First Line Antimicrobials in Children with Complicated Severe Acute Malnutrition
NON-TRIAL
CASE REPORT FORM

Study site	☐ KILIFI ☐ MOMBASA ☐ NAIROBI ☐ MBALE
Participant Initials	___ _____ _____
Inpatient/Serial Number	___ ___ ___ ___ ___ ___
Study Number	F 4 2 7 5

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Instructions for Handling and Completing the Case Report Form

- Please use only black ball point pen to complete CRFs
- Only authorized individuals should write on these CRFs
- Please fill in the header on each page
- Data correction: Cross out the mistake (the mistake has to remain readable), write the correction alongside together with your initials and date of correction. In Case of a not self-explanatory mistake please add the reason for correction. Do not use typewriter correction fluid (Tipp-Ex).

~~01~~	11	2	0	0	8

03 RCH 03/11/2008

- Into open boxes / numeric fields please enter

numbers | 4 | 9 |

Or ticks ☑

- Always enter digits **right aligned** and fill **open spaces** to the left with **zeroes**

0	7	5

- Please mark data which could **not** be recorded as follows: **Cross out** boxes and write **"NOT DONE"** on the side
- Date: Day. Month. Year:

2	0	1	1	2	0	0	8
D	D	M	M	Y	Y	Y	Y

- Please enter initials in the following order: First letter of the first name, First two letters of the surname

M	A	M

First MI Last

- Please do not omit to date and sign the pages where required.

Child Initials | | | |

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Eligibility Checklist		
Age between 2 months and 13 years inclusive	☐ Y	☐ N - ineligible
Being admitted to hospital **without** Severe Acute Malnutrition	☐ Y	☐ N- ineligible
Meets WHO criteria for IV antibiotics	☐ Y	☐ N- ineligible
This child has not previously been enrolled in the FLACSAM trial	☐ Y	☐ N- ineligible
Consent given	☐ Y	☐ N- ineligible

I confirm this child is eligible for the FLACSAM NON-trial study	*Initials* ___ ___ ___	*Signed*

Admission, Consent & Enrolment			
Sex	☐ Male ☐ Female	**Date of Birth**	__ __/ __ __/ __ __ __ __ *D D / M M / Y Y Y Y*
		Is the DOB	☐ True ☐ Estimated*
		**if DOB is estimated, and the day or month is uncertain, write '15' for DD and '07' for MM*	
DATE of ADMISSION	__ __/ __ __/ __ __ __ __ *D D / M M / Y Y Y Y*	**TIME of ADMISSION**	__ __: __ __ *24h Clock*
DATE of CONSENT	__ __/ __ __/ __ __ __ __ *D D / M M / Y Y Y Y*	**DATE of ENROLMENT**	__ __/ __ __/ __ __ __ __ *D D / M M / Y Y Y Y*
TIME of CONSENT	__ __: __ __ *24h Clock*	**TIME of ENROLMENT**	__ __: __ __ *24h Clock*
CONSENTED by *initials*	___ ___ ___	**ENROLLED by** *initials*	___ ___ ___

Anthropometry at Admission			
Weight	___ ___ . ___ ___kg	**Oedema**	☐ None ☐ + ☐ ++ ☐ +++
MUAC	___ ___ . ___ cm	**Length/Height**	☐ Length ☐ Height ___ ___ ___ . ___ cm
Measured by (initials)	___ ___ ___	☐ Length measurement not possible due to physical reasons	

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What was the main reason for bringing the child to this hospital <u>today</u>? *Reasons given, select one*	
☐Inpatient referral by health care worker	☐ Caregiver concern of child's condition
☐Outpatient referral by health care worker	☐ Primary caregiver returned home (e.g. if working away)
☐ Received money for transport to hospital (e.g. from family, neighbour, paid work)	
☐Other _____	

