

FIEBRE Standard Operating Procedure F.03a		
Title	Completion of clinical CRF for child patients (aged <15 years) on Day 0	
<i>SOP Reference</i>	<i>Version</i>	<i>Date of effect</i>
F.03a	1.1.2	17 Dec 2018

SOP Development

	Name	Title	Signature	Date
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Review Tracker

Due date for next review	Reviewer name	Signature	Date reviewed
31 July 2018	Kate Haigh		20 Nov 18
18 Dec 2018	Kate Haigh		17 Dec 18
12 Feb 2019			

Revision History

Version No.	Effective date	Reason for change
1.1.2	17 Dec 2018	Correction of formatting

SOP User Confirmation

I acknowledge that I have read, understood and agree to follow this SOP

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1 Title: Completion of clinical CRF for child patients (aged <15 years) on Day 0

2 Purpose: To describe the procedures for completing the above CRF

3 Responsible staff: [Site-specific]

4 Background & Rationale:

The rationale for using CRFs in a study is to ensure that the data is collected in a way that minimizes inter-observer bias and data collection errors. It is also necessary to ensure that the data collected is complete and traceable to the health care worker collecting the data and the patient who has consented to supply it. The CRF's will collect all the patient data that has been set out in the protocol.

The data recorded within the CRF is used directly as the basis for the trial report, and any publications resulting from it. It is of fundamental importance to the study that it is filled in correctly and conscientiously

5 Supplies and Materials

- Data collection tablet loaded with ODK data capture forms
- Pen

6 Procedures:

6.1 The ODK data capture system contains prompts at each data entry page which are an integral part of this SOP. It is important to work methodically through the CRF and to use the prompts to guide you. This SOP should therefore be used in conjunction with the hints and prompts in the ODK system.

6.2 If a particular piece of information is not available you may skip a page and go back to it later.

6.3 You may save a partially completed form by clicking to floppy disk icon if you are waiting for further information (for example drug history) and go back to the form later

- 6.4** All forms should be fully completed by the end of the day and uploaded to the server regardless of their completeness
- 6.5** Every effort should be made to complete each form in full, however if a piece of information is not available the question should be appropriately marked and the reason for the information not being available recorded.
- 6.6** The CRF questions should not be read out verbatim to participants. The collection of data should follow a conversation with the participant (and/or guardian) about their illness, followed by the clinician or field worker completing the form, in the same way that a normal medical history is taken from a patient. However do complete the form by working through it in sections to ensure the data collected is complete and avoid unnecessary toing and froing through the document.
- 6.7** One form should never be started by one clinician and finished by another, however it is perfectly acceptable to confer and to seek advice if it is ever unclear what a response should be.
- 6.8** Section 1 Background
- 6.8.1** Ask to see the Child Health Record. Fill in items from the Child Health Record if available, and if not available then ask the guardian:
- 6.8.2** Sex and Date of Birth
- 6.8.3** Immunisation status
- 6.8.4** Maternal HIV status (can ask these questions later if not in child health record)
- 6.8.5** Child's HIV status (can ask these questions later if not in child health record)
- 6.8.6** For inpatients, fill in date and time of admission

6.9 Section 2 Symptoms

6.9.1 Confirm the relationship between the guardian and the child.

6.9.2 Confirm that he/she is able to answer questions re. child's illness

6.9.3 If they are not able to, then briefly describe why. Ask how long the child has had fever. Is the fever there all the time (write "continuous" or does it come and go "intermittent")

6.9.4 Ask if the child has a cough. If yes, ask how many days and record any other relevant information mentioned by guardian e.g. That the cough is so severe that the child changes colour or vomits

6.9.5 Ask if the child has "diarrhoea" (Use the local term). If yes, confirm that the stools is more watery and more frequent than normal. If yes, then ask how many days and ask if there is blood in the stool

6.9.6 Ask if child is vomiting. If yes, ask how many days. Record any other relevant information mentioned by guardian e.g. if they are vomiting blood. [If >5 years] ask if child has had headache

6.9.7 Ask if child has measles

6.9.8 Ask how the child is fed

6.9.9 Ask if they are feeding normally. If not feeding normally, for how long have they not been feeding normally

6.9.10 Ask if the child has difficulty breathing. If yes, try to understand that they mean. Is the child breathing fast or noisily? Did the guardian notice indrawing?

6.9.11 Ask if child has fitted during this illness. If yes, how many days ago did they start to fit?

6.9.12 Ask the carer to describe the “fit” . Sometimes it is difficult to tell the difference between a “rigor” and “fit”. If you are not sure then indicate this

6.10 Examination

6.10.1 Start by asking “Do you think the child has pain anywhere? Head? Ears? Abdomen?”

6.10.2 Is he/she moving his/her arms and legs normally?”

6.10.3 If the guardian indicates that there may be pain somewhere then ask for how many days and where it is painful. If they indicate that they do not know then tick “don’t know”

6.10.4 Ask if the child has pain passing urine. If yes, duration.

6.10.5 Ask if the child has had any other symptoms. If yes describe and ask about duration

6.10.6 Ask if child has ever had measles. If yes, when was it?

6.11 Section 3 Medications in the past week

6.11.1 Have a discussion with the patient/guardian about which medications the child has taken in the past week

6.11.2 Probe to find out if the child has been given any medicines for this current illness, if so do they know what they were for and the names?

6.11.3 Ask sensitively if the child on any regular medicines for example penicillin, or TB or antiretroviral drugs. If yes, then continue to ask them about the names of the drugs and when they started (This will help you to fill in the next section!)

