International Livestock Research Institute and the Department of Disease Surveillance and Response, Ministry of Public Health

Workshop report

Review of protocols for a study on Rift Valley fever and other acute febrile illnesses in humans in Ijara and Tana River Sub-counties, Kenya

December 2013

AUTHORS

Ian Njeru, Department of Disease Surveillance and Response, Kenyatta National Hospital,
P. O. Box 20781-00202, Nairobi, Kenya

Joan Karanja, Department of Disease Surveillance and Response, Kenyatta National Hospital,
P. O. Box 20781-00202, Nairobi, Kenya

John Muriuki, International Livestock Research Institute
P.O. Box 30709-00100, Nairobi, Kenya

Damaris Mwololo, International Livestock Research Institute
P.O. Box 30709-00100, Nairobi, Kenya

Salome Bukachi, Institute of Anthropology, Gender and African Studies, University of Nairobi,
P.O. Box 30197-00100, Nairobi, Kenya

Bernard Bett, International Livestock Research Institute
P.O. Box 30709-00100, Nairobi, Kenya

Citation

Njeru I, Karanja J, Muriuki J, Mwololo D, Bukachi S and Bett B. 2013. *Review of protocols for a study on Rift Valley fever and other acute febrile illnesses in humans in Ijara and Tana River sub-counties, Kenya.* ILRI workshop report. Nairobi, Kenya: ILRI.

Acknowledgement

This work "Dynamic Drivers of Disease in Africa: Ecosystems, livestock/wildlife, health and wellbeing: REF:NE/J001422/1" was partly funded with support from ESPA. ESPA is funded by the Department for International Development (DFID), the Economic and Social Research Council (ESRC) and the Natural Environment Research Council (NERC). Other funding was provided by CGIAR Research Program on Agriculture for Nutrition and Health (http://a4nh.cgiar.org).

Summary

A workshop involving the DDDAC – RVF case study team, medical and laboratory officers from the health centers in the project sites (Garissa, Ijara, Sangailu, Hola and Bura) and enumerators hired by the project to conduct questionnaire surveys was convened in Garissa on 4th to 7th December in The Nomad hotel, Garissa (the list of participants is given in Annex II). The workshop aimed to (i) review the objectives, design, the expected benefits and ethical requirements of the human health component of the DDDAC – RVF case study and (ii) develop work plans and implementation teams. The meeting was officially opened by the Garissa Country Director of Medical Services.

In the first day of the meeting, the DDDAC project team took the participants through the objectives and the design of the project, and the reasons why their area had been chosen as a study site. The participants were were informed that the area had been chosen because it is one of the areas in Kenya that is undergoing land use changes through irrigation. The project team described some of the expected linkages between irrigation and human health risks. The session also reviewed alternative vector-borne and zoonotic diseases that the local health centres needed to consider while making differential diagnosis of febrile conditions given that they presented similar symptoms.

A study guide that had been developed for the human health study (made up of community and hospital-based surveys) was presented and discussed in detail. The project team highlighted the roles that each medical and laboratory technician would play in the survey. On the second day of the workshop, discussions on the RVF study guide were succeeded by those of the standard ethical principles that guide research on human subjects including:

- Autonomy – researchers must allow potential subjects make independent choices on their participation. The investigator must ensure that: the participant has received a full disclosure of the nature of the study, the risks, benefits and alternatives, with an extended opportunity to ask questions
- Beneficence -- the investigator must attempt to maximize benefits for the individual participant and/or society, while minimizing risk of harm to the individual
- Justice – equitable selection of participants, benefits or burdens among groups likely to participate in research

The process of obtaining informed consent was also discussed. It was agreed that various stages of consent needed to be used starting with obtaining consent from the community gate keepers, followed by those of the household heads and the specific participants that were to be sampled.

The third and the fourth day of the workshop focussed on the development of work plans and the fifth day was devoted for pretesting the questionnaires that were to be used to collect subjects' metadata.

1 Background

The Rif Valley fever (RVF) case study is being implemented by ILRI in partnership with the Division of Disease Surveillance and Response (DDSR), Kenya Medical Research Institute (KEMRI), Department of Veterinary Services (DVS), the School of Biological studies and the Institute of Anthropology, Gender and African Studies, University of Nairobi (UoN) and the, Ministry of Public Health and Sanitation. The case study investigates whether land use change (through irrigation) promotes the occurrence and persistence of RVF. The case study has several components including human health, livestock health, entomology, ecology, socio-economics and anthropology. Study sites that have been identified for the work include Ijara division in Ijara district, Bura and Hola irrigation schemes in Tana River district. The case study also intends to screen for other diseases that present similar signs as RVF (including Crimean-Congo Haemorrhagic Fever (CCHF) virus, yellow fever virus, Dengue fever virus, Ngari virus; Chikungunya *Brucella* spp. [brucellosis], *Coxiella burnetii* [Q fever] and *Leptospira* spp. and malaria) in order to generate data that can be used to build capacity on differential diagnosis of febrile illnesses in the area.