Have you sought treatment for this illness prior to coming to hospital? *Select all that apply*	
☐ Shop	☐ Traditional/Homoeopathy/Herbalist
☐ Government hospital	☐ Pharmacy
☐ Government dispensary	☐ Private Medical Facility
☐ Other_____	☐ No treatment sought

<u>Are there any documented</u> antibiotics given within the last 24 hours prior to this admission?	☐ Yes	☐ No

Child recently admitted to hospital	☐ No	☐ < 1 week ago	☐ <1 month ago
	☐ 1 to 6 months ago	☐ >6 months ago	

HIV Status at Presentation
(Follow the arrow)

HIV Status *(tick one)*

☐ **Known HIV infected**
PCR +ve or >18 months old & antibody +ve

Fill this box →

Current ART *(tick one)*
☐ NVP/AZT prophylaxis
☐ Full ART
☐ None
☐ Unknown

Co-trimoxazole prophylaxis *(tick one)*
☐ Y
☐ N
☐ Unknown

☐ **Known HIV exposed**

☐ Antibody +ve under 18 months old, not confirmed by PCR

☐ PCR negative

☐ Known to be HIV exposed but child untested

Fill both boxes ↕

☐ **Not known HIV infected or exposed**

Fill this box →

RDT *(tick one)*
☐ Reactive
☐ Indeterminate
☐ Non-reactive
☐ Declined

If reactive and below 18 months/indeterminate, PCR sent:
Y ☐
N, missed ☐

All Participants: Is anyone else in the household taking co-trimoxazole prophylaxis?	☐ Y	☐ N	☐ Unknown

Suspected Chronic Conditions

Select confirmed, suspected or none for all conditions:	None	Suspected *(clinician's impression)*	Confirmed *(diagnosed previously/ recorded)*
Cerebral palsy/neurological problem/ epilepsy	☐	☐	☐
Sickle Cell Disease	☐	☐	☐
Cardiac disease	☐	☐	☐
Visual problem / Blindness *Not fixing and following*	☐	☐	☐
Losing weight or not gaining weight	☐	☐	☐
Other congenital abnormality (incl. cleft palate, downs)	☐	☐	☐

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TB Screening			
Known TB (on treatment)	**Child has cough >14 days**	**Household contact has TB, or cough >14 days**	**Child has suspected extra-pulmonary TB**
☐ Y ☐ N	☐ Y ☐ N	☐ Y ☐ N	☐ Y ☐ N

INITIAL TREATMENT PRESCRIBED			
IV ANTIMICROBIALS		**ORAL ANTIMICROBIALS**	
Penicillin	☐	**Oral Amoxicillin**	☐
Gentamicin	☐	*(e.g. augmentin)* **Co-Amoxiclav**	☐
Ceftriaxone	☐	**Ciprofloxacin**	☐
Ampicillin	☐	**Erythromycin**	☐
Amikacin	☐	**Azithromycin**	☐
Ciprofloxacin	☐	**Oral Cephalosporin**	☐
(e.g. augmentin) **Co-Amoxiclav**	☐	**Co-trimoxazole <u>treatment</u>**	☐
Chloramphenicol	☐	**Co-trimoxazole <u>prophylaxis</u>**	☐
Cefotaxime	☐	**Nitrofurantoin**	☐
Ceftazidime	☐	**Nalidixic acid**	☐
Clindamycin	☐	**Clindamycin**	☐
Flucloxacillin/Cloxacillin	☐	**Metronidazole**	☐
Other_____	☐	**Other _____**	☐
Other_____	☐	**Other _____**	☐
Other_____	☐	**Other _____**	☐
NO IV ANTIBIOTICS	○	**NO ORAL ANTIBIOTICS**	○

Admission Study Samples			
Rectal swabs taken *(should be two)*	☐ Y BEFORE ABX ☐ Y AFTER ABX ☐ N	**Tick which were taken:**	☐ For culture (transport media) ☐ For storage (dry)
Rectal Swabs taken by *initials*	__ __ __		

Name: _____ **Sign**_____ **Date** |__|__|/|__|__|/201_

Investigator or nominee dd/mm/yyyy

Suspected Initial Diagnoses

Tick up to THREE most likely diagnoses.

