyses and adjusted analyses. | Data Management and Statistical Methods |
|  | 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | Data Management and Statistical Methods |
| ***RESULTS*** | | | |
| Participant flow | 13a | Flow of *clusters and* individual participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of *clusters and* participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons. | Recruitment and Enrollment, Figure 1 |
| 13b | For each group, losses and exclusions after randomisation, together with reasons. For each group, losses and exclusions for both clusters and individual cluster members | Recruitment and Enrollment, Figure 1 |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up. | Study Design |
| 14b | Why the trial ended or was stopped | Not applicable |
| Baseline data | 15 | Baseline information for each group *for the individual and cluster levels as applicable* | Results, Figure 2, Tables 2-3 |
| Numbers analyzed | 16 | Number of *clusters and* participants (denominator) in each group included in each analysis and whether the analysis was by “intention-to-treat”. State the results in absolute numbers when feasible (e.g., 10/20, not 50%). | Outcomes, Figure 1 |
| Outcomes and Estimation | 17a | For each primary and secondary outcome, a summary of results for each group measures *for the individual or cluster level as applicable*, and the estimated effect size and its precision (e.g., 95% confidence interval) | Outcomes, Tables 2-3 |
| 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended | Outcomes, Tables 2-3 |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory | Outomes, Table 3 |
| Adverse events | 19 | All important adverse events or side effects in each intervention group. | Not applicable |
| ***DISCUSSION*** | | | |
| Interpretation | 20 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | Discussion |
| Limitations | 21 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | Limitations |
| Generalizability | 22 | Generalizability (external validity) *to individuals and/or clusters (as relevant)* of the trial findings | Discussion |
| Overall evidence | 23 | General interpretation of the results in the context of current evidence. | Conclusion |
| ***OTHER INFORMATION*** | | | |
| Registration | 24 | Registration number and name of trial registry | Not applicable |
| Protocol | 25 | Where the full trial protocol can be accessed, if available | Study Design, Weaver et. al. [12] |
| Funding | 26 | Sources of funding and other support (such as supply of drugs), role of funders | Acknowledgements |

**Supplementary File 2:**

**IDCAP HIV Clinical Observation Form** A.**Observation #:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| --- | --- | --- |
| BSite #: | C.Trainee #: | D.Date of visit (d/m/y): |
| E.Observer #: | | F.Quality Control #: |
| G.**Triage status:**  H.Emergency (A B C D O)  I.Priority (Specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_)  Not Emergency | | |
| **If emergency, support trainee to manage patient. Emergency treatment is higher priority than clinical assessment.** | | |

J.Language of patient during visit: \_\_\_\_\_\_\_\_ K.Translation? Yes No

L.Gender of patient: F M Age of patient: \_\_\_\_\_\_\_ M.months (LT 5 years) \_\_\_\_\_\_N.years (GE 5 years)

|  |  |
| --- | --- |
| **I.Vital signs:** 1.Reported by other health professional or volunteer before consultations? Yes No |  |
| 2.Temperature **\_\_\_\_\_C** 3.If no thermometer, febrile to touchY N  4.Current weight **\_\_\_\_\_ kg** 5.Weight last visit **\_\_\_\_kg** 6.Peak weight **\_\_\_\_ kg** 7.Height **\_\_\_\_\_cm** 8.BP\_\_\_**\_\_\_** |