A workshop was convened in Garissa to develop plans for the initiation of the human health component.

2 Workshop sessions

2.1 Review of the case study guide

The objectives and design of the human component of the RVF case study

This session commenced with a review of the DDDAC research questions including:

- How do ecological changes as shaped by human-ecosystem interactions affect pathogen dynamics and hence the likelihood of zoonotic spillover and transmission?
- How do different peoples' interactions with ecosystems affects their exposure to the disease?
- What are the impacts of the disease on poverty and well-being,
- How do regional, national and global drivers (e.g. climate, land use, population, urbanization, economy) shape these local dynamics,
- How do different actors (local people, government agencies, policy-makers) understand and represent ('frame') ecosystem services and related health problems within a political economy of knowledge, and how does this shape their practices and interventions?

This was followed by a review of the objectives of the human component of the RVF case study:

1. To determine whether land use changes associated with the development of irrigation schemes promotes the occurrence and persistence of Rift Valley fever (RVF) in people and livestock
2. To determine relative prevalence of pathogens that should be considered for differential diagnosis of febrile diseases in humans

- hemorrhagic fever viruses (Crimean-Congo Haemorrhagic Fever (CCHF) virus, yellow fever virus, Dengue fever virus, and Ngari virus);
- other important arboviruses (e.g., Chikungunya virus);
- bacterial agents (mainly *Brucella* spp. [brucellosis], *Coxiella burnetii* [Q fever] and *Leptospira* spp. [leptospirosis]), Typhoid
- Protozoal agents (mainly *Plasmodium* spp [malaria]), leishmaniasis

3. To assess whether the impacts of RVF in irrigated areas (Tana River district) differ both quantitatively and quantitatively from those observed in a pastoral area (in Ijara district) with minimal land use change
4. To build capacity among the local public and veterinary health service providers on surveillance and diagnosis of RVF and related febrile illnesses

The components of the study were also listed as:

- Hospital based study – Cross-sectional study
  - Systematic random sampling of AFI cases in 4 Health Centres

- Community based study – Cross-sectional study
  - Multi-stage sampling of in each district (Ijara and Tana River)
  - Random selection of households

- Questionnaire surveys

Sampling

Procedures for recruiting subjects and obtaining blood samples were also reviewed in detail. These have been described in detail in the proposal. In summary, the points made were:

- Up to 10 ml venous blood will be collected from all participants using vacutainer needles
  - Half of this sample will be collected in heparinised vacutainer tubes for pathogen identification using targeted multiplex PCR screening
  - The other half will be collected in non-heparinised vacutainer tubes for serum extraction for serological analysis
- Samples will be barcoded and linked to the participant and other metadata
- The blood and serum samples will be transported in dry ice to ILRI Nairobi where they will be kept at -20^{o}C until analysed

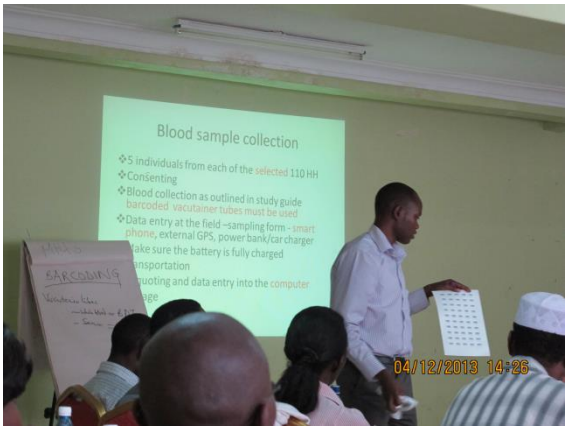

Plate 1. Workshop participants being trained on barcoding blood samples

2.2 Ethics

The general principles that govern ethics in human health research were discussed; those reviewed included:

- Autonomy – researchers must allow potential subjects make choices. The investigator must ensure that:
  - the participant has received a full disclosure of the nature of the study, the risks, benefits and alternatives, with an extended opportunity to ask questions
- Beneficence -- the investigator must attempt to maximize benefits for the individual participant and/or society, while minimizing risk of harm to the individual
- Justice – equitable selection of participants, benefits or burdens among groups likely to participate in research

A conceptual framework for obtaining informed consent published by WHO was used for reference in the session (Figure 1). Principles of informed consent were also reviewed as listed below:

- Disclosure
  - That the individual is invited to participate in the research, reasons for considering the individual and that participation is voluntary
  - That the individual is free to refuse to participate, will be free to withdraw without penalty or loss of benefits to which he or she will be entitled to
  - The purpose for the research, procedures to be carried out by the investigator and the subject and an explanation of how the research differs from routine medical care
  - Features of the research design,
  - Expected duration of the subject's participation
  - Whether money or other material good will be provided in return for participation
  - Subjects will be informed of research findings in general and individual subjects will be informed of any finding that relates to their particular health status

  - Any foreseeable risks associated with participation in the study
  - Benefits of participation to the society at large
  - How long, where will the samples be stored
  - That treatment will be provided for specific types of injuries or complications associated with the study
  - That an ethical review has cleared the study
- Understanding
  - The participant must understand what has been explained and must be given an opportunity to ask questions
  - Consent form must be written in lay language
- Voluntariness
  - Participation should be voluntary, free of coercion or promises of benefits
- Competence
  - Participants must be competent to give consent
  - If not, due to mental illness, disease or emergency, a surrogate may provide consent if it is in the best interest for the person to participate
- Consent
  - Potential subject must authorise his or her participation in the research preferably in writing
  - Oral consent may be given

Fig. 1. **Conceptual framework for the process of obtaining informed consent**

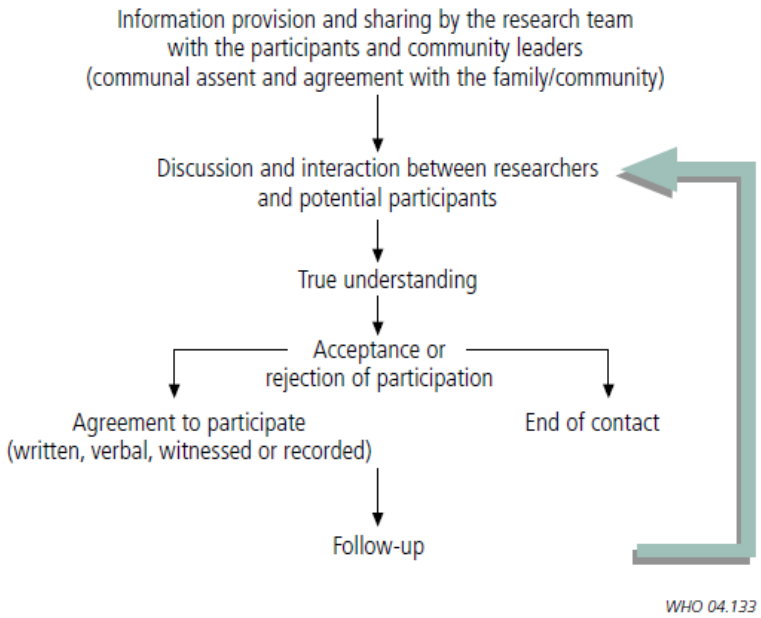

Plate 2. Discussions on the ethics of the study

2.3 Enumerator training

A total of 16 enumerators were identified and invited to the workshop. These were:

1. Caroline Murimi
2. Zahra Boch
3. Lydia Nina
4. Hasera Raha
5. Fatuma Osman
6. Salim Hiribae
7. Mohamed Guracho
8. Boba Abdalla
9. Ahmed Barako
10. Mustafa Daudi Juge
11. David Gafo Jillo
12. Ibrahim Mohamed Dido
13. Barre Hussein
14. Adbdi Elmoge
15. Mohamed Ali
16. Dhadho Jillo

These enumerators attended the main sessions on the first and the second day on the objectives of the DDDAC project, study design, ethics and consenting processes. However on the third, fourth and fifth day, they were given specific trainings on the questionnaire administration. The sessions held included:

- Review of the questionnaire using the hard copies
- Administration of the questionnaire using the ODK system
- Pretesting of the questionnaire using the ODK system.

The program used for these sessions are shown in Table 1.

Table 1. Program used for the enumerator training

Date	**Activity**	**Facilitator**	**Evaluation**
4th	Introduction DDDAC objectives and study design	Dr Bett	Questions and answers
5th	DDDAC study guide Barcording and data entry	Joan John and Damaris	Q/A Practical
6th	Ethics and consenting DDDAC cross-sectional questionnaire	Dr Bett John and Damaris	Q/A Q/A
7th	Questionnaire administration using ODK collect	Jason and Eunice	Practical
8th	Field visit to administer questionnaire	Jason, Eunice, Millicent, Damaris, John, Bett	Type of data collected

Given that only 10 enumerators were required for the survey based on the availability of the tablets, 6 were discontinued. The selection criteria used to select those who were finally hired included ability to comprehend their roles and the type of data collected during the pretesting session. They were then grouped into two teams as follows:

Bura and Hola team

1. Caroline Murimi
2. Lydia Nina
3. Mustafa Daudi Juge
4. Mohamed Guracho
5. Zahra Boch
6. David Gafo jillo
7. Salim Hiribae

Sangailu and ijara team

1. Abdi Elmoge
2. Barre Hussein
3. Fatuma Osman

Millicent Lianni was asked to supervise the team at Bura and Hola while Mohamed Ali the team at Sangailu and Ijara.