Respiratory

- ☐ LRTI/pneumonia
- ☐ Bronchiolitis
- ☐ URTI
- ☐ Pulmonary TB
- ☐ Otitis media
- ☐ Asthma
- ☐ Aspiration e.g. of feed

General

- ☐ Anaemia
- ☐ Sickle Cell Disease
- ☐ Renal impairment
- ☐ Nephrotic syndrome
- ☐ Nephritis
- ☐ Liver dysfunction
- ☐ Ileus
- ☐ Cardiac disease

Infection

- ☐ Gastroenteritis
- ☐ Sepsis
- ☐ Confirmed Malaria
- ☐ Extra pulmonary TB
- ☐ Soft tissue infection
- ☐ UTI
- ☐ HIV related illness
- ☐ Measles
- ☐ Varicella
- ☐ Osteomyelitis
- ☐ Confirmed enteric fever
- ☐ Febrile illness unspecified
- ☐ Typhoid/paratyphoid with perforation

CNS

- ☐ Febrile convulsions
- ☐ Epilepsy
- ☐ LP confirmed meningitis
- ☐ Clinically suspected meningitis
- ☐ Other encephalopathy
- ☐ Hydrocephalus
- ☐ Developmental delay unspecified
- ☐ Cerebral palsy
- ☐ Congenital syndrome

Other diagnosis:

- ☐ Failed appetite test only/malnutrition only
- ☐ Suspected drug toxicity
  (if due to study drug, complete toxicity CRF)
- ☐ Other known diagnosis

  _____
- ☐ Unknown diagnosis

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Further social history should be taken once all admission procedures have been completed

Initials of person interviewing caregiver and completing this section	___ ___ ___ ☐ Doctor ☐ Clinical officer ☐ Nurse ☐ Field worker ☐ Other

Primary Caregiver Information This is the person who has responsibility for day to day care of the child, but is not a substitute carer such as childminder or grandparent who cares for child whilst, for example, mother is at work.			
Who is the Primary Caregiver? *(Select one)*	☐ Biological Parent ☐Grandparent ☐ Sibling ☐ Aunt/Uncle/Cousin ☐ Stepmother/Stepfather ☐Care home/Orphanage ☐ Other_____		
Is the child's biological father alive?	☐ Y ☐ N ☐ Unknown	**Is the child's biological mother alive?**	☐ Y ☐ N ☐ Unknown

Coming to Hospital					
How did you travel to the hospital? *(tick all that apply)*					
☐ Car/Taxi**(K)**/Special Hire**(Ug)**	☐ Bus/Matatu**(K)**/Taxi**(Ug)**	☐Motorbike	☐ Tuk-tuk		
☐ Bicycle	☐ Train	☐ Walking	☐ Ambulance		
☐ Other_____					
How long did it take you to travel to hospital?	☐ <1h	☐ 1-<2h	☐ 2-4h	☐ >4h	☐ > 1 day
How much did it cost you and the child to travel to hospital today (in local currency)?	___ ___ ___ ___	☐KSh ☐UGX ☐Don't' know			

Coming to Hospital **Birth History**		
Source of information	☐ Maternal/caregiver recall ☐ Book/medical records	
Birth details *(Select any that apply)*	☐ Premature ☐ Born underweight (<2.5kg) ☐Twin/multiple birth ☐ Born at term ☐Unknown	
Delivery location *(Select one)*	☐ Born in hospital ☐ Community facility/clinic with midwife/nurse midwife/doctor ☐ Home with midwife/nurse ☐ Home without birth attendant ☐ Other ☐ Home with traditional birth attendant (untrained) ☐ Unknown	
Mother's age NOW	___ ___years ☐ unknown/unavailable	
Participant birth order	___ ___ of ___ ___ total live births (*e.g. if youngest of 3 children 3 of 3, if oldest of 3 children 1*	