**II. History**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1.New enrollee at site?Y N 2.If yes, new dx or transfer? | | | | 3.Date of HIV diagnosis(m/d/y)\_\_\_\_/\_\_\_\_/\_\_\_\_ | | |
| **Medication**:  4.Current ART? Yes No 5.If Yes, regimen: 3TC AZT d4T TDF FTC NVP EFV  6.If yes, ART start date (d/m/y) \_\_\_/\_\_\_/\_\_\_  7.Previous exposure to ARV? Yes No 8.If Yes, regimen: 3TC AZT d4T TDF FTC NVP EFV 9.If yes, indication*:* Chronic care PMTCT Other\_\_\_\_\_\_\_\_ 10.If yes, ART stop date(d/m/y) \_\_\_/\_\_\_/\_\_\_  11.TB? Never Suspect Active(12.intensive continuation) Previous; (13.d/m/y)last dose\_\_/\_\_/\_\_  14.CTX preventive? Yes No NR 15.Other medication ? Yes No NR(specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | |  |
| 16.**Allergy to Medication:** None CTX SP Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_NR | | | | | |  |
| 17. **Additional history:** None Previous OI (specify) \_­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ NR | | | | | |  |
| 18.**If female, now pregnant:** Yes No NR Suspected, not confirmed20.**LNMP:** \_\_\_\_/\_\_\_\_/\_\_\_\_\_ | | | | | |  |
|  | | | | | | |
| **III. Symptoms** | Patient | Code |  | | Patient | Code |
| 1.Fever:  2.Duration \_\_\_\_\_ days | Y N NR |  | ART adherence:  9.How many taken?  10.How many prescribed?  11.Prescription date? (m/d/y) | | \_\_\_\_\_\_pills NRNA  \_\_\_\_\_\_pills NRNA  \_\_/\_\_/\_\_\_ NRNA |  |
| 3.Coughing:  4.Duration \_\_\_\_\_\_days | Y N NR |  | 13.Side effects of ART  14.Specify\_\_\_\_\_\_\_\_\_\_\_\_ | | Y N NR NA |  |
| 5.Night sweats: | Y N NR |  |
| 6.Weight loss:  7.Specify % \_\_\_\_\_ | Y N NR |  | 15.Functional status  16.If bedridden, % of time:\_\_\_\_\_ | | Able to work  Ambulatory  Bedridden |  |
| 8.Recent contact with someone who has TB: | Y N NR |  |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 17.**Does patient have specific complaints or concerns?** Y N NR (If yes, specify below with Y, N or V.) | | | | | | | | | | | |
| 18.Abdominal pain |  |  | 23.Convulsions |  |  | 30.Headache |  |  | 36.Skin lesions |  |  |
| 19.Anxiety |  |  | 24.Depression |  |  | 31.Loss of appetite |  |  | 37.Skin Rash |  |  |
| 20.Breathing – shortness of breath |  |  | 25.Diarrhea  26.Duration\_\_\_days  27.Blood? Y  N |  |  | 32.Mouth problems |  |  | 38.Swallowing difficulty |  |  |
| 21.Burning, tingling, loss or change in sensation |  |  |  | 33.Myalgias |  |  | 39.Vomiting |  |  |
|  | 28.Fatique |  |  | 34.Nausea |  |  | 40.Other (specify): |  |  |
| 22.Chest pain |  |  | 29.Genital problem  Specify\_\_\_\_\_\_\_\_\_\_\_\_ |  |  | 35.Skin itching |  |  |  |

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| **IV. Physical Exam** | | | |
| 1.**General** |  |  | A.normal B.wasting C.palor D. jaundice E.oedema F.lymphadenopathy  G.agitation H. fat change(lipodystrophy) I.temperature\_\_\_\_\_\_\_\_\_**C**  J.other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 2.**Mouth** |  |  | A.normal B.abscess C. oral thrush D.caries E.gingivitis F.Kaposi G. ulcers  H.other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 3.**Skin** |  |  | A.normal B. abscess C.ecchymosis D. erythema E.herpes zoster scar F. Kaposi  G.nodules H.papules I.pus J. pustules K.scaling L. vesicles M.wound  N.other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 4.**Lungs** |  | 1.  2.  3. | A.normal B. breathing difficulty C.chest in-drawing D.stridor  If cough, E.RR–trainee\_\_\_\_\_\_\_\_\_\_\_\_bpm F.RR–observer\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_bpm  Listen to lung: G.clear H.abnormal sound on percussion I.tenderness  J.crepitations K. rhonchi L. wheezing M.decreased breath sounds  N.other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 5.**Cardio-vascular** |  |  | A.pulse\_\_\_\_\_\_\_\_\_ B.gallop C.murmur D. rub E. other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 6.**Abdo-men** |  |  | A.normal B.distended C.tenderness D.abnormal sound on percussion  E.hepatomegaly F.splenomegaly G.abnormal mass H.pregnancy I.ascites  J.other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ K.For findings, note where\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 7**.Genita-lia** |  |  | A.normal B.discharge C.tenderness D.ulcers E.other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 8.**Muculo skeletal** |  |  | A.normal B.other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 9.**Neuro** |  |  | A.normal B.coma C.confusion, disorientation D. focal deficit E.meningismus  F.paresthesia G.seizure H.other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 10.**Other-Specify: \_\_\_\_\_\_\_** |  |  | Specify A.exam and B.findings\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| 11.Did equipment or resource gaps affect trainee’s physical exam for this patient?Yes No  12.If yes, please explain\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| IX1.Did trainee conduct a focused and thorough history that is relevant to evolution of current symptom/complaint? .Yes No IX2.If no, summarize reason.  Omission (Specify if not obvious on checklist)  Misinterpretation (Must specify)  Unnecessary (Must specify) |