6.12 Section 4 Other health conditions

6.12.1 By now, you may know if the child has other health conditions for example HIV or TB because of the questions you have already asked about the medications

6.12.2 Ask if the guardian if they know if the child has sickle cell anaemia or any other illness like asthma

6.13 Section 5 Contact with ill people

6.13.1 Ask anyone in the household is ill with fever, cough, rash or diarrhoea, or if there have been any deaths in the household in the last month. If yes, then ask about the relationship to the child and how much contact the child had with this person

6.13.2 Fill in ODK according to the response

6.14 Section 6 Other exposures

6.14.1 Explain that you would like to find out if there are other things that might related to child getting an infection. Explain that some of these questions might seem strange!

6.14.2 Ask whether the child has drunk milk that has not been boiled in the last month

6.14.3 Ask whether the child has been bitten by insects in the last month. Probe what kind of insect like tick, biting fly? When was the most recent bite?

6.14.4 Ask if the child is in physical contact with farm: cows, pigs, goats, chickens, in the last month. If they say yes, ask if the animal or chickens have been sick

6.14.5 Ask if the child has been playing or wading in or near a lake, pond or river in the last month

6.14.6 Ask if the child has worked or played in rice fields

6.14.7 Ask if the child has had any recent injuries in the last month. If yes, did this break the skin or bones? (We are interested whether bacteria can enter through a recent wound). Describe what kind of injury it was e.g. did they step on a nail, fall over etc

6.15 Section 7. Household characteristics

6.15.1 What is there MAIN source of water in the dry season?

6.15.2 Where do they go to the toilet (to defecate)?

6.15.3 What fuel is used for cooking?

6.16 Section 8. Physical examination

6.16.1 Assess vital signs and measurement

6.16.2 Record the vital signs on a piece of paper including: axillary/tympanic temperature, HR, oxygen saturations, height, weight, MUAC and in children > 5 years try to get a blood pressure

6.16.3 Look & listen! - Do as much of the examination that you can do without touching the child!

6.16.4 Does the child look ill to you? (This is just your impression)

6.16.5 Are they lethargic or irritable?

6.16.6 Are they crying or speaking normally?

6.16.7 Observe the breathing – does it look deep (or “labored”)

6.16.8 Count the respiratory rate

6.16.9 Listen to the breathing (without stethoscope). Do they have grunting, stridor or wheezing?

- 6.16.10** Look for sub-costal indrawing
- 6.16.11** Can they sit or stand?
- 6.16.12** Is their posture normal?
- 6.16.13** Are they moving their arms and legs spontaneously?
- 6.16.14** Are their eyes sunken?
- 6.16.15** Are they opening their eyes?
- 6.16.16** Are the sclera yellow? Is there conjunctivitis? Any pus?
- 6.16.17** Look at the palms - are they very pale (compare to the guardians)?
- 6.16.18** Look at the feet - any pedal oedema?
- 6.16.19** Touch - now you can touch the child!
- 6.16.20** If < 1 year old - feel the fontanelle - is it still open? If yes, is it flat, bulging or depressed?
- 6.16.21** Feel the mastoid (the bony bit behind the ear lobe) for any swelling or tenderness
- 6.16.22** Using the stethoscope, auscultate the back of the chest on the left and right side - listen for crepitations
- 6.16.23** Gently pinch the abdominal skin - does it take 2 seconds or more to return to normal
- 6.16.24** Gently palpate the abdomen - 4 quadrants. Any tenderness?
- 6.16.25** Assess the capillary refill time ideally centrally on the sternum or forehead but if skin very dark then try to finger.
- 6.16.26** Assess the Blantyre score if < 5 years:

- 6.16.27** If the child has been asleep, try to wake him/her up by calling his/her name.
- 6.16.28** Does the child open his/her eyes? Does he/she watch and follow?
- 6.16.29** Rub the child's sternum with your finger nail
- 6.16.30** Does the child try to take your hand away? Do they cry out? Is it a normal cry?
- 6.16.31** If child did not try to take our hand away, press down hard on one their finger nails. Does the child try to withdraw the hand?
- 6.16.32** Now examine skin all over for rashes, insect bites and wounds. Try to be systematic if you can. For example starting from head, face, neck, arms hands, chest, abdomen, nappy area, front of legs, feet, toes, back of the body and legs
- 6.16.33** Palpate the shoulders, elbows, and wrists - any tenderness, hotness or swelling? Lift up the arms, extending the elbows and wrist to see if there is any limitation of movement
- 6.16.34** Palpate the legs from the top of the legs to the toes - any tenderness, hotness or swelling? Fully extend and then flex the leg to see if there is any limitation of movement
- 6.16.35** Use the otoscope
- 6.16.36** For young children, ask the guardian to hold the child, sitting the child on their lap facing forward. The guardian should hold one of their arms across the child's body to stop the child lifting up his/her arms, and place their other hand on the child's head to stabilise the child's head against the guardian's chest

6.16.37 Use the otoscope to exam both ears - looking for red and bulging ear drum. This may be quite difficult. If you can not see it, don't worry - but record that you did not manage to visualise

6.16.38 Now (or earlier if the child cries with big open mouth!), examine the mouth and back of the throat looking for mouth ulcers, exudate on the tonsils etc

6.16.39 Sensitive questions - pregnancy (and maybe HIV in Lao and Myanmar?)

6.16.40 Use your judgement to decide how and when to ask about menarche, the possibility of pregnancy or recent childbirth (+/- about HIV status in Laos and Myanmar)

6.16.41 Assessment and working diagnosis

6.16.42 Record the working diagnosis - this can be based from the clinical notes or discussion with the doctor/senior nurse looking after the child

7 Documentation: FIEBRE protocol (version 2.5, 31 Jul 2018) section 7.6.3, and [site appropriate Malawi/Zim/Moz HIV rapid test CRF or logbook [ODK vs paper]