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Assessment of HOUSEHOLD WASH
(please answer all questions including children in care homes)

What is the MAIN source of drinking water for members of your household? *tick the MAIN one*

☐Piped water to dwelling	☐Cart with small tank	☐Bought from vendor
☐Piped water to yard/plot	☐Tanker truck	☐Rainwater
☐Piped water at neighbour	☐Bottled water	☐Stream/river/lake/pond/dam
☐Public tap/ Standpipe	☐Protected spring	☐Unknown
☐Protected well/borehole	☐Unprotected spring	
☐Unprotected well	☐Other_____	

What is the MAIN source of water used by household for other purposes such as cooking and handwashing? *(tick the MAIN one)*

☐Piped water to dwelling	☐Cart with small tank	☐Bought from vendor
☐Piped water to yard / plot	☐Tanker truck	☐Rainwater
☐ Piped water at neighbour	☐Bottled water	☐Stream/river/lake/pond/dam
☐Public tap/standpipe	☐Protected spring	☐Unknown
☐Protected well/borehole	☐Unprotected spring	
☐Unprotected well	☐Other_____	

How long does it take to get DRINKING water and come back? (State 0 if water supplied within home or compound)	__ __ __minutes ☐ Don't know
In the past 2 weeks was the water from this source not available for at least one full day?	☐ Y ☐ N ☐ Unknown

Do you usually do anything to the water to make it safer to drink? *Select all that apply*

☐ None	☐ Bleach/ chlorine / waterguard	☐ Strain through a cloth
☐ Let it stand and settle	☐ Use water filter (ceramic/sand/composite)	☐ Solar disinfection
☐ Boiling	☐ Other	

Does your household have mains supplied electricity?	☐ Y ☐ N ☐ Unknown
What kind of toilet facility does your household usually use?	☐ Flush ☐ Pit latrine ☐ No facility / bush/ field/bucket
Do you share this toilet facility with other households?	☐ Y ☐ N ☐ Unknown
Where is this toilet facility located?	☐ In own dwelling ☐ In own yard / plot ☐ Elsewhere

Which animals does this household own? *(tick all that apply)*

☐ Cows/bulls	☐ Sheep	☐ Chickens or Ducks
☐ Horses/Donkeys/Mules	☐ Goats	☐ Other _____ ☐ None

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Primary caregiver earns an income now? *Ask the person accompanying the child and select one*	
☐Employed full time by someone else	☐Employed part time by someone else
☐Works for self	☐No work income
☐Works casually/irregularly for someone	☐Don't know
☐N/A care home	

How many days worked a week? *Select one*			
☐ <3	☐ 3-5	☐ >5	☐ N/A, does not work for income

If the primary caregiver earns, main source of income? *Select one*			
☐ Farmer	☐ Business/trader	☐ Labourer	☐ Domestic work
☐ Other private sector employment	☐ Public sector employment	☐ Retired with pension income	
☐ Begging	☐ Other_____	☐ N/A (not earning)	

If the primary caregiver works (earning or non-earning), main place of work? *Select one*		
☐ In/around home (where child lives)	☐ Away for <4 hours per day	
☐Away >4 hours but comes home daily	☐Away > 8h a day but returns home daily	
☐Away >1 day, comes home weekly	☐ Away comes home, less than weekly	
☐Primary caregiver lives and works away	☐ Don't know	☐ N/A (not working at all)

Level of education completed the care giver? *Select one*			
☐None	☐ Primary not completed	☐ Primary completed	☐Secondary completed
☐Graduate/Tertiary	☐N/A (Care home/Orphanage)	☐ Unknown	

Substitute Care: Who usually looks after child when primary caregiver is working? *(Select all that apply)*		
☐ Caregiver looks after child full time	☐ Biological Mother	☐ Biological Father
☐ Sibling <18 years old	☐ Sibling ≥18 years old	☐ Grandparent
☐ Aunt/Uncle/Cousin	☐ Childcare facility outside home	☐ Childminder/ day care at home
☐ Care home/Orphanage	☐ No substitute care – child left alone	☐ Other substitute care, or unclear

****THIS IS THE END OF ENROLMENT****

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Final Diagnosis ***(to be filled in at discharge)***

Tick up to THREE diagnoses.