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| IX3.Did trainee conduct a complete physical exam? Yes No IX4.If no, summarize reason.  Omission (Specify if not obvious on checklist)  Misinterpretation (Must specify)  Unnecessary (Must specify) |

**Site/trainee/Observation #:\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_**

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| **V. Please tell me the relevant information from the patient’s file.**  1. Not available | | | | | |
| Code |  | Results | Code |  | Results |
|  | 2.Ab (HIV antibody) |  |  | 3.Ag/PCR (child< 18mo) |  |
|  | 4.CBC (hemogram) |  |  | 5.HB (haemoglobin) |  |
|  | 6.CXR |  |  | 7.Creatinine |  |
|  | 8.Glucose |  |  | 9.HepB |  |
|  | 10.LFT transaminases |  |  | 11.Malaria BS |  |
|  | 12.Malaria RDT |  |  | 13.Pregnancy (HCG) |  |
|  | 14.RPR |  |  | 15.TB Sputum |  |
|  | 16.Viral Load |  |  |  |  |
|  | 17.Other1- Specify |  |  | 18.Other2- Specify |  |
|  | 19.CD4 cells/mm3 | 1. |  | 20.Date (m/d/y) of CD4 | 1. |
|  | 21.CD4 cells/mm3 | 2. |  | 22.Date (m/d/y) of CD4 | 2. |
|  | 23.CD4 cells/mm3 | 3 |  | 24.Date (m/d/y) of CD4 | 3. |
| 25.**What is the highest confirmed WHO clinical disease stage for this patient:**  I  II  III  IV  26.What is the basis for this staging decision? (specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  27.Date (d/m/y) of staging diagnosis\_\_\_\_/\_\_\_\_/\_\_\_\_\_ | | | | | |

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| IX5.Did the trainee demonstrate accurate interpretation of laboratory values and schedule for routine laboratory surveillance of HIV/AIDS? Yes No IX6.If no, summarize reason.  Omission (Specify if not obvious on checklist)  Misinterpretation (Must specify)  Unnecessary (Must specify) |

**VI. Differential Diagnosis**

1.**Does this patient have any clinical staging conditions today?** Yes No If yes, what were they?

A.Trainee 1\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ B.Observer Agree? Yes No C.Observer 1\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

D.Trainee 2\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_E.Observer Agree? Yes No F.Observer 2\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

G.Trainee 3\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_H.Observer Agree? Yes No I.Observer 3\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| IX5.Did the trainee accurately diagnose clinical staging conditions? Yes No IX6.If no, summarize reason.  Omission (Specify if not obvious on checklist)  Misinterpretation (Must specify)  Unnecessary (Must specify) |

2.**Does this patient have other diagnoses today?** Yes No NA .If yes, what were they?

A.Trainee 1\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ B.Observer Agree? Yes No C.Observer 1\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

D.Trainee 2\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_E.Observer Agree? Yes No F.Observer 2\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

G.Trainee 3\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_H.Observer Agree? Yes No I.Observer 3\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

J.Trainee 4\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_K.Observer Agree? Yes No L..Observer 4\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| IX7.Did the trainee accurately diagnose other problems? Yes No IX8.If no, summarize reason.  Omission (Specify if not obvious on checklist)  Misinterpretation (Must specify)  Unnecessary (Must specify) |

3.**What is the patient’s clinical stage today?** I II III IV I-T II-T III-T IV-T

What was the supporting evidence?

A.Trainee 1\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ B.Observer Agree? Yes No C.Observer 1\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

D.Trainee 2\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ E.Observer Agree? Yes No F.Observer 2\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

G.Trainee 3\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ H.Observer Agree? Yes No I.Observer 3\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| IX9.Did the trainee accurately assess WHO clinical stage? Yes No IX10.If no, summarize reason.  Omission (Specify if not obvious on checklist)  Misinterpretation (Must specify)  Unnecessary (Must specify) |

4.**Is the patient eligible for ART?** Yes No NA If yes, what was the supporting evidence?

A.Trainee 1\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ B.Observer Agree? Yes No C.Observer 1\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

D.Trainee 2\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ E.Observer Agree? Yes No F.Observer 2\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| IX11.Did the trainee accurately identify eligibility for ART? Yes No NA IX12.If no, summarize reason.  Omission (Specify if not obvious on checklist)  Misinterpretation (Must specify)  Unnecessary (Must specify) |

5.**If on ART, what % of drugs were taken?** ≥95% 85-94% <85% NR NA

% = No. of drugs taken x 100/Total no. of pills expected to be taken

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| --- |
| IX13. Did the trainee address ART adherence? Yes No NA IX14.If no, summarize reason.  Omission (Specify if not obvious on checklist)  Misinterpretation (Must specify)  Unnecessary (Must specify) |

6.**If on ART, do you suspect side effects?** Yes No NA If yes, what were they?