2.4 Workplan

A group comprising clinical officers and laboratory technicians sat together on the third and fourth day to lay out a strategy for sampling. They suggested that the study should commence with a community survey. Teams that were constituted for each site include:

Bura

1. Patrick Mbandi
2. Abdisame Abduahi

Hola

1. Said Aden
2. Said Shushe

Sangailu and Ijara

1. Mariam Hamud
2. Hassan Hussein

Materials that were required for the survey to commence were listed (Multivitamins, heamatins, deworkers, pain killers, antifungal cream, bed nets)

The team resolved to commence the field work immediately with the hospital survey being postponed to February 2014.

Plate 3. Development of a survey workplan with clinical officers and laboratory technicians

Annex I: Workshop program

4th Dec 2013	**Session**	**Presenter**
0830-0900	General introduction	
0900-0920	Objectives of the workshop	Bernard
0920-1000	DDDAC project Design RVF case study	Cris
1000-1030	Break	
1030-1050	Opening remarks	Director
1050-1300	RVF case study guide	Ian/Joan
	Lunch	
1400-1700	RVF case study guide	Ian/Joan
5th Dec 2013		
0830-0850	Review of day 1 sessions	Ian
0850-1000	Ethics	Bernard
1000 - 1030	Break	
1030-1300	Facility/Community questionnaires	Joan/Damaris/John
1300 - 1400	Lunch	
1400-1500	Facility/Community questionnaires	Joan/Damaris/John
1500 - 1700	Consent forms	Ian/Joan
6th Dec 2013		
0830 - 0850	Review of day 2 sessions	Ian
0850 - 1100	Work plan	Ian/Bernard
1400- 1500	Questionnaires/ODK sampling form (community survey)	Jason/Damaris/John
7th Dec 2013		
0830 - 1300	Field testing	Eunice/Jason
1400 - 1700	Evaluate field testing responses	Eunice/Jason

Annex II: List of participants

Damaris Mwololo	MSc Student, ILRI	22910652	0721275954
Eunice Kariuki	Database manager and Analyst, ILRI	13622741	0726790902
Jason Rogena	Systems Developer, ILRI	28074002	0715023805
Zablon Jilo	Technologist, DVS	8296659	0788228841
Ibrahim Dido Mohammed	Enumerator	27585568	0721820447
Lokapel L. Mark	Medical Officer, MPH	20673253	0727994508
Barako Ahmed	Enumerator	27797320	0727958277
Mohamed Mohamud Guracho	Enumerator	25339762	0720839892
Joan Karanja	Medical Epidemiologist, MPH	22484964	0722421524
John Muriuki	MSC student, ILRI	25795594	0725773661
Bobba A. Boru	Enumerator	26696742	0726375721
Saeed Adan	Lab Technologist, MPH	23713287	0720963523
Mustafa J. Daud	Enumerator	27932598	0711108861
Zahra Boch Abarea	Enumerator	24157895	0715079335
Peter Lokamar	Medical Epidemiologist, MPH	10125677	0722447176
Stephen Kitundu	Lab Technologist, MPH	20034990	0727771582
Godfrey Mutua	Lab Technologist, MPH	22299980	0726578836
Johnson Dhadho Hiribae	Enumerator	23367391	0726806940
Said Shushe Wario	Lab Technician, MPH	8297570	0735820388
Fatma Osman	Enumerator	27511944	0728471133
Maryan Hamud	Lab Technician, MPH	27777415	0727337769
Abdisamet Abdullahi	Lab Technician, MPH	13701515	0722507062
Salim Hiribae	Enumerator	24793982	0710521742
Caroline M. Murimi	Enumerator	27446504	0717589403
Patrick Mbandi	Lab Technician	24006593	0720345797
Raha Hasera Verna	Enumerator	28593983	0727503455
David Gafo Jillo	Enumerator	25885702	0723857537
Lydia Hadia Hiribae	Enumerator	28968263	0714892088
Hassan Abdi Mohammed	Lab Technologist, MPH	0035997	0722918439
Hassan Hussein	Chief Lab	0540237	0724179083
Titus Mutai	Medical Officer, MPH	25194559	0724043980
Bernard Bett	Epidemiologist, ILRI	11204477	0722841938