Respiratory	**Infection**	**CNS**
☐ LRTI/pneumonia ☐ Bronchiolitis ☐ URTI ☐ Pulmonary TB ☐ Otitis media ☐ Asthma ☐ Aspiration e.g. of feed	☐ Gastroenteritis ☐ Sepsis ☐ Confirmed Malaria ☐ Extra pulmonary TB ☐ Soft tissue infection ☐ UTI ☐ HIV related illness ☐ Measles ☐ Varicella ☐ Osteomyelitis ☐ Confirmed enteric fever ☐ Febrile illness unspecified ☐ Typhoid/paratyphoid with perforation	☐ Febrile convulsions ☐ Epilepsy ☐ LP confirmed meningitis ☐ Clinically suspected meningitis ☐ Other encephalopathy ☐ Hydrocephalus ☐ Developmental delay unspecified ☐ Cerebral palsy ☐ Congenital syndrome
General		**Other diagnosis:**
☐ Anaemia ☐ Sickle Cell Disease ☐ Renal impairment ☐ Nephrotic syndrome ☐ Nephritis ☐ Liver dysfunction ☐ Ileus ☐ Cardiac disease		☐Failed appetite test only/ malnutrition only. ☐Suspected drug toxicity *(if due to study drug, complete toxicity CRF)* ☐Other known diagnosis _____ ☐Unknown diagnosis

Name: _____ **Sign**_____ **Date** |__|__|/|__|__|/201_

Investigator or nominee dd/mm/yyyy

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ANTIMICROBIALS GIVEN IN HOSPITAL		
IV ANTIMICROBIALS	**TICK IF GIVEN**	**NUMBER OF DAYS GIVEN***
Penicillin	☐	
Gentamicin	☐	
Ceftriaxone	☐	
Ampicillin	☐	
Amikacin	☐	
Ciprofloxacin	☐	
(e.g. augmentin) **Co-Amoxiclav**	☐	
Chloramphenicol	☐	
Cefotaxime	☐	
Ceftazidime	☐	
Clindamycin	☐	
Flucloxacillin/Cloxacillin	☐	
Other_____	☐	
Other_____	☐	
NO IV ANTIBIOTICS	○	
ORAL ANTIBIOTICS		
Oral Amoxicillin	☐	
(e.g. augmentin) **Co-Amoxiclav**	☐	
Ciprofloxacin	☐	
Erythromycin	☐	
Azithromycin	☐	
Oral Cephalosporin	☐	
Co-trimoxazole <u>treatment</u>	☐	
Co-trimoxazole <u>prophylaxis</u>	☐	
Nitrofurantoin	☐	
Nalidixic acid	☐	
Clindamycin	☐	
Metronidazole	☐	
Other _____	☐	
Other _____	☐	
NO ORAL ANTIBIOTICS	○	

DISCHARGE FROM HOSPITAL

For all participants: date of discharge:

D	D	M	M	2	0	1	Y

Discharge Study Samples			
Rectal swabs taken *(should be two)*	☐ Y ☐ N	**Tick which were taken:**	☐ For culture (transport media) ☐ For storage (dry)
Rectal Swabs taken by *initials*	__ __ __		

If Rectal swabs not taken, state the reason *(tick one):*

- ☐ Withdrawal from study
- ☐ Absconded
- ☐ Died
- ☐ Missed discharge rectal swab
- ☐ Declined discharge rectal swab
- ☐ Other: _____

Name: _____ **Sign**_____ **Date** |__|__|/|__|__|/201_

Investigator or nominee dd/mm/yyyy