A.Trainee 1\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ B.Observer Agree? Yes No C.Observer 1\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

D.Trainee 2\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ E.Observer Agree? Yes No F.Observer 2\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| IX15.Did the trainee accurately diagnose side effects? Yes  No NA IX16.If no, summarize reason.  Omission (Specify if not obvious on checklist)  Misinterpretation (Must specify)  Unnecessary (Must specify) |

7.**If on ART, does the patient have signs of treatment failure?** Yes No NA If yes, what were they?

A.Trainee 1\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ B.Observer Agree? Yes No C.Observer 1\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

D.Trainee 2\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ E.Observer Agree? Yes No F.Observer 2\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| IX17.Did the trainee accurately assess for treatment failure? Yes No NA IX18.If no, summarize reason.  Omission (Specify if not obvious on checklist)  Misinterpretation (Must specify)  Unnecessary (Must specify) |

**Site/trainee/Observation#\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_**

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| --- | --- | --- | --- | --- | --- |
| **VII. What laboratory investigations would you order today?** 1. None | | | | | |
| Code |  | Results | Code |  | Results |
|  | 2.Ab (HIV antibody) |  |  | 3.Ag/PCR (child< 18mo) |  |
|  | 4.CBC (hemogram) |  |  | 5.HB (haemoglobin) |  |
|  | 6.CD 4 |  |  | 7.Creatinine |  |
|  | 8.Glucose |  |  | 9.Hep B |  |
|  | 10.LFT Transaminases |  |  | 11.Malaria BS |  |
|  | 12.Malaria RDT |  |  | 13.Pregnancy |  |
|  | 14.RPR |  |  | 15.TB Sputum |  |
|  | 16. Viral Load |  |  |  |  |
|  | 17.Other1- Specify |  |  | 18.Other2- Specify |  |
| 19.Did equipment or resource gaps affect trainee’s investigations for this patient? Yes No  20.If yes, please explain\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | |
|  | | | | | |
| 21.**Would you order other investigations or procedures today?** Yes No If yes, specify below. | | | | | |
| Code |  | Results | Code |  | Results |
|  | 22.Chest x-ray |  |  | 23.Ultrasound scan  Specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
|  | 24.Other x-ray -Specify \_\_\_\_\_\_\_\_\_\_\_ |  |  | 25.Other3-Specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |

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| IX19.Did the trainee recommend appropriate investigations? Yes No NA IX20.If no, summarize reason.  Omission (Specify if not obvious on checklist)  Misinterpretation (Must specify)  Unnecessary (Must specify) |

**Please use this space to document additional relevant information about this case.**

|  |  |  |  |
| --- | --- | --- | --- |
| **VIII. What treatment would you recommend?** | | | |
| 1.**Prevention?**  **CTX:**  Start  Stop  Continue | | **2.Observer agree w/ CTXI?** Yes No, Specify  3.**CTX:**  Start  Stop  Continue | |
| 4.**Tx for OI?:** Yes No If yes, specify  6.Treatment 1? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  8.Route:oral parenteralSpecify \_\_\_\_\_\_  10.Treatment 2\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  12.Route: oral parenteral Specify \_\_\_\_\_\_ | | 5.**Observer agree w/Tx for OI**Yes No Specify  7.Treatment 1? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  9.Route: oral parenteralSpecify \_\_\_\_\_\_\_\_\_\_\_  11.Treatment 2\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  13.Route: oral parenteral Specify \_\_\_\_\_\_\_\_\_\_ | |
| 14.**Tx for other dx?** Yes No If yes, specify  16.Treatment 1? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  18.Route: oral parenteral Specify \_\_\_\_\_\_  20.Treatment2\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 22.Route: oral parenteralSpecify \_\_\_\_\_\_ | | 15.**Observer agree w/Tx for other dx?OI**YesNoSpecify  17.Treatment 1? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  19.Route: oral parenteral .Specify \_\_\_\_\_\_\_\_\_\_\_  21.Treatment 2\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  23.Route: oral parenteral Specify \_\_\_\_\_\_\_\_\_\_\_ | |
| 24.**ART:**Continue Start Stop Modify  26.If change, new regimen**:** 3TC AZT d4T TDF FTC NVP EFV Other\_\_\_\_\_\_\_\_  28.Reason:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | 25.**Observer agree w/ART:** Yes No, Specify  27. Continue Start Stop  Modify  29.If change, new regimen**:** 3TC AZT d4T  TDF FTC NVP EFV Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  30.Reason:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| 31.**Tx for side effects?** Yes No If yes, specify  33.Treatment 1? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  35.Route: oral parenteral Specify \_\_\_\_\_\_\_  37.Treatment 2\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  39.Route: oral parenteral Specify \_\_\_\_\_\_\_ | | 32.**Observer agree w/Tx for side effects?** Yes No, Specify  34.Treatment 1? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  36.Route:oral parenteral Specify \_\_\_\_\_\_\_\_\_  38.Treatment 2\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  40.Route: oralparenteral Specify \_\_\_\_\_\_\_\_\_\_ | |
| 41.**Internal referral or consult?:**Yes No  43.Who? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  45.Reason? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  47.**External referral or consult?:** Yes No  49.Where? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  51.Reason? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  53.**Admitted this site:** Yes No  55.**Date of next visit: \_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_** | | 42.**Observer agree w/ internal referral or consult:**  YesNo, Specify. 44.Who?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  46.Reason?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  48.**Observer agree w/ external referral or consult:**  Yes No, Specify. 50.Who? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  52.Reason?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  54.**Observer agree w/admission?:** Yes No  56.**Observer agree w/Date of next visit?:**Yes No | |
| **Prevention provided?**  57.Positive prevention message:  58.Recommend mosquito net:  59.If female, recommend family planning | Yes No NA  Yes No  Yes No NA | |  |
| 60.Did equipment or resource gaps affect trainee’s treatment plan for this patient? Yes No  61.If yes, please explain\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |

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| IX21. Did the trainee recommend appropriate drug treatment? Yes No NA IX22. If no, summarize reason.  Omission (Specify if not obvious on checklist)  Misinterpretation (Must specify)  Unnecessary (Must specify) |

**Brief Tool Marking & Scoring Protocol**

During Observation:

1. Mark all questions asked by the trainee and patient findings in blue or black ink.
2. Mark all questions asked by the clinical faculty and patient findings in red ink.

Scoring Observation:

1. If the trainee asks the appropriate questions or performs task correctly, as determined by the clinical faculty, the score of the item is 1.
2. If the trainee did not ask the appropriate questions or performs task incorrectly including errors of omission and commission, as determined by clinical faculty, the score of the item is 0.

|  |  |
| --- | --- |
| Outcome (Total Score Possible) | Scored Items (Item number on HIV/ART Clinical Observation – Patient Form) |
| History Taking (7-11) | Required for all patients   1. Current weight (I.4) 2. Current ART Status (II.4) 3. Cotrimoxazole history (II.14) 4. Fever (III.1) 5. Cough (III.3) 6. Functional status (III.15 and III.16) 7. Asked for any other symptoms (III.17)   Only appropriate if indicated by patient status or symptoms   1. (if female 13-49) Pregnancy status (II.18) 2. (if fever) fever duration (III.2) 3. (if cough) cough duration (III.4) 4. (if on ART) ART status (III.13) |
| Physical Examination (5-6) | Required for all patients   1. General (IV.1) 2. Skin (IV.2) 3. Mouth (IV.3) 4. Lungs (IV.4) 5. Abdomen (IV.6)   Only appropriate if indicated by patient history or initial findings of physical examination   1. Any other examination based on signs/symptoms (IV.10) |
| Laboratory Test (1) | Summary score that all appropriate laboratory and other investigations were ordered correctly based on differential diagnosis. (VII1-VII18, VII22-VII25) |
| Diagnoses (2) | Required for all patients   1. Summary score for Clinical staging conditions (IV.1 B/E/H) Other diagnoses (IV.2 B/E/H), and Treatment side effects (IV.6 B/E/H)   Required only for patients not on ART   1. ART eligibility (IV.4 B/E)   Required only for patients on ART   1. Treatment failure (IV.7B/E) |
| Treatment (2-3) | Required for all patients   1. Prescribes cotrimoxazole correctly (VIII.1 and VIII2) 2. All other treatments are correct (VIII4 and VIII5, VIII14 and VIII15, VIII31 and VIII32)   Required only for patients on ART   1. Prescribes ART correctly (VIII.24 and VIII.25) |
| Patient/caregiver  Education (2) | Required for all patients   1. Positive prevention (VIII.57) 2. Recommend Mosquito Net (VIII.